

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



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

April 26-28, 2022

Record of the Proceedings

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Executive Summary

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

CDC and HRSA Welcome and Updates

The meeting began with detailed updates from CDC and HRSA. The CDC update highlighted a number of important areas of interest from the NCHHSTP HIV, STD, viral hepatitis, and school/adolescent health programs including: a brief update on the continuing impact of COVID-19; NCHHSTP's equity initiative and strategic plan; harm reduction and Syringe Services Programs; discussion of mental health concerns in youth; Ending the HIV Epidemic (EHE) update; discussion on updated hepatitis B vaccination and screening and testing recommendations; and integrating STI and HIV services to address the syndemic. Highlights from the HRSA/HAB presentation included the introduction of a new Administrator, launch of a new Ryan White website, release of the National HIV/AIDS Strategy (2022–2025) in December 2021, and policy and data updates. CHAC members discussed recent policy changes and their potential impacts on LGBTQ (lesbian, gay, bisexual, transgender, and questioning) youth's access to information, resources, and equitable care.

Strategizing an Approach to Providing Comprehensive STI Services

During this panel, CHAC heard from programs in Mississippi, New York, and Minnesota that highlighted innovative strategies they are employing to increase access to testing and comprehensive STI services. These strategies included using the school space to increase access to health services for young people, leveraging technology, and the effort to align that with the COVID-19 pandemic response to: 1) innovate and modernize the public health infrastructure, which can serve as a good model moving forward in jurisdictions; and 2) determine how to secure and sustain funding to support these efforts moving forward in a post-COVID world.

Leveraging Policy to Advance HIV, VH, and STI Priorities

This panel focused on utilizing policy as a public health intervention as an approach to solving expansive issues in public health. The National Viral Hepatitis Roundtable presented on the state of Medicaid access with respect to Hepatitis C. The California Department of Public Health (CDPH) Office of AIDS provided an update on Senate Bill (SB) 159 pertaining to HIV pre-exposure and post-exposure prophylaxis (PrEP & PEP) for California pharmacists and the STD Control Branch presented on leveraging policy changes for STI and VH prevention, testing, and treatment. The Louisiana Office of Public Health STD/HIV/Hepatitis Program described Louisiana's *Hepatitis C Elimination Plan: 2019-2024*. The Transitions Clinic Network described issues pertaining to the Medicaid Inmate Exclusion Policy (MIEP) which reduces barriers to care for post-incarceration, reintegrating individuals.

Turning the Tide on Self-Testing and Sample Collection

This special presentation focused on self-testing and sample collection, highlighting the pipeline and approval process for self-collection kits. CHAC heard data on how impactful self-collection kits could be on communities that historically have not utilized traditional brick-and-mortar structures. The availability of self-collection kits has been demonstrated to increase testing practices in a number of communities. Discussion focused on how the Food and Drug

Administration (FDA) views HIV versus HCV and manufacturers' willingness to produce self-testing kits and seek FDA approval. Additionally, CHAC members discussed the differences in the criteria used for regulatory authorization of collection kits/methods domestically versus internationally and the potential for the review and revision of FDA process to increase access to and use of self-test kits.

Applied Syndemic Approach to HIV, VH, and STIs: Focusing on People

This panel focused on implementation of programmatic syndemic approaches, which underscored the need to take a “whole person” approach in terms of the issues that influence an individual’s ability to access the resources that are being put forward, utilize them effectively, and achieve successful health outcomes. The New Mexico Department of Health (NMDOH) described its comprehensive harm reduction program focused on meeting people where they are to support HCV treatment and syphilis services. The North Dakota State Correctional Health Authority emphasized that corrections health is an important part of public health and represents a vulnerable and underserved population and can be an ideal setting for delivering comprehensive services. The San Francisco Unified School District (SFUSD) described policies and mandates, community partnerships, resources, training, and initiatives that help support comprehensive sexual health services to SFUSD youth. Finally, CDC’s Division of HIV Prevention (DHP) provided an update focused on advancing syndemic approaches through cluster detection and response, emphasizing that cluster detection and response can guide tailored implementation of proven treatment and prevention strategies for HIV and other syndemic conditions where transmission is occurring most rapidly.

Telehealth/Telemedicine Working Group (WG)

The Telehealth/Telemedicine WG put forth several recommendations focused on enhancing routine screening through virtual services for all populations, health equity’s relationship to telehealth service provision, and deployment of the Tele-PrEP initiative for Federally Qualified Health Centers (FHQCs).

Presidential Advisory Council on HIV/AIDS (PACHA)

CHAC was provided an update on PACHA’s 73rd full council meeting that was convened virtually on March 14-15, 2022. This presentation emphasized the importance of hearing the voices of the community that will help guide PACHA in moving forward in terms of making recommendations to support EHE and in implementing the National HIV/AIDS Strategy (NHAS).

Business Session

The Business Session focused on CHAC actions and proposed future agenda topics. The next CHAC meeting is scheduled for November 1-3, 2022.

Future Agenda Topics Proposed

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

CHAC Actions

During this meeting, CHAC members voted unanimously to:

- Adopt the November 2021 CHAC meeting minutes, with no edits proposed.
 - Send the letter of recommendations presented by the Telehealth WG to the HHS Secretary, with a minor revision of repositioning the health equity recommendation as the first bullet.
 - Develop and send a letter to the HHS Secretary regarding LGBTQ youth.
 - Create a Self-Collection Self-Testing WG to consider issues related to self-testing, potentially including: 1) Differences in FDA risk classification of HCV and HIV; 2) Criteria required and data available for the FDA approval process; and 3) Downregulation to class II diagnostics. In addition, this WG will draft a letter to be presented to CHAC for a potential vote during the November 2022 meeting.
 - Establish a Workforce WG to liaise with PACHA on their efforts, to discuss the main issues CHAC is to consider on workforce including exploring the role of other professionals and community health workers (CHWs) in this space, and to discuss topics to potentially inform a panel for the November 2022 CHAC meeting.
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**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 26-28, 2022**

Minutes of the Meeting

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

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

Day 1: Opening of the Meeting and 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 11:00 AM Eastern Time (ET), reviewed ground rules, and provided instructions for discussion periods. She indicated that members of the public would have an opportunity to provide oral comments at 3:30 PM ET during the second day, and that public comments would 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
Centers for Disease Control and Prevention

On behalf of CDC and HRSA, Dr. Mermin welcomed those present and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest (COIs) identified by the Committee Management Office (CMO) and recuse themselves from voting or participating in any discussions for which they could be conflicted. He then conducted a roll call to determine the CHAC voting and *Ex-Officio* members who were in attendance and establish quorum. Quorum was maintained during all 3 days of the meeting.

Conflict of Interest Disclosures

CHAC Voting Member Institution/Organization	Disclosure of Conflicts
Jean R. Anderson, MD Johns Hopkins Medical Institutions	Stocks: Apple, Amazon, Cisco, Alphabet, Splunk Research Funding: Merck, Gilead
Wendy Armstrong, MD Emory University School of Medicine	Research Funding: HRSA/Ryan White Parts A, B, D that supports part of her salary as well
Jodie Dionne-Odom, MD, MSPH University of Alabama, Birmingham	Research Funding: NIH
Shannon Brown Dowler, MD North Carolina Medicaid	None
Daniel Driffin, MPH D3 Consulting	None
Travis Gayles, MD, PhD Hazel Health	Self-recusal for Telehealth related topics
Meredith Greene, MD University of California, San Francisco	Research Funding: Gilead, NIH Works in a Ryan White-funded clinic
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN Duke University	Research Funding: NIH, ACF
Kali Lindsey amfAR, Foundation for AIDS Research	None
Christine Markham, PhD University of Texas Houston	Research Funding: NIH, ACF, OMH
Shruti Mehta, PhD, MPH Johns Hopkins Bloomberg School of Public Health	Research Funding: NIH, USAID Materials Support For Research Studies: Abbott
Johanne Morne, MSED AIDS Institute, New York State Department of Health	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program
Kneeshe Parkinson Washington University/Project ARK	Research Funding: HRSA/Ryan White HIV/AIDS Program Parts A, B, C, and D
Robert Riester Denver Element	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program, Part A
Leandro Rodriguez, MBA Latino Commission on AIDS	Research Funding: HRSA/Ryan White HIV/AIDS Program, CDC, SAMHSA, Gilead, ViiV
Samuel So, MD Stanford University	Research Funding: CDC, NIH

Ex-Officio members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA), Dr. Maureen Goodenow of the National Institutes of Health (NIH), Dr. Neerja Gandotra of the Substance Abuse and Mental Health Services Administration (SAMHSA), Ms. Kaye Hayes of the HHS Office of HIV/AIDS and Infections Disease Policy (OIDP), Mr. Rick Haverkate of the Indian Health Service (IHS), and Dr. Richard Wild of the Centers for Medicare and Medicaid Services (CMS). Liaison member Dr. Ada Steward of the

Presidential Advisory Council on HIV/AIDS (PACHA Liaison Representative) organization, Eau Claire Cooperative Health Centers, receives Ryan White Funding Parts B and D.

Dr. Mermin confirmed that a quorum of 22 was achieved and that CHAC could move forward with conducting its business on April 26, 2022.

Welcome and Agenda Review

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Gayles and Anderson welcomed everyone to the April 26-28, 2021 CHAC meeting. Dr. Gayles thanked CHAC members, federal officials, CDC and HRSA staff, and the general public for their attendance and commitment. He expressed particular gratitude to Dr. Stewart for her efforts to promote vaccination in the pediatric population, as well as her commitment across the full breadth of public health issues. He reviewed the agenda for the day, pointing out that it highlighted the continued need to be nimble and versatile in the ever-changing post-COVID world with the increased attention on public health issues and budget demands and supplies. He observed that many of the topics to be discussed during this meeting demonstrated how CHAC must continue to evolve in terms of considering what should be included in a comprehensive STI testing program in 2022, determining the types of policies that need to be put into place to impact service delivery in a more meaningful way, and examining how federal policies might influence the delivery of those services. As always, they looked forward to great presentations, robust discussions, and tangible action items.

CDC DFO Welcome and Updates

NCHHSTP 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 welcomed new CHAC Voting Members, Mr. Kali Lindsey and Dr. Christine Markham. He also welcomed Dr. Maureen Goodenow, Director of NIH's Office of AIDS Research, who is replacing Dr. Paul Gaist as the NIH *Ex-Officio* member.

To update CHAC correspondence, responses were sent on March 7, 2022, for the HIV and HCV classification letter; the Viral Hepatitis Workgroup (WG) letter; the Youth Engagement letter; and an interim response to the Perinatal Infection WG letter. CDC and HRSA are working on a detailed response currently and hope to have that finalized in the next couple of months.

In terms of COVID-19 pandemic, the number of deaths officially attributed to COVID-19 is close to 1 million in the US and there have been over 80 million total cases. Although mortality and hospitalizations decreased with the decreasing incidence of COVID-19 in the early part of 2022, cases and hospitalizations increased as the new subvariant began to spread. Challenges continue for all of public health and clinical care, as well as policies and other aspects of trying to keep America healthy in an environment where there are various other pressures

simultaneously. NCHHSTP continues to have multiple deployments for the COVID-19 response, with over 700 employees deployed since the beginning of the epidemic, over 1600 cumulative deployments, 53 people currently deployed, and 17 staff soon to deploy. NCHHSTP also is taking responsibility for several aspects of the incident management structure as CDC begins to reorganize its response to COVID-19, with the understanding that this is going to be a long-term effort.

NCHHSTP's Equity Initiative Strategy launched in 2021. This long-term strategy is intended to help achieve workplace equity and eliminate health disparities by addressing racism and other systems of oppression that hinder the center's mission. An implementation plan was developed that outlines the first steps of this process, though NCHHSTP already has been implementing many of the strategies. The overall goal is to help integrate health equity and equity in the workplace as core activities to which NCHHSTP is committed. NCHHSTP is focused on pervasive disparities associated with HIV, viral hepatitis, STDs, and TB, as well as adolescent health. The Equity Initiative involves all aspects of the center, with each division developing action plans that they have been implementing for some time.

An assessment was completed of external work for improving public health, internal workforce, organizational change, and analysis. Based on the analysis of the workforce, over 50% of NCHHSTP's staff are racial/ethnic minorities and close to 70% are women. The proportion of racial/ethnic minorities has increased at least 20% over the past decade. NCHHSTP also was the first group at CDC to conduct a survey of staff regarding sexual orientation and gender identity. Approximately 18% of NCHHSTP staff identified as LGBTQ (lesbian, gay, bisexual, transgender, questioning), with that proportion being the same in lower and higher General Schedule (GS) levels. NCHHSTP is committed to continue to perform these demographic analyses, develop fact sheets, and improve the inclusiveness of the day-to-day experience of staff within the center.

Part of the Equity Initiative is the development of an external public health dashboard that assesses the overarching measures of inequity in the diseases under NCHHSTP's purview. There are relative comparative measures and absolute measures, which follow current scientific practices for analyzing inequities. While these measures vary for each condition and population, the center is committed to reducing health inequity.

CDC's cross cutting strategic plan to reduce the infectious disease consequences among people who use drugs is complete. The mission is to decrease morbidity, mortality, and incidence of infectious diseases associated with injection drug use, as well as stigma experienced by people who use drugs. Several strategic priorities have been identified, including expanding the infrastructure of syringe services programs (SSPs) nationwide and integrating SSPs into the public health system, and establishing coordinated surveillance, monitoring, and program implementation. "Strengthening Syringe Services Programs" Notice of Funding Opportunity (NOFO) was issued recently that will expand SSP and support a network of SSPs across the country.

Additionally, this year CDC is implementing the 6th surveillance cycle among people who use drugs via the National HIV Behavioral Surveillance or NHBS which monitors prevalence and trends of HIV infection, risk behaviors, and prevention services among populations at increased risk for HIV, across 20-23 cities in the US. CDC is also launching the Microinfluencing project with the CDC Foundation and the Public Good Projects. This is a pilot to engage social media influencers to grow support for SSPs starting in West Virginia and other jurisdictions across the country. The campaign launched mid-April called "Appalachian Influencers," recruiting both paid

and volunteer influencers to begin posting messages, focusing on 4 audiences including law enforcement, health care, faith leaders, and community leaders.

Similar to what has been experienced in other infections, tuberculosis (TB) cases decreased in 2020 for a variety of reasons that are still under exploration and increased by 9% in 2021, however, not to the levels of 2019. Factors likely contributing to the observed decline include delayed or missed TB diagnosis due to disruptions in health care access, underdiagnosis, or a true decline from the reduced TB transmission due to pandemic mitigation efforts and fewer new arrivals from high TB incidence countries. TB incidence in the US continues to decrease over time, but not at the pace that would be necessary to achieve TB elimination goals.

Division of Adolescent and School Health (DASH) Update

Kathleen Ethier, PhD

Director, Division of Adolescent and School Health
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Ethier reminded everyone that DASH has been presenting to CHAC for a number of years about what has been observed through the Youth Risk Behavior Survey (YRBS) regarding the health and wellbeing of young people in the country. New data recently were released that were collected through the Adolescent Behaviors and Experiences Survey (ABES), a version of the YRBS that was implemented in Spring 2021. Students were recruited through schools, same as is done for the YRBS, but they were able to complete the survey online instead of in a classroom. This engagement allowed sample students who were learning virtually, as well as those who were learning in-person in school to participate.

These data reveal the magnitude of challenges that youth are experiencing, particularly related to mental health, experiences of abuse in the home during the pandemic, experience of racism in schools, and a variety of other issues. There is a continuing mental health crisis among youth, which was seen prior to the pandemic, particularly among female students and students who identify as being LGBTQ. These data show 26% of students who identify as LGBTQ attempted suicide in the year prior to the data collection during the pandemic and more than 50% of all students experienced emotional abuse in the home (e.g., verbal abuse by a parent or other adult), speaking to the level of stress experienced by students and families. Among respondents, 64% of Asian students and 55% of Black and Multiracial students reported having experienced racism in school not related to the pandemic.

Youth who identify as LGBTQ have been disproportionately impacted by the pandemic, experiencing higher levels of poor mental health, more than 3 times the likelihood to have attempted suicide in the past year, and more emotional abuse at home during the pandemic compared to their heterosexual peers. This data shows that access to schools and other places in the community where students can be supported is critical and was limited due to the pandemic. One of the hopeful findings was that connectedness mitigated mental health issues. Students who reported that they felt connected were less likely to experience mental health problems and were less likely to consider or attempt suicide. At the same time, students who identify as LGBTQ and students who experienced racism were less likely to feel connected to others at school. This sets up a challenge for those who work in schools in how to make schools safer and more supportive, particularly for those youth.

CDC's "What Works in Schools" approach improves adolescent health and wellbeing. This approach includes quality sex education, systems to connect youth to services, and a set of activities around improving school connectedness and providing support for LGBTQ students. In schools implementing this approach within CDC-funded districts, students were less likely to have ever had sex, have 4 or more sexual partners, be currently sexually active, miss school because of safety concerns, be forced to have sex, and/or use marijuana.¹ Sexual assault is known to be a predictor of lifelong trauma as well as posing STD and HIV risks.

Schools that put a set of policies and practices in place to support LGBTQ students such as identifying safe spaces, having professional development for educators, and having anti-harassment policies that are enforced leads to improvements in mental health outcomes and reductions in suicidal thoughts and behaviors. Improvements are observed in all students including LGBTQ in schools that put these policies and practices in place. The reverse is also the case—that when these policies and practices are not in place, mental health problems are exacerbated for students who identify as LGBTQ and also for heterosexual students. This has significant implications for the currently state of schools across the country. As schools are made less toxic for the most vulnerable students, schools are made less toxic for everyone and the reverse is also the case.²

Division of HIV Prevention (DHP) Update

Demetre Daskaliakis, MD, MPH

Director, Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Daskaliakis reminded everyone that has CDC requested \$310 million in the FY23 President's Budget in order to continue its focus on the 4 pillars of EHE, as well as to amplify these efforts by investing in key strategies to advance health equity. Some of the highlights are to focus efforts on increasing access to testing by scaling up self-testing, and to think specifically about the use of self-testing in high impact settings such as community-based organizations (CBOs), LGBTQ-focused clinics, correctional facilities, and SSPs. Syndemic approaches would be expanded to create efficiencies and broaden the reach to many key populations. Lessons learned during the COVID-19 pandemic will be assessed to identify ways to better improve capacity in small priority population-focused CBOs to increase the benefit of EHE prevention and care services. The focus on PrEP uptake would continue to be promoted and delivered, including a newly available injectable PrEP and working on increasing delivery of tele-PrEP. This funding also would support expanding implementation of innovative status neutral approaches to care delivery by providing peer-to-peer training and implementation support to health departments that currently are not providing such services. This all part of EHE and is one of the 5 equity interventions and is part of the focus to increase the reach of HIV prevention and care services to Black, Brown, and LGBTQ people as well as other priority populations.

¹ Robin L, Timpe Z, Suarez NA, Li J, Barrios L, Ethier KA. Local Education Agency Impact on School Environments to Reduce Health Risk Behaviors and Experiences Among High School Students. *J Adolesc Health*. 2022 Feb;70(2):313-321. doi: 10.1016/j.jadohealth.2021.08.004.

² Centers for Disease Control and Prevention, National Youth Risk Behavior Survey (YRBS), 2015 & 2017; Centers for Disease Control and Prevention, School Health Profiles (Profiles), 2014 & 2016

DHP is in the midst of a renaissance of community engagement with a focus on 3 types of engagement:

1. Information gathering, an example of which is a refresh of the domestic HIV program strategic plan
2. Topic-specific discussion, examples of which are cluster detection and response and status neutral approaches
3. Ongoing community-centered engagement. Community-centered engagement began in March when regional Town Halls were convened to educate, encourage, and focus on empowering local community implementation of the EHE Initiative. The goal is to work together to understand and address longstanding inequities and strategies that can be used to further nuance addressing those inequities.

At the beginning of April, CDC funded 36 CBO grantees in 18 states with \$400,000 in funding per grantee to focus on HIV prevention with young men of color who have sex with men and young transgender persons of color.³ Since the last group of grantees, 6 more organizations were identified, and each received an increased funding level. CDC also recently announced and received applications for a funding opportunity⁴ to support organizations that work in transgender clinics and partner with CBOs that focus on transgender populations to develop community-to-clinic models to integrate status-neutral HIV prevention and care services where people seek gender-affirming care. This takes advantage of navigation and other strategies that are designed to increase knowledge, confidence, and use of PrEP and other interventions.

One of the great innovations that came out of the COVID-19 pandemic was the self-testing program, which is being expanded and will be funded over the next 5 years to distribute 150,000 self-tests per year. Conversely, there were significant interruptions in care services due to the pandemic that have made surveillance data harder to interpret and more complex. The HIV Surveillance Data Tables will be released when the full reports are available and the commentary is able to guide how this is interpreted. Because of the disruptions, there are some derived estimates (incidence, knowledge of status, prevalence) that will not be possible to produce for 2020. Work is underway to update data collection to better capture these data, for which approval is expected by the end of 2022 from the Office of Management and Budget (OMB) and collection will begin in early 2023.

Division of Viral Hepatitis (DVH) Update

Carolyn Wester, MD MPH

Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Wester shared some of the work that the DVH has accomplished recently to address health disparities in viral hepatitis (VH). VH elimination has moved from risk-based to universal recommendations among adults. In November 2021, the Advisory Committee on Immunization Practices (ACIP) voted unanimously to update the hepatitis B vaccination recommendations to include the following recommendations:

1. All adults 19-59 years and adults ≥ 60 with risk factors should receive hepatitis B vaccines
2. Adults ≥ 60 without known risk factors may receive hepatitis B vaccines

³ <https://www.cdc.gov/hiv/funding/announcements/ps22-2203/index.html>

⁴ <https://www.cdc.gov/hiv/funding/announcements/ps22-2209/index.html>

CDC formally published these guidelines in the *Morbidity and Mortality Weekly Report (MMWR)* on April 1, 2022.⁵ The move away from risk-based recommendations will help reduce health disparities by eliminating the need for patients disclose potentially stigmatizing risk factors and also provide healthcare providers with a simplified vaccine decision-making process.

As reported during previous CHAC meetings, CDC is currently updating its hepatitis B screening recommendations from risk-based to universal recommendations as well. This will complement the vaccination approach, as well as the hepatitis C and HIV screening guidelines among adults. The proposed updated recommendations are 2-fold. The first recommendation is that screening be performed at least once in a lifetime for all adults ≥ 18 years of age and the second is to expand existing risk-based testing recommendations for ongoing testing for additional groups, including people who are currently or formerly incarcerated people with a history of STIs, and people with a history of hepatitis C virus infection. These recommendations are currently available on the *Federal Register*⁶ for public comments, which closes on June 3, 2022. Formal publication of this update is anticipated later in the year.

The prevalence of hepatitis C is increasing among reproduction aged individuals and pregnant persons, with approximately 6% of perinatally exposed children becoming infected.⁷ Of the recommendations currently available, the most consistent is to test exposed children with a hepatitis C antibody test at or after 18 months of age. There is no clear guidance regarding hepatitis C RNA testing beginning at 2 months of age despite the fact that this testing may possibly decrease loss to follow-up and misidentification. CDC is working to develop evidence-based hepatitis C testing recommendations for perinatally exposed children to ensure that exposed infants and children are appropriately tested and linked to care and curative treatments. Peer review and public comments for these recommendations are expected to take place in Fall 2022, with publication anticipated in early 2023.

Viral hepatitis cannot be eliminated without also addressing the challenges posed by the national opioid crisis. People who inject drugs (PWID) are at high risk for viral hepatitis, HIV, and other infections. They also experience unique barriers to testing and treatments. Harm reduction service programs are a proven effective component of community-based programs to prevent the spread of infectious consequences from injection drug use. In 2019, the DVH established the National Harm Reduction Technical Assistance Center (NHRTAC) to strengthen the capacity of SSPs.⁸ DVH first partnered with the National Alliance of State and Territorial AIDS Directors (NASTAD) to build the infrastructure of this center. As the program grew, partnerships were expanded to include the National Harm Reduction Coalition (NHRC) and the University of Washington. Now in Year 3, the center has broadened involvement of the NHRTAC to include CDC's Injury Center and SAMHSA and National Association of County and City Health Officials (NACCHO) and 6 additional TA-providing organizations are joining for bridging expanded expertise and offering harm reduction from health departments and recovery communities, as well as experts from SAMHSA's Addiction and Prevention Technical Training Centers.

As part of the effort to build up comprehensive programs to support the needs of PWID, CDC released a NOFO in March 2002, Strengthening Syringe Services Programs (CDC-RFA-PS22-2208), with 2 key components that will increase access to harm reduction services for PWID. Component 1 will support the development of a national network of SSPs to facilitate

⁵ <https://stacks.cdc.gov/view/cdc/115806>

⁶ <https://www.federalregister.gov/d/2022-07050>

⁷ Centers for Disease Control and Prevention. 2019 Viral Hepatitis Surveillance Report. <https://www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm>

⁸ harmreductionhelp.cdc.gov

communication among SSPs and other harm reduction programs and health organizations trusted by the PWID community and improve data about SSPs by conducting an annual national survey of SSPs to document capacity, needs, access, and service gaps. Component 2 will increase support and resources to SSPs for implementation of these programs, including syringe distribution and disposal, testing, treatment, and prevention of the infectious complications of infections of injection drug use. This program will enhance and expand harm reduction services leading to reductions in new viral hepatitis infections.

In conclusion, the DVH will continue to promote innovative and holistic approaches to reduce health disparities and meet the needs of people living with or vulnerable to viral hepatitis.

Division of STD Prevention (DSTDP) 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 reported that DSTDP is in the process of developing a new division strategic plan for 2022-2025. This effort will include alignment with the Sexually Transmitted Infections National Strategic Plan for the United States | 2021–2025.⁹ The new proposed goals will be to:

1. Prevent new STIs
2. Improve the health of people by reducing adverse (harmful) outcomes of STIs
3. Accelerate progress in STI research, technology, and innovation
4. Reduce STI-related health disparities and health inequities
5. Achieve integrated, coordinated efforts that address the STI epidemic

The new plan is projected to be finalized in early Fall 2022. DSTDP envisions a whole nation response to preventing and controlling STIs in the US that goes beyond disease to address the health and wellbeing of the individual, recognizing that this will require support of partners and collaborators.

The National Strategic Plan and the DSTDP strategy call for reductions in disparities and health inequities. This key approach will be reflected in NOFOs and activities to ensure that there is high population-level impact. The strengthening of STD prevention and control for health departments has had a tremendous response, with an additional \$200 million going to recipients each year for the next 5 years for which there is an emphasis on expansion of the workforce and to strengthen disease outbreak and response capacity by bringing on an additional 1800 staff members. DSTDP continues to strengthen its supplemental surveillance projects, including strengthening US surveillance of drug-resistant gonorrhea with the use of whole genome sequencing (WGS) to better understand the epidemiology of gonorrhea. Investments are being made in innovation, particularly in syphilis diagnostics and in training of Disease Intervention Specialists (DIS). Some of these innovations and trainings will be funded from the \$1.13 billion that was allocated to DSTDP last year through the America Rescue Plan Act.

⁹ <https://www.hhs.gov/sites/default/files/STI-National-Strategic-Plan-2021-2025.pdf>

The 2020 STD Surveillance Report¹⁰ was released in early April 2022 along with preliminary 2021 syphilis data. In 2020, there were increases in gonorrhea, syphilis, and congenital syphilis. Increases are being seen in syphilis and congenital syphilis for 2021 as well. Conversely, there was a 12.7% decline in cases of chlamydia from 2019. This decline is likely due to decreasing STD screening and diagnosis during the pandemic rather than a reduction in new infections since chlamydia is usually asymptomatic. While syphilis cases are increasing, they do present an opportunity for HIV prevention. Since 2015, the number of primary and secondary syphilis cases reported among HIV-negative MSM has surpassed the number of cases reported among HIV-positive MSM. While overall cases reported among HIV-positive MSM may be leveling off, there are no signs of syphilis slowing down among heterosexuals. Reported cases of primary and secondary syphilis cases increased 420% among women from 2011-2022. The intersection of HIV and syphilis presents a clear opportunity in which syndemic approaches can be beneficial to addressing these infections, as well as the conditions that contribute to their occurrence.

Along with the new plans, some key actions DSTDP is taking include identifying opportunities for collaboration and integration of services, increasing access to stigma-free healthcare, expanding partner services and DIS programs, improving STI diagnostics and therapeutics, and enhancing surveillance systems to inform public health actions and better understand root causes of increasing STIs at the national and local levels. For each of these activities, DSTDP is committed to a process that prioritizes access to and extension of services that address disparities and inequities. Social health services can be a gateway for overall health and wellness. DSTDP will move from a disease-focused approach to a social health promotion and wellbeing framework.

HRSA DFO Welcome and Update

Laura Cheever, MD, ScM

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

Dr. Laura Cheever extended her welcome to new CHAC Voting Members, Mr. Lindsey and Dr. Markham. She also welcomed new NIH *Ex-Officio* member, Dr. Goodenow, and expressed her gratitude to Dr. Gaist for his years of service to CHAC as the NIH *Ex-Officio* member.

Dr. Cheever announced that Carole Johnson was named the HRSA Administrator in January 2022. Before coming to HRSA, Ms. Johnson served as the Testing Coordinator on the White House COVID-19 Response Team. She also served as the Commissioner of the New Jersey Department of Human Services, leading the state's largest agency and providing healthcare and social services to 1 in 5 New Jerseyans. During her tenure as Commissioner, the Department expanded Medicaid coverage of mental health and substance use disorder (SUD) services, created new Medicaid benefits to improve maternal health outcomes, and integrated Medicaid into the newly launched state-based Affordable Care Act (ACA) marketplace. Ms. Johnson served for more than 5 years as the Domestic Policy Council public health lead in the Obama White House, working on the Ebola and Zika responses, implementation of the ACA, and combatting the opioid epidemic. In addition to several key positions on Capitol Hill, Ms. Johnson was Policy Director for the Alliance of Community Health Plans, Program Officer with the Pew Charitable Trust health program, and Senior Government Relations Manager with the American Heart Association (AHA). Dr. Cheever welcomed Ms. Johnson back to HRSA where

¹⁰ <https://www.cdc.gov/std/statistics/2020/default.htm>

she previously worked in workforce policy, and she thanked Diana Espinosa for leading the agency as the Acting Administrator for the last year and a half. HRSA is fortunate to have someone with Ms. Johnson's experience and deep knowledge of HRSA's programs, as well as her passion about health equity in the work the agency does.

HRSA's HAB vision is optimal HIV care and treatment for all to end the HIV epidemic in the US. The 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. Health equity is a core concept of the RWHAP, which has been working many years to reduce disparities. It is very exciting to have a new environment in which health equity is in the forefront across the entire federal government.

HRSA is excited that the HAB website has been officially relaunched with a new look and the new URL of <https://ryanwhite.hrsa.gov/>, which should help people searching for information on the Ryan White HIV/AIDS Program (RWHAP). The website navigation has been updated and the content has been reorganized to help visitors find information and resources more efficiently.

Since the last CHAC meeting on December 1, 2021, the *National HIV/AIDS Strategy (NHAS, the Strategy)*¹¹ was released and provides stakeholders across the nation with a roadmap to accelerate efforts to end the HIV epidemic in the US by 2030. In order to guide the nation toward realizing the vision, the strategy includes 4 overall goals, which are to:

1. Prevent new HIV infections
2. Improve HIV-related health outcomes of people with HIV
3. Reduce HIV-related disparities and health inequities
4. Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and stakeholders

The strategy has been used across HRSA and government to help focus efforts and refine the work that is being done in this area.

HRSA is developing an NHAS Implementation Plan that outlines specific actions to achieve the Strategy's goals and objectives. Representatives from across HAB and HRSA have been working to identify strategic policies, programmatic activities, and initiatives to leverage support of the goals, objectives, and strategies outlined in the plan as part of the Strategy implementation. Partnering across the federal agencies is a very important part of this step in the work. HRSA has actively engaged CDC, Administration for Community Living (ACL), Housing and Urban Development (HUD), and others in thinking about the work that needs to be done in order to achieve the goals. Given the Strategy's whole of society approach, HAB leadership conducted a series of listening sessions to engage directly with the RWHAP stakeholder community to hear thoughts and ideas on ways HRSA can support the goals and objectives outlined in the NHAS in the effort toward EHE. Key stakeholder groups included patient advocacy organizations, HIV provider organizations, constituency-based organizations, and coalition groups. Dr. Cheever expressed gratitude for the contributions of the many divisions and offices that took part in this collaborative effort, including HRSA's regional offices and CDC that were part of all sessions.

¹¹ <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>

The NHAS also calls for the development of a quality of life (QOL) indicator. The White House Office of National AIDS Policy (ONAP) asked CDC and HRSA to Co-Chair a federal WG to make recommendations. The WG's charge from the White House was to use existing federal datasets that include measures of QOL or measures that can assist in gauging QOL. ONAP held a community listening session to receive input on these datasets. The WG was asked to complete its work by May 2021. QOL has been part of the fabric of the RWHAP over many years. In the absence of a method to measure QOL, HRSA has been addressing it through various domains, such as housing instability, employment, and food insecurity. Critical thought also is being given to domains around health, wellbeing, and psychological factors and work has begun on a framework to conceptualize the efforts and identify work that still needs to be undertaken.

HAB has a relatively new and productive partnership with ACL. ACL's mission is to foster safe, high quality health care for the aging population. This is particularly important for the RWHAP where many clients are aging with HIV. In 2020, about 48% of clients in the RWHAP were over 50 years of age. The goal of this partnerships is to work together to share resources among recipients and cultivate partnerships with other federal and non-federal partners. HAB and ACL have collaborated on several webinars to share information about the RWHAP and to hear from ACL about their programs and services. HAB and ACL also have teamed up with training for ACL grantees and Ryan White recipients on the Older Americans Act (OAA) and Area Agency on Aging (AAA). There is a tremendous amount of expertise in the community on aging, which should be leveraged in the efforts to expand the work in the RWHAP in order to improve services for older people with HIV quickly.

HAB also has a longstanding committed partnerships with HUD. HAB is currently assessing how the RWHAP can better address the housing needs of people with HIV. Because HAB is not primarily a housing provider, they are grateful for the partnership with HUD. The focus traditionally has been on the federal Housing Opportunities for People with AIDS (HOWPA) program. HAB also is working to expand its efforts with HUD beyond the HOWPA program and to continue to work together to address the needs of RWHAP clients. HAB and HUD will continue to partner on educational events at the intersection of housing and HIV and other opportunities broadly across HUD programming.

The 2022 National Ryan White Conference (NRWC) on HIV Care & Treatment will be convened August 23-26, 2022. Dr. Cheever thanked the RWHAP community providers, recipients, and partner organizations who submitted a total of nearly 400 abstracts for consideration in the 2022 conference. Abstract approvals were sent out the week of April 12, 2022. In light of the constantly evolving COVID-19 pandemic, HAB has made the decision to host the 2022 NRWC virtually. This is a shift from the initially proposed hybrid format that included both virtual and in-person components. The conference dates will remain the same, but times will be adjusted to accommodate the different time zones. Recognizing the unpredictability of the COVID-19 pandemic over the last several years, HAB holds true to its commitment to providers, recipients, stakeholders, partner organizations, planning council members, and more than the half million people they serve every day to reduce any risk of potential COVID-19 transmission. All of the recipients, providers, stakeholders, and people with HIV who are a part of the RWHAP will have an opportunity to attend the conference and not be taken away from the communities HAB serves. This means that the RWHAP part-specific caps that were applied to the hybrid format no longer apply. The virtual format will utilize the same platform as the 2020 conference that had incredible engagement during the chat as sessions were occurring. All breakout sessions will be pre-recorded.

Turning to policy updates, transgender people with HIV continue to be a priority for HAB. There are tremendous disparities for this particular population. In December 2021, HAB released a letter to RWHAP service providers reaffirming the importance of providing culturally-affirming health care and social services to the transgender community as a key component of improving the lives of transgender people with HIV and eliminating health disparities. The letter is not a new policy or approach to the services delivered by the RWHAP, but builds upon HAB-funded initiatives that support patient-centered, trauma-informed, and inclusive environments of healthcare for people with HIV to help reduce medical mistrust and other barriers to adherence from transgender populations.¹²

To highlight a few RWHAP updates, 2 new Executive Summary documents have been published that are on the RWHAP website. The first is a high-level summary of what was learned during the 2021 EHE in the US listening sessions with public health leaders and communities mentioned earlier. This document discusses the key themes from those sessions and provides a high-level look at how HAB is moving forward to build on what has been learned. The second Executive Summary is based on the telehealth white paper that shares how RWHAP have been leveraging telehealth during the COVID-19 pandemic. Both of these publications should be useful to RWHAP.¹³

Moving to data updates, all states showed improvements in viral suppression among RWHAP clients by state from 2010 to 2020. However, some states continue to have room for improvement—particularly in the Southeast US. Also notable was a significant improvement in viral suppression in 2020 even though at that time, states and recipients were responding to the COVID-19 pandemic. Among key populations served by the RWHAP, viral suppression of all RWHAP clients was 69.5% in 2010 and 89.4% in 2020. The improvement in suppression occurred across all key populations. However, it is important to note that challenges remain in achieving viral suppression for certain populations. Most notably in 2020, there were disparities in viral suppression overall for African Americans and Blacks at 86.7%, transgender clients of 84.5%, youth 12-24 years of age at 81.5%, and clients with unstable housing at 76%. This illustrates that more work needs to be done.

Viral suppression increased for all RWHAP clients nationally by about 19.9 percentage points from 2010-2019. Key populations had even greater improvements in viral suppression. For example, viral suppression increased by 23.4 percentage points among African Americans. This demonstrates that while disparities remain, the disparity gap has been decreased. Among youth transgender populations and people who are homeless, larger disparities remain with significant work to do.

The inaugural *2020 HRSA HAB Ending the HIV Epidemic in the U.S. Data Report* was released and is posted on the HRSA HAB website. This is the first publication to highlight data submitted through the EHE Triannual Module data system. This module collected aggregate-level data 3 times a year on the number of new and existing clients receiving services and the number of clients prescribed antiretroviral therapy from EHE-funded providers. EHE recipients, sub-recipients, and stakeholders have been doing important work in response to the COVID-19 public health emergency to meet the needs of clients during that emergency while simultaneously doing incredible work in this new EHE Initiative that launched in March 2020 simultaneously with the COVID-19 pandemic nationally and submitting high-quality, complete EHE triannual data to HRSA HAB.

¹² <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/hiv-care/gender-affirming-care-rwhap.pdf>

¹³ <https://targethiv.org/library/innovation-rwhap-telehealth>

Many EHE recipients used their EHE funding to expand and innovate the delivery of existing RWHAP service categories. For example, RWHAP EHE recipients focused on what could safely be accomplished during the pandemic such as emphasizing self-care within the community, leveraging virtual spaces, and staggering or scaling back activities in order to provide them safely. Recipients also introduced flexibilities that prioritize health and safety, such as offering telehealth and remote work for staff, contactless prescription delivery, e-prescribing, providing 90-day supplies of antiretrovirals, and delivering socially distant case management and navigation—something most providers had not done previously.

EHE recipients scaled up services to address new activities or activities where there was greater demand, such as transportation, rental assistance, emergency financial assistance, and food or delivered meals. Recipients also worked to streamline the client experience, including consolidating services in clinics and creating policies and procedures to simplify future client interactions. Beyond EHE, recipients were able to leverage their existing RWHAP knowledge, partnerships, experiences, and resources so their jurisdictions could respond to the COVID-19 pandemic. It is amazing what recipients have been able to achieve throughout this pandemic.

CHAC Member Discussion On CDC & HRSA Updates

The following questions, observations, and suggestions were raised:

- Dr. Gayles observed that all of the teams demonstrated the ability to be flexible in pivoting to new ways to deliver services to meet the needs of those who utilize CDC and HRSA services. Mental health crisis in children was significant before COVID-19 and is further exacerbated. This is a key moment in terms of responding to this need in terms of building infrastructure. Equity remains important as disparities continue to be seen in incidence across populations and continued gaps in access to services such as PrEP. There are exciting new funding opportunities from CDC and HRSA and continued inclusion of the SDOH and the impact that those play on service delivery. It also was affirming to hear the continuing commitment from both agencies in providing affirming services to different communities, given the political environment in many places across the country that potentially affect the way services are delivered. Given the increased attention on mental health in young people and the impact that mental health issues can play on risk-taking behaviors, he inquired as to how services are being implemented across the board in various divisions in thinking about rolling out new projects.
- Dr. Ethier said that from a school health perspective, DASH has layered in additional resources received from Coronavirus Aid, Relief, and Economic Security (CARES) Act dollars to transition some of the school services into the virtual setting and to help support the infrastructure that already had been created to connect youth to sexual health services and to mental health services. Schools received an influx of funds and an array of additional resources, but it is not clear whether they were able to use those funds effectively toward these efforts. There have been discussions with partner organizations to establish services outside of schools and determine the best way to connect with school districts. As often is the case with community-based services, a 2-pronged approach is needed. Something is needed to motivate the school district to create infrastructure to connect to services in the community, but that is not sufficient. It is also important to make a connection to the community to help them establish connections in schools. They have consistently seen that it is not going to be possible to “mental health professional” our way out of this. There are not sufficient trained mental health providers to be able to deal with the influx. Mental health services are just not available for adolescents. This also speaks to the pipeline issues. In

order to convince providers to train or retrain to work with youth, the mental health professional pipeline has to be made possible, affordable, and attractive.

- Based on the data Dr. Cheever presented, Mr. Driffin noted that close to 90% of people living with HIV return back to care. He wondered whether the data team would pose additional inquiries to determine why those individuals decided to stop care and ultimately return to care during the pandemic or connected to EHE activities, and how those findings could be incorporated into better healthcare delivery for people living HIV.
- Dr. Cheever indicated that they are not collecting this from the recipients. The reporting is kept high-level because of the burden on recipients. Many EHE programs do inquire about what keeps people out of care so that they can better respond in the future. A challenge over time has been the difficulty in finding people who are out of care, understanding who they are and the challenges they face. Dr. Cheever will take this idea back to the Project Officers.
- Dr. Mermin observed that the viral load suppression data highlighted by Dr. Cheever showed remarkable increases in viral load suppression with a 30-point absolute increase in 10 years and an almost elimination of racial and ethnic disparities in viral suppression. He wondered what the most important factors were that led to that increase, as well as how to get to the next 10% to achieve 100%. He also requested an update on the HRSA-initiated hepatitis C program that screened, diagnosed, and cured people in RWHAP of hepatitis C.
- Dr. Cheever noted that HAB has been focused on data quality and quality improvement. There have been several large collaboratives with hundreds of thousands of patients in which individual recipients assess their data and then experts, including people with lived experience, to help figure out what works through a quality improvement rapid cycle. A number of these over the years have been successful and the rates of improvement in these initiatives have been remarkable. That is why they are adamant about developing best practices communication so people can demonstrate improvements by publishing what works in this key population so others are able to replicate. There is some improvement with easier drugs to take, but overall improvement is due partly to specific quality improvement activities. The hepatitis C chart abstraction work slowed down during the pandemic because it is difficult to collect data at the national level, especially regarding treatment and sustained viral response. HAB has a chart abstraction contract through which these data were going to be collected in individual clinics, but that was delayed significantly by the pandemic. All they have at this point are anecdotal inputs.
- Given that many cities are experiencing increasing problems with homeless populations, Dr. So inquired as to whether CDC has programs to try to improve prevention, testing, and treatment for HIV and hepatitis in homeless populations and whether SSPs across the country are experiencing any pushback by states.
- Dr. Mermin indicated that there is a lot of interest in homeless populations at CDC. They have been engaging with HOPWA and HUD in general, and DDID has taken on a role of looking across the agency to determine whether there are ways to work at the more fundamental social determinants side. Housing and homelessness affect almost all aspects of public health, so CDC is increasingly trying to work in that field. In terms of SSPs, it is a project that takes concerted effort and continual monitoring and support over time. In some places, SSPs have been initiated and expanded and sometimes there is not a lot of pushback. SSPs become normalized with engagement with the community and law

enforcement, and when there is supportive legislation in the state or local areas that enable SSPs to continue over time. There are other places where SSPs are going well and then there is pushback for a variety of reasons (e.g., political conflict in the community, certain events that result in loss of trust with law enforcement or politicians, et cetera). There are a lot of services that cannot be offered now due to minimal resources, lack of technical capacity, and or lack of infrastructure.

- Dr. Daskalakis added that really great work is occurring with HUD beyond HOPWA in a more status-neutral space. One exciting area is the work with HOPWA to think about housing as an outbreak intervention which is moving in a great direction. They are looking at ways testing interventions can be deployed specifically in those environments as social determinants are also being addressed. DHP's most recent NOFO for young MSM and transgender women of color has a component that asks the grantees to select areas of social determinants to pursue, one of which is housing.
- Dr. Wester added that people who use drugs, injection and non-injection, and people experiencing homelessness are some of the populations most heavily impacted by the multistate outbreaks of hepatitis A, which now include 37 states and over 44,000 cases. The TA efforts that have been provided to states and other jurisdictions experiencing that have made a lot of inroads into those communities.
- Dr. Anderson emphasized how impressive the increases in viral load suppression and reduction in disparities were that Dr. Cheever presented. She asked how DASH plans to follow up on the data regarding mental health issues among adolescents, particularly the data on LGBTQ adolescents and the outsized concerns in these issues. This includes more than individuals who are HIV-affected. She asked whether the data on LGBTQ includes transgender and lesbian, gay, bisexual or if they were separated out. The issues are probably slightly different.
- Dr. Ethier indicated that for the ABES data, they were not able to include a question on transgender identify. At this point, that question is on the state optional list. However, they were able to include the transgender identify question on the ballot process for the questions to be included in the 2023 YRBS. They are optimistic that this question will be included on the national survey. Hopefully for the next CHAC meeting, she will be able to provide an update on some of the improvements they will be able to make for the 2023 survey. ABES was done in Spring 2021 and the regular YRBS was moved to Fall 2021. Approximately 30 states and locals included the transgender identify question on the state YRBS. This allows them to group those data together to look in more depth at those students.
- Mr. Lindsey noted that substance use is an area that has not had as much data to contribute to prevention efforts and healthcare engagement efforts, and that he was happy to hear about the marijuana data in Dr. Ethier's presentation. Particularly given the increase in stimulant use over the past couple of years due to isolation and other social dynamics that have arisen, especially in urban communities. He wondered if they have been able to or plan to collect those data.

- Dr. Ethier indicated that they do assess stimulant use as one of the substances. They did not find an impact of the program on stimulant use, but that could be because it was relatively low for young people—at least when those data have been collected. Prior to the pandemic, all substance use apart from alcohol and marijuana had been decreasing. They have not collected opioid data for long enough to know whether there has been an increase or decrease.
- Dr. Daskalakis added that the National HIV Behavioral Surveillance (NHBS) survey is able to tease out stimulant use, which is something that DHP is following.
- Dr. Cheever added that they are taking a deeper dive into SUD and what people are actively using in their chart abstraction survey, so that will be a topic every other year.
- With the current political climate regarding LGBTQ in Florida, Dr. So asked Dr. Ethier whether she is worried about the coming year in terms of how much progress can be made. Already there are mental health issues. He wondered whether the politicians know how much harm they are doing. He also asked whether it would be appropriate for them to raise this concern through a CHAC statement, perhaps.
- Dr. Ethier responded that as a federal employee, she was unable to comment on any particular state law or policy. She said that she is extremely concerned about whether the gains made over time in implementing the policies and practices that she mentioned are effective for all youth with respect to mental health and wellbeing. In 2018, close to 80% of schools had safe spaces for LGBTQ students, more than 90% had anti-harassment laws, and about 75% had professional development on inclusivity for teachers. That had improved dramatically over time, but now changes have been made to directly take some of those important practices out of schools. She is extremely worried about the mental health crisis for young people. Taking away those supports will be threatening not only for LGBTQ students, but also for other students. As she mentioned earlier, making schools more toxic for anyone makes them more toxic for all students.
- In terms of whether there is something CHAC can do, Drs. Gayles and Anderson will discuss this offline and will get back to the group about what is/is not within CHAC's purview as a committee.
- Mr. Riester noted that a bill recently passed the House that would criminalize certain amounts of fentanyl, which could increase the number of people who are incarcerated and also would require mandated substance use counseling. There is a very large problem with fentanyl across the country, so this is something to think about in the future. Regarding mental health status and LGBTQ youth, he asked whether there is a correlation to visibility, inclusion, awareness, and/or a specific geographic prevalence.
- Dr. Ethier responded that the ABES data is nationally representative, so it does not tie back to specific geographic areas. They do not ask about visibility, inclusion, and awareness in this survey. Therefore, they do not know whether the more "out" someone is increases the reaction and stigma associated with their identity. However, this is a very important question. It might be possible to look at some of these difference by state in the 2021 YRBS data. This did come up to some extent with regard to parental abuse questions related to

issues around whether healthcare providers and school personnel are required to report back to parents if they have conversations with young people about their sexual identity. They do not ask these questions, but it is difficult to imagine that there is not some aspect of being out to one's family and then experiencing abuse, otherwise they would not see the difference between students who identify as heterosexual and those who identify as LGBTQ.

- Dr. Markham added that as a youth sexual health researcher in Texas, she echoed Dr. Ethier's concerns. They hear a lot from school-based personnel and clinicians that the climate in Texas is definitely a concern in terms of the mental health of youth and also their families trying to be supportive of them. With the abuse cases and reporting cases, it is getting quite dire. Whatever CHAC might be able to do, she would love to be part of that. She also expressed interest in information about additional initiatives for provider training, influences, and other programs to address rises in congenital syphilis, for which Texas may be #1. There also is an overlap with teen STI rates in Texas.

Panel 1: Strategizing an Approach to Providing Comprehensive STI Services

Moderator: Robert McDonald, MD, MPH, LCRD, USPHS; Medical Officer, Division of STD Prevention, NCHHSTP, CDC

Addressing STIs in Mississippi

Thomas E. Dobbs, MD

State Health Officer

Mississippi Department of Health

Dr. Dobbs first shared a photograph from an 1881 photograph atlas on cutaneous syphilis to illustrate that history is reality and that a lot of work remains to be done. For instance, based on the 2020 published STD rates, Mississippi ranked first in chlamydia per capita by a substantial margin of almost 100/100,000 population higher than Louisiana, ranked second highest for gonorrhea, and tied for first place in primary and secondary syphilis rates. This is the worst STI performance he has seen during his tenure at the State of Mississippi. While that is awful and embarrassing, there are interventions for improvement.

There has been a transition in the landscape of care. The health department and its STD clinics traditionally have been thought of as a go-to location for STD treatment and diagnostics in Mississippi. However, data by ordering facility type in 2020 showed that the majority of STD cases were being identified primarily in private physician offices and other health clinics. Some reasons for this are the general transition away from public health services for clinical care and funding issues. Compared to 10 years ago, they have half of the nurses they had in 2010. They have less nurses now in 2022 than in 2019—even with the COVID-19 pandemic funds. While there is a paucity of providers in general, nurses are responsible for much of the frontline work in STI treatment. If the Mississippi Department of Health is addressing only 10% of the pie, they are missing 90% of the opportunity and must rethink how to address STIs in Mississippi.

To demonstrate a parallel lesson, the fertility rate in Mississippi has been declining gradually since 2001 other than an interesting increase from 2006 to 2008 that was observed across the country for unknown reasons. There also has been a decline in teen births in Mississippi, with the exception of an increase in 2007. Although fertility and teen birth rates have been

decreasing, the health department has been losing ground in providing reproductive health services. This suggests that there are solutions to the problem that transcend what a county health department or STD division can do, but depending upon third parties who do not have the same authorities or a more holistic view of STI intervention also raises a number of challenges in addressing STIs and HIV.

Community health centers offer an opportunity for interventions in Mississippi where there are 11 Federally Qualified Health Centers (FQHCs) that operate 69 school-based clinics. This presents an excellent opportunity to provide sexual health resources to young people who are at risk. The majority of chlamydia and gonorrhea cases occur among older teens and young adults in their early 20s. While there are only 69 school-based clinics currently, there are 530 high schools in Mississippi. This means that there are many uncovered locations that could be served.

As pointed out in Healthy People 2020, one of the correlates associated with STD transmission is social determinants of health (SDOH). Mississippi Department of Health has struggled to expand its role beyond just STDs. While they can get shots in people's arms, test for chlamydia, et cetera, they must address SDOH—most of which pertains to racial and ethnic disparities. Otherwise, they will continue to try to “bail water from a sinking ship.” The majority of STD cases are now among African Americans, which are a minority population. SDOH issues must be addressed to get ahead of the problem. These include racial and ethnic disparities, structural issues (including structural racism), poverty and marginalization, access to healthcare, substance abuse, stigma pertaining to sexuality and secrecy and/or HIV transmission, risky sexual network, and so forth.

Most adults and the vast majority of children in Mississippi have health insurance. However, about 24% of adults are uninsured. Mississippi adults 19-25 years of age represent a high-risk group who do not have access to care and impoverished communities are over-represented. There are multiple difficulties in Mississippi. They do not have contact tracing and treatment, especially within private clinic settings. If someone is diagnosed within the health department, they will be given a referral card. While Mississippi does not yet have partner expedited therapy, an effort to offer this option is underway. The private clinic setting does not have the same public health focus that county health departments and STD-focused clinics have. Stigma and reluctance to discuss sexual health among patients and providers is a major problem, especially in the era of a 15-minute medical visit—10 minutes of which are spent on a computer. Ensuring that clinicians are up front diagnosing people with STIs and that there is access to care are critical issues. Mississippi is a non-expansion state with no anticipation of that changing in the near future. This state also has a very high poverty rate, is a rural location, and has a low provider to population ratio. People with STIs or symptoms do not want to go to a local clinic for various reasons, which results in major delays in care.

There are many potential opportunities, such as using some of the lessons learned from the COVID-19 pandemic to move forward. COVID-19 provided an opportunity to build remarkable new partnerships that included making remarkable inroads with the Spanish-speaking community, faith communities, local leaders, and others. These partnerships should be fostered and translated into successes in sexual health and STI prevention, treatment, and diagnosis. Continued work must be done to advance partner expedited therapy, though it is going to be challenging to move that outside of the health department to places where the majority of people are being seen. Mississippi plans to perform targeted contact tracing. For a small state with a shrinking workforce and 30,000 cases of chlamydia, comprehensive contact tracing poses a major challenge, but an effort must be made to try to interrupt some high-risk sexual networks.

Telehealth offers a major opportunity. While Mississippi Department of Health already offers universal PrEP through free telehealth, it is currently underutilized. It also is important to break down silos such that all services are providing comprehensive care that are not focused only on STIs or HIV. Mississippi has a major challenge within its epidemiology infrastructure and is underfunding its workforce. Mississippi has one epidemiologist for HIV/STDs. The state also is traditionally unfriendly to government employees and tries to keep the wages artificially low. Hence, people who complete top-notch training programs are not flocking to the Mississippi workforce. Despite the challenges, Mississippi will continue to seek opportunities for improvement.

Innovative Models to Support New York City (NYC) Sexual Health Clinics

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Dr. Aracena described innovative models that the NYC Department of Health and Mental Hygiene (NYC Health) have incorporated during the COVID-19 pandemic to reach and continue to serve New Yorkers with sexual health services. NYC Department of Health went through a reorganization during the pandemic, so the Bureau of STI no longer exists and the clinics have been folded into the Bureau of Public Health Clinics (BPHC). Bringing innovative services to the community was done through innovative approaches such as telemedicine, an STI Hotline, STI Quickie, and a COVID-19 Pivoting Model.

The BPHC was created on July 1, 2021 and oversees the health department's clinics that offer direct services to New Yorkers. This includes 8 Sexual Health Clinics (SHCs), 4 Tuberculosis Chest Centers, and 9 COVID Express Testing and Vaccination Clinics. The rationale behind this reorganization was that under centralized clinical operations, they are in a better position as a bureau and agency to achieve their goals to integrate services where common interventions are effective; create new pathways to expand services, especially telehealth services that are new for NYC Health; implement innovative approaches; and improve resilience to budget challenges.

Pre-pandemic in 2017, NYC Health serviced close to 80,000 patients. Among them, 53% are MSM and 47% percent are men who have sex with women (MSW). The 4 clinics operating in 2021 saw less than 50,000 patients, the demographics continued to narrow, and they were still reaching similar populations. Interestingly, there was an increase in MSW presenting for services or who received services via telemedicine. In terms of the SHCs' annual volume, there was a peak in 2019 and a major decline in 2020 during the height of the COVID-19 pandemic. Clinic visits and telemedicine visits began trending back up in 2021. In terms of efforts to reduce sexual health disparities, the clinics offer same-day HIV testing and PrEP and post-exposure prophylaxis (PEP) and PrEP JumpstART. Other services include STI screening and treatment, condoms, partner services, emergency contraception, QuickStart contraception, crisis counseling, and substance use services.

In terms of the impact of COVID-19 on SHCs, the BPHC is within the Division of Disease Control. Therefore, many NYC Health staff were deployed to the pandemic response and 7 of 8 clinics had to be closed as part of the deployment and lockdown. The Chelsea clinic in Manhattan remained open and NYC Health quickly had to identify a model on how to continue to serve New Yorkers during this time in the absence of the clinics. The telemedicine operation was launched by the end of March 2020 to provide all EHE services. Not only were they able to assess individuals during this time, but also they were able to prescribe. They quickly published an RFP to contract with a pharmacy to deliver medications to individuals' homes at no cost to the patient. An additional layer was added to the pharmacy delivery that included home HIV test kits.

In May 2020, they were able to reopen the Fort Greene Clinic with limited services, given that many staff were still deployed to the COVID response. In June 2020, express visits resumed, and long-acting reversible contraception (LARC) services resumed at one clinic. Express visits and LARC services resumed in the 4 currently operating SHCs in July 2020. The Jamaica clinic reopened in July 2020 with limited services and telemedicine was expanded as staff came off of deployment. By August 2020, COVID Express Clinics were opened in SHCs and Tele-PrEP began. They had about 12 weeks to convert spaces that were not previously laboratories into laboratories to be able to respond to COVID testing. Morrisania opened in November 2020 for limited services, so now there is representation in 4 of 5 boroughs. They do not have a presence in Staten Island. In July 2020, they were able to pivot one of the instruments being used for COVID testing to be able to do STI testing in parallel.

Telemedicine services included management of positive/abnormal STI tests results, with HIV treatment initiation for those diagnosed with HIV who wished to start HIV treatment for the first time; consultation for PrEP initiation for NYC residents ≥ 13 years of age, including daily PrEP and PrEP on demand; medical evaluation for those who think they have signs or symptoms of HIV; medical evaluation for those who might have or have been exposed to a HIV; contraception services, including emergency contraception and consultations for other contraceptive methods (e.g., pills, ring, patch, shot, LARC); and prescriptions for STI treatment and HIV home test kits. To highlight telemed trends, there was an increase in the volume of calls during the peak of the pandemic. However, this declined when clinics began to reopen and it was possible to work with community partners to link individuals to services. There were 523 Tele-PrEP visits in 2021. Among these, 376 (72%) patients visited a SHC post-telehealth visit within 14 days of the telehealth visit and 332 (88%) patients received PrEP medication on the day of their visit.

Services offered at STI Quickie Clinics include provision of services such that individuals are in and out of a clinic within a cycle time of under 30 minutes compared to 1.5 hours in regular SHC. Services offered include HIV testing with 1-minute results; and CT/NG testing with 24-hour or less results; syphilis serology testing and hepatitis serology testing for HEP A-B-C with results in 3-5 days. There continues to be an increase in STI Quickie Clinic visits that now reach capacity each day. The positivity rate of either gonorrhea or chlamydia is over 13%, which provides an opportunity to test/diagnose someone who is asymptomatic and engage in conversations with them on PrEP and additional services they may need. BPHC now operates 8 Covid Express clinics across Bronx, Brooklyn, Manhattan, and Queens within existing SHCs.

To highlight some expansion plans, STI Quickie Services will be scaled up in the outer boroughs with Fort Greene anticipated to come online in Summer 2022. A patient-facing scheduling platform will be implemented. A PrEP Continuity Clinic will open in Summer 2022. There are plans to build up an Emergency Response Unit to allow for pivoting between COVID

Express Clinics and STI services as needed, and future reagent cartridges will be explored for implementation as they are FDA-approved.

Minnesota Community Care

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Ms. Drake and Ms. Naughton described Minnesota Community Care's Health Start Clinics-School Based Health Clinics in St. Paul Public Schools (SPPS) and their comprehensive STI outreach. The Health Start School-Based Clinics began as a maternal and child health (MCH) organization housed in a hospital across the street from a high school. They realized quickly that teens, especially pregnant teens, were not keeping their appointments, even though the organization and school were across the street from each other. They were then given space within the school and now have 10 school-based clinics. Young people who have access to school-based care have much better health outcomes, and the mantra at the time was to make those clinics acceptable, accessible, and available and they still view their provision of services this way.

The clinics are designed with an integrated team approach that includes an Advanced Practice Provider, Mental Health Provider, Health Educator, Registered Dietician, Medical Assistant, and Clinic Coordinator. One of the school-based clinics is open to adolescents 13-22 years of age regardless of ability to pay. Confidential care is provided under the Minnesota Minors Consent Law, without notification to adolescents' families. Given that the Health Start School-Based Clinics can help to provide this care for free, it overcomes a barrier in other types of clinics that may bill insurance and send home an explanation of benefits (EOB). The 10 clinics within the SPPS see an average 4,000 unique patients a year between the 4 disciplines and have a total of approximately 25,000 visits.

In addition to the 4,000 students seen in the clinics, about 100,000 students are seen through classroom visits provided all year. They are often invited to Health and Social Studies classes to talk about a variety of topics (e.g., hygiene, risk reduction, risk management et cetera). Each year, CRUSH (Community, Restoring, Urban Youth, Sexual, Health),¹⁴ a partnership of youth serving organizations and community members, holds a statewide STI Day in June. CRUSH focuses only on chlamydia and gonorrhea on the day that youth come in. During the summer, 3 clinics are kept open so that young people never lose their access to health care. Even though the focus is on chlamydia and gonorrhea on the testing day, adolescents are invited back for a fuller panel of testing. On the CRUSH testing day, clinics can see as many as 50 to 70 young people in this stigma-free situation. When this began, the idea was to do testing for students who felt they might need testing. That felt very stigmatizing, so now it is presented as visiting the clinic to talk about staying safe for life.

¹⁴ <https://www.health.state.mn.us/diseases/chlamydia/crush.html>

This teen-friendly, stigma-free introduction to the clinics that focuses on outreach into the classrooms and beyond the clinic walls, offers walk-in testing and basic sexual health screening, and makes it fun and exciting (e.g., decorate the clinic, play music, have a raffle for attendees, provide treats, incentives, et cetera). These testing days are the first time some young people visit the clinic. This is the first time that they have visited the clinic, so there is visibility. While this was the first clinic to open in a school building, there are now thousands of school clinics. This is a wonderful way to provide adolescent healthcare. The SPPS school-based clinics are holistic in that they teach, test, and treat in a stigma-free manner. A longer screening form has been shortened just for CRUSH STI Day. Every adolescent who attends completes the screening form, which helps to determine what kind of care they need and provides contact information so that they can be reached for follow-up care if needed. They do make it clear that adolescents do not have to have had sex to attend a CRUSH STI Day, because it also includes education and outreach.

For ease of flow, only a urine screen is done for chlamydia and gonorrhea. The screening tool is used to schedule further education and screening for additional STI testing, including blood draws and throat and rectal screening. Condoms are provided to all students and as noted, the clinics can provide care for all students regardless of parental consent under the Minnesota Minor Consent law. The clinics within SPPS require parental consent for all services except reproductive healthcare. Clinic staff can help uninsured students apply for the Minnesota Family Planning Program (MFPP)¹⁵ to help assist with reimbursement rates for the services the clinic is able to provide.

The last CRUSH STI Day event was in Spring 2019 because SPPS did not return students to in-person education until the middle of April 2021. CRUSH STI Day 2022 is now being kicked off. During these events, approximately 400 teens are seen and about half of them are screened based on their sexual history and risk factors. There is about a 10% positivity rate.

CHAC Member Discussion on Panel 1

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 can CDC/HRSA support the expansion of STI care to include ART and PrEP services in clinical care sites and service areas?
2. How can CDC/HRSA support the integration of comprehensive care into school health clinics?
3. How do we equip school districts with a means to improve the linkage of healthcare in communities?
4. What else does CDC/HRSA need to consider when expanding STI care?

The following questions, observations, and suggestions were raised:

- Dr. Gayles noted that during COVID times, health department directors often have been met with surprise and confusion from political and community leaders for not having tons of contact tracers or a sophisticated surveillance system to follow COVID cases, which health department directors frequently pointed out that this was a side effect of years of budget cuts due to under development/underfunding of public health infrastructure. He asked how NYC was able to leverage CARES Act funding to support their rebranding and if they were

¹⁵ https://www.dhs.state.mn.us/dhs16_137813

able to identify new potential funding streams for other public health programs to support their work.

- Mr. Aracena indicated that there was a lot of cross-collaboration among agencies and hospitals throughout the city leveraging any current infrastructure.
- Dr. Dowler reported that North Carolina also is a non-expansion state, and they experienced a lot of the same issues as Mississippi. She has worked very hard over the last couple of years to expand PrEP access within the Medicaid family planning benefits. While this is a much smaller benefit, she encouraged Mississippi to reach out to their Medicaid partners. North Carolina was able to get everything within that program except for the drug, which can be obtained through HRSA's program to make it reimbursable for folks and to encourage health departments and FQHCs to reach out to that population that is essentially uninsured. An important part of North Carolina's initiative was that men need family planning as well.
- Dr. Dobbs indicated that Mississippi does have a full benefit for a family planning waiver for PrEP and they pay for the medicine as well. The problem is that it is underused.
- In terms of EOBs, Dr. Dowler indicated that North Carolina has viewed the EOBs being suppressed as a requirement for any Medicaid Claim. Particularly for managed care companies, EOBs cannot go out to the homes because North Carolina Medicaid does not want that to be a barrier for care. They want school-based health clinics or health departments to bill Medicaid as a payer source whenever possible so they can save their dollars for the uninsured. Some areas of the country experience barriers with school boards as well.
- Ms. Drake clarified that the public assistance program does not send home EOB, but private insurance does. Minnesota has only a handful of Planned Parenthood and other types of clinics left since so many have been closed over the last 10 years. Adolescents without access to school-based clinics suffer even more without access to other types of clinics. They are able to have a pharmacy in their school-based clinics through their 340B funding that permits them to provide various types of oral contraceptives, and they work with their obstetrics team to get IUDs placed.
- In terms of CHAC's role on advising CDC and HRSA, Dr. Greene inquired as to how the committee could support expansion and perhaps advise on how federal support could help with the interplay with local or state policies that are more restrictive. Given that the workforce is a challenge across all sectors right now, she also wondered what would help to increase the workforce or work in Mississippi or other areas that perhaps are not as desirable.
- Dr. Dobbs said that while he knew it was a pipe dream, the most beautiful thing that happened during COVID-19 was the HRSA portal. People used that like it was a de facto way for things to happen. His dream would be to have a HRSA portal for these other needs. In a non-expansion state, there are still major financial barriers for people to get access even to FQHCs. People who are undocumented are really in trouble because they do not have proof of income and are paying market rates for healthcare in a community health center. It would be helpful to find a way to have no cost visits for community health centers. The health department is the only place with no cost care, except for a few free clinics that do not provide reproductive health services. A lot of activities must happen, but there often are not enough people to get to the desired depth. Part of the issue pertains to deciding

what to do and handing off other activities to partners who are better suited for them. The issues with the epidemiology component involve low pay and the need to create a training program locally since people in Mississippi tend to stay there. Some strides have been made in pay, but now they do not have enough human resources (HR) staff to bring on new people. It is literally like trying to build a sandcastle in a hurricane.

- Dr. So commended NYC Health for thinking about expanding the usage of the laboratory capacity they built for COVID-19 to test for other diseases. He asked whether hepatitis A, B, and C testing is offered to all the patients who have no history of previous testing, infections, and/or who have not been vaccinated. CDC recently published a study that showed that in addition to the current recommendation, offering people a one-time hepatitis B test also would identify an estimated 1000 people every year who acquire hepatitis B from sexual activities and will save vaccine doses if they already have been infected or have immunity.
- Mr. Aracena said it was based on certain categories originally. Recently, they began offering testing and vaccination to all patients.
- Mr. Lindsey pointed out that while there is discussion about “risky sexual networks” and “social sexual networks” in the HIV area, he had not heard that as much in terms of STIs. He wondered whether there were opportunities to evolve the language to talk about “open sexual networks” instead of “risky sexual networks” in the future in terms of engaging communities in thinking about getting tested for STIs. He asked whether prophylactic interventions are a dead conversation in terms of STIs, even after the success of COVID-19 vaccines and some promising thoughts about the potential for an mRNA HIV vaccine. Consideration also should be given to work that is being done at the global level and whether that might make sense for local communities, such as the Dean Street Clinic in Atlanta that used some of the resources from the EHE planning. There are a lot of advantages to 24/7 online access to schedule STI screening and treatment, order HIV self-tests, order condoms and lubricants, obtain information to connect with health literacy training online or in-person, et cetera.
- Dr. Dobbs noted that Mississippi is making an effort to implement interventions in the community at the highest impact points. Part of that involves targeted contacts investigation and work with community partners to find the engagements that can pay the most dividends. When there are many bottlenecks, it creates “inverse energy” and more bottlenecks. Mississippi cannot even do GIS mapping because they cannot assemble staff. There is a lot of infrastructure to build out, but this is hard, laborious, boring, and no one wants to fund generalized infrastructure that is self-sustaining and builds on each piece.
- Mr. Aracena noted that like the Dean Street Clinic, the Quickie model was born out of being so busy during that pandemic that there were no opportunities for static. They were able to innovate and continue to evolve to try to stay ahead of the curve of not just the pandemic, but also in order not to lose sight of EHE as well. They were fortunate at NYC Health to have one STI Quickie model at Chelsea that they were quickly able to mirror and convert to a COVID-19 express testing model, which gave them the opportunity to expand out and extend their vision. It would have taken decades to stand up laboratories at all of the SHCs. Due to the pandemic, all sites have them. Now it is a matter of finding the funding to be able to turn them on and pivot them to extend the service.

- Dr. Gayles emphasized that with the pandemic funding streams drying up, consideration must be given on how to sustain the work that everyone has put in place. This is likely to be an ongoing conversation. As Mr. Lindsey raised earlier, what happened to creative science and technology to improve and prevent STDs and HIV (e.g., better diagnostics, point-of-care self-tests, better vaccines and more of them for a lot of infections, better treatments, et cetera)? These are all areas that respective parts of NCHHSTP have been exploring in terms of their role in moving these efforts forward, including working with NIH, FDA, and industry partners. This is a nascent topic that is ripe for growth, and it is possible that in the next CHAC or the one after that, it may be possible to talk more practically about what can be done about it. CDC is going to be funding new diagnostic research into syphilis testing.
- Dr. Mermin observed that telemedicine is a great opportunity to provide services and reduce inequities. One of the biggest obstacles for Tele-PrEP is the diagnostics. That is also true for STD diagnosis. There are good scientific data showing that the OraQuick® HIV test is insensitive compared to other tests in early infection and that it can be problematic particularly in regard to PrEP. Some anecdotal cases have reported several months before seroconversion with OraQuick®. He asked whether NYC Health has capacity to use surveillance and/or other data sources to look back at all of the people who participated in Tele-PrEP and use some form of person years of PrEP use and then HIV seroconversion rates. If it is low, that could be very useful for other jurisdictions that are considering this kind of programming and it could be compared to people who are taking PrEP in-person.
- Mr. Aracena clarified that their Tele-PrEP was more of a consult in which everything would be started for the individual, but it would not be initiated until the first day at the clinic. The at-home test kits were provided with a prescription for any STI treatment. They are still considering ways to evolve their Tele-PrEP initiative.
- Ms. Borges added that they did perform a surveillance match with their colleagues in HIV to assess HIV seroconversion.
- Dr. Anderson observed that the presentations offered nice snapshots of the urban, rural, and school-based settings. She asked whether the individuals presenting the Quickie Clinics differ from those who are accessing different services, and whether they were advertised differently. She asked to what extent each group was using peers or community-based workers in all settings, which could be enormously helpful in extending health services, reducing stigma, education, and using a task-sharing and task-shifting model.
- Mr. Aracena indicated that the demographics of the people accessing the Quickie and COVID Express services were very similar. When they expand to Fort Greene in the summer, they will be able to do further comparisons. NYC Health funds a lot of community organizations, FQHCs, and various institutions, so there is a lot of cross collaboration in NYC and they also have CBO liaisons within the BPHC who work closely with community partners. During this pandemic, they have been able to expand their reach and collaboration in different settings that they did not work closely with previously, so they want to continue to leverage those partnerships going forward as they begin to pivot their instruments as well.
- Ms. Naughton indicated that Minnesota Community Care was partnering with a college in St. Paul on a Youth Advisory Board (YAB) that was taking off and doing well until COVID hit, so it all has been very distanced. Before COVID, they had representatives in each of the schools working with these college students who helped develop materials that are used in

the clinics, as well as advising them on activities they can host, distance learning, et cetera. They plan to continue this YAB work as COVID restrictions are lifting.

- Dr. Anderson asked whether anyone was using Peer Navigators (PN) as part of a telehealth system for education, counseling, linkage to care, et cetera.
- Ms. Naughton said that they have done a great deal of peer education around issues of sexual safety, especially in terms of HIV. They have not done this in telehealth, partly because of the need to be careful about not providing incorrect information. In previous peer education, a professional staff member went with peer educators to assist them with answering questions.
- Dr. Akolkar asked if/how compliance is being monitored of those people who are receiving PrEP via telehealth.
- Dr. Dobbs said it is early and they do not have enough data to support it, but it is challenging for them to keep folks on PrEP regardless. Telehealth is no different.
- Ms. Borges said that in New York they are not currently retaining patients who they start on PrEP. They start it and then refer to a community provider. The most they do is make sure the patient attends the appointment made for them. They are given a prescription for the first month, except during COVID-19 it was 3 months because it was a lot harder to get a quick appointment in most places. Once they are connected to their community provider, they are no longer a patient.
- In terms of funding streams, Dr. Mermin pointed out that they are interested in becoming as efficient as possible with providing holistic services to certain people and in certain venues. That applies to STIs at STI clinics, community health clinics, or student health clinics. Yet the funding streams tend to come from multiple sources. With that in mind, he asked what could be done better.
- Dr. Dobbs suggested finding a clearer way to braid funding. Project Officers see things very black and white, it is almost impossible to blend multiple streams of funding.
- Ms. Naughton added that something that makes school-based clinics work so well and have such good outcomes is that the team is very integrated. That is always hard to find support for, especially considering the effects of SDOH on every kind of behavior and health outcome. They are very attached to their integrated program and when they have had a chance to do that in their larger ambulatory care sites, they find better outcomes as well.
- Mr. Aracena noted that because things are so selective in these buckets, they have to continuously seek additional funding to complete the wheel on the vision and the pathway they are trying to reach.
- Ms. Borges agreed, emphasizing that they all do their best to piece together different funding sources. That can be complicated in terms of reporting and justifying/explaining to Project Officers the best they can.

- Dr. Gayles asked Ms. Drake and Ms. Naughton to speak more about having achieved a higher level of integration of services in the school-based program comparable to community services and to share more about how within that integration, how they have tapped into the community resources to improve and enhance linkage to care services and any particular best practices that could be scaled up into a community model that CDC and HRSA could support.
- Ms. Naughton indicated that within their own system, they have a very comprehensive health history and they are very careful about linking within their own system to all the disciplines and they have developed community resources that go beyond what they can do within their clinics, which are widely available to everyone within their full organization. That is a constant build and a constant nurturing of those resources.
- Ms. Drake added that having the services that are most needed for adolescents within the school-based program results in easy access to care (mental health, nutrition, therapist for counseling, et cetera) and students do not have to leave school to go outside for services. While the mental health team is able to bill and get reimbursed, health educators and registered dietitians cannot except through private insurance. There is a lot of frustration with medical assistance and public funding in terms of not getting reimbursement for those services. Seeking funding for these services is a never-ending process.
- Mr. Lindsey asked whether the NCHHSTP retired program coordination and service integration (PCSI) in the reorganization.
- Dr. Mermin indicated that PCSI is not retired and is a core part of the center's strategy. They prioritized certain aspects of PCSI that they thought would make the biggest difference, but then COVID hit, and people were shifted in general. They have a new reinvigorated conceptual framework that initially was called PCSI 2.0, but now they are thinking of pulling in the conceptual framework of syndemics because it is very similar but more cutting-edge and pulls in a slightly different concept of population health and holistically valuing people, groups of people, and populations. PCSI was focused more on structured service provision. There is a lot of support from the Division Directors, but NCHHSTP recognizes the difficulty in identifying the specific interventions, research areas, programmatic areas, and policy areas that will make the biggest difference. That was part of the reason he asked the question about just funding streams, because that comes up a lot and has been insoluble at times. Congress allocates funds by diseases and conditions, but public health thinks about health by individuals, populations, and sometimes geography. COVID showed the importance of the skills, energy, and smarts of DISs. The new resources CDC has for DISs which Dr. Mena discussed is a comprehensive approach to COVID, infectious diseases, and STIs. Regardless of size, most health departments focus on at least HIV and STDs and sometimes venture into hepatitis and TB. They might be able to build on that.
- Dr. Anderson encouraged everyone to think about the advice that has been requested from CHAC by CDC and HRSA and potential motion, action items, suggested WGs, et cetera that they might discuss during the business meeting.
- Dr. Dowler emphasized the importance of standardizing payment for testing more broadly. Right now, this is very limited. She is in a state with 100 counties and every health department has its own funding stream that is different from the one next, none of which is patient-centered. A gold standard is needed for screening availability and provision of tests

for everybody regardless of where the testing is done (e.g., home, laboratory, clinic), geographies, political issues, or financial status.

- Dr. Gayles summarized that this panel discussion highlighted significant continued funding needs, the need to be flexible and nimble in services provision, reimbursement issues, the need to define what is included in a post-COVID approach, et cetera. Just as a zip code should not determine life expectancy, it also should not determine what type of STI services, testing, et cetera are available. Consideration should be given to the potential impact on the incidence of new cases that could be arrested and curbed if services were readily available.

Panel 2: Leveraging Policy to Advance HIV, VH, and STI Priorities

Moderator: Michael Williams, MPH; Office of Policy, Planning, and Partnerships, NCHHSPT, CD

Hepatitis C: State of Medicaid Access

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP
Director of Programs National Viral Hepatitis Roundtable

Julia Harvey, JD
Clinical Fellow, Center for Health Law and Policy Innovation
Harvard Law School

Dr. Simmons and Ms. Harvey provided an overview of a 5-year project called *Hepatitis C: State of Medicaid Access*;¹⁶ recent progress and the current state of hepatitis C treatment access in Medicaid programs; remaining barriers to care; and next steps for this project. To provide a brief history of hepatitis C treatment access in Medicaid, the first direct-acting antiviral (DAA) Sovaldi came to market in 2013. It was commonly known as the “thousand dollars a day pill.” Due to the high cost of treatment, most payers imposed restrictions on access to treatment. In 2014, a group of researchers published a preliminary review of Medicaid coverage policies, which showed that restrictions to hepatitis C treatment were common and commonly enforced by prior authorizations. In 2015, CMS issued guidance to states that Medicaid must cover medically necessary DAAs in the hope that Medicaid programs would voluntarily loosen their restrictions. Following little voluntary progress, in 2016 Washington Medicaid was sued for requiring severe liver damage in order to access hepatitis C treatment. In 2017, the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) launched *Hepatitis C: State of Medicaid Access*, which detailed Medicaid restrictions by state.

At its core, the *Hepatitis C: State of Medicaid Access* project was developed in direct response to treatment restrictions occurring in the Medicaid Program. The project conducts individual state-by-state assessments of treatment access policy and tracks national trends in treatment access over time. This project is meant to serve as a resource to state officials and advocates to help provide a comparative lens across Medicaid programs as to the state of hepatitis C treatment access, and to identify clear opportunities for policy improvement within state Medicaid programs. Historically, this project has tracked 3 primary types of treatment restrictions in hepatitis C treatment Medicaid programs. The first type is restrictions based on fibrosis score or the amount of liver damage a patient would have to have before they were eligible for treatment. The second type is restrictions based on patient abstinence from alcohol

¹⁶ www.stateofhepc.org

and drugs, most often implemented as a required sobriety period of 1, 3, or 6 months to access treatment. The third type is restrictions based on which providers are eligible to prescribe treatment. In some cases, states would narrow the pool of providers eligible to prescribe (e.g., hepatologist, gastroenterologist, infectious disease doctors). These restrictions have been tracked because federal agencies and courts have declared that they are incompatible with federal law, and it is known that these types of restrictions have had severe impacts on individuals who are trying to access care who otherwise certainly would benefit from treatment.

In terms of progress over the last 5 years, there continue to be severe restrictions and states that have been hard-hit by hepatitis C. In terms of prior authorization (PA), 12 states now allow access to hepatitis C treatment without requiring a PA for most patients. Those states include: Washington, Louisiana, New York, California, Indiana, Wisconsin, Missouri, Michigan, Rhode Island, Virginia, Alaska, and Massachusetts. Oregon will soon be the 13 state to join this list. The majority (67%) of these states removed PA without using a subscription or what is called a “Netflix model.” This is a tremendous improvement that will help streamline access to treatment by eliminating burdensome paperwork.

Moving to fibrosis, the most progress made to date has been removing this barrier, with 33 states having either eliminated or reduced their fibrosis restrictions. Only 2 states have restrictions remaining. Regarding sobriety, many states have required patients to abstain from substances or alcohol for a specific period of time before approving hepatitis C treatment despite injection drug use driving new infections. Fortunately, 29 states have loosened their sobriety restrictions and the majority of states no longer require a minimum period of abstinence. While many improvements have been seen with restrictions related to substance use, this remains the most widespread barrier of the barriers that are currently tracked. Important improvements have been seen in removing prescriber restrictions, with 28 states having scaled back on prescriber restrictions. However, barriers remain in 18 states that require specialist involvement to prescribe hepatitis C treatment and 1 state that requires prescriptions to be written by a specialist.

Despite the progress that has been made in terms of access to hepatitis C treatment within Medicaid programs, it also is known that fibrosis, sobriety, and caregiver restrictions are not the complete universe of barriers to hepatitis C treatment. Over the last few months, in an effort to understand what some of these barriers are and specifically how they impact patients, the project team has been soliciting input from patients, providers, policy-makers, and others with the goal of understanding how to improve tracking and reporting out on state Medicaid programs to best meet the needs of individuals seeking access to hepatitis C treatment. Over the last few months, the team hosted a public listening session, disseminated a public survey, and convened a provider-led steering committee to identify the most pressing barriers. In terms of the breakdown of the 275 individuals who participated in the survey, the majority (~52%) of responses were from providers and other members of the healthcare team, followed by government staff (~23%), advocates (~11%), individuals personally impacted by hepatitis C and others (~6%).

What was learned from these conversations was that there are many key barriers to hepatitis C treatment and access beyond what has been tracked to date. Many of these have not previously been comprehensively tracked across Medicaid programs. This is not a complete list of everything that was identified, but barriers include the PA process, chronic infection diagnosis, time-based laboratory values, genotype reporting requirements, adherence assessments, retreatment restrictions, specialty pharmacy requirements, and differences in requirements between Medicaid fee-for-service and managed care. Responders indicated that all of these really play a role in meaningfully inhibiting access.

In terms of the impact of these barriers, they have heard anecdotally and objectively that these barriers result in delays, denials, and interruptions to care and ultimately impede the ability to eliminate hepatitis C by 2030, particularly among communities who are disproportionately impacted by hepatitis C. Rhode Island estimated that PA can take between 45 to 120 minutes per patient, not including time addressing denials and appeals. Patients are frequently lost to follow-up due to administrative barriers at every step of this process. The following quotes from the survey describe the impact of these barriers:

“In my state, there is actually investigation into adherence for other medications for the patient. For instance, if a person has picked up their diabetes meds late before, [Medicaid] will deny [hepatitis C] treatment.”

“The burdens include the wasteful cost of repeat labs and negative impact on patients regarding cost and access to transportation. Genotype results have a long turnaround time, sometimes creating delays.”

“Some of the specialty pharmacies have requirements to speak with the patient before mailing the medication. It becomes a barrier, and possibly even a delay in treatment.”

The impact of these barriers also is evident in data recently published by CDC, which shows that the number of people who initiated hepatitis C treatment in the US declined from 2015 to 2020.¹⁷ The National Academies of Sciences, Engineering, and Medicine (NASEM) has estimated that at least 260,000 people must be treated each year to eliminate hepatitis C by 2030. However, only 120,000 people on average are treated each year and that number continues to decline in the context of the COVID-19 pandemic.

In terms of next steps, the project team is currently in the process of updating *Hepatitis C: State of Medicaid Access* project to reflect what has been learned about these other barriers to care and to include many of them in the assessment process moving forward. Based on the stakeholder input received, the state evaluation criteria have been updated and the project team is in deep data collection mode. The release of the updated report cards and full report is targeted for late May 2022.

Senate Bill 159 (SB 159) HIV PrEP & PEP For California Pharmacists Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment

Marisa Ramos, PhD

Chief, Office of AIDS

California Department of Public Health

Dr. Ramos presented on Senate Bill 159 (SB 159), HIV Pre-Exposure and Post-Exposure Prophylaxis (PrEP & PEP) For California Pharmacists. As a reminder, oral PrEP is a once-a-day pill (Truvada/Descovy) that can reduce a person’s risk of acquiring HIV by up to 99% from sexual contact. Among individuals who inject drugs, there is a 70% reduction in acquisition of HIV. PrEP provides maximum protection when taken daily for 7 days after engaging in anal sex and 20 days for vaginal sex or injection drug use. It is important to note that while an injectable version of PrEP given once every 8 weeks has been approved by the FDA, it is not relevant for SB159. Pep is a regimen to reduce the risk of contracting HIV after an exposure. PEP is the

¹⁷ Eyasu H Teshale, MD, Henry Roberts, PhD, Neil Gupta, MD, MPH, Ruth Jiles, MS, MPH, PhD, Characteristics of persons treated for hepatitis C using national pharmacy claims data, United States, 2014–2020, *Clinical Infectious Diseases*, 2022; [ciac139](https://doi.org/10.1093/cid/ciac139), <https://doi.org/10.1093/cid/ciac139>

“Plan B” of HIV that reduces the risk of contracting HIV if taken in the 72-hour window from the moment of possible exposure. PEP is most effective when started as soon as possible and typically consists of Truvada or Descovy plus another agent, which is usually an HIV integrase inhibitor. Unlike PrEP, PEP is a complete antiretroviral regimen against HIV. Once prescribed, it must be taken for 28 days.

SB 159 was introduced by State Senator Weiner and was signed into law on October 7, 2019. SB 159 provides authority for pharmacists to determine if patients meet clinical criteria for PEP or PrEP and allows them to furnish 30 or 60 days of PrEP once every 2 years or furnish 28 days of PEP. The pharmacist must inform the patient’s primary care provider (PCP) or provide the patient with a similar report to give to their provider themselves. The law also requires that before providing PrEP or PEP, pharmacists have to complete training that is approved by the California Board of Pharmacy or that is delivered by an accredited provider. Free training is available.¹⁸ Participants must pass a quiz with a 70% score, maintain the record of training for 4 years, and retrain every 4 years. There is a website¹⁹ to find pharmacists who are permitted to provide PrEP/PEP and who have signed up for the website. It is important to note that pharmacists are not automatically enrolled in this website.

Patients must meet certain conditions to qualify for pharmacist-furnished PEP. The pharmacist must screen the patient and determine that exposure occurred within the previous 72 hours. The patient must meet the clinical criteria for PEP consistent with CDC guidelines, and there must not have been any signs or symptoms associated with acute HIV. Given that education must be provided, the patient may not waive the consultation with the pharmacist. The pharmacist is required to provide information to the patient’s PCP or provide the patient with a list of where to seek care or start PrEP if they do not have a PCP. PEP initiation should not be delayed for baseline laboratory testing, but the patient should follow-up with a provider for laboratory testing.

To qualify for PrEP, the patient must have a negative HIV test in the previous 7 days (negative antigen/antibody test or negative rapid test) and no signs or symptoms associated with HIV infection. The patient must not be taking any contraindicated medication. As with PEP, the patient must receive education and may not waive the consultation. The patient must consent to follow-up with a PCP for additional prescriptions. The pharmacist must maintain a record of the prescription provided and provide information either to the PCP if the patient has one or provide a list where the patient may seek additional care for PrEP.

In summary, pharmacists have played an important role in HIV prevention for decades. They provide condoms, sterile syringes, and supporting adherence to HIV treatment. The notion behind SB 159 is that pharmacists are uniquely situated to improve access to new preventive tools, PrEP, and PEP—especially for patients who are underserved. There are typically pharmacies within walking distance or nearby. Pharmacists also have relationships with prescribers and can support linkage to care for ongoing PrEP prescriptions, HIV testing, and laboratory monitoring. Financial assistance is available on the PrEP-AP Webpage.²⁰ Evaluation of implementation of this program begins this year to assess use, barriers, and facilitators.

¹⁸ https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml

¹⁹ https://www.dca.ca.gov/webapps/pharmacy/services_search.php

²⁰ <https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAadap.aspx#prep>

Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment

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Chief, Policy and Viral Hepatitis Prevention
Sexually Transmitted Diseases (STD) Control Branch
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Ms. McLean reported on additional policies and laws passed in California, as well as their implications. In terms of background, STD rates increased significantly in California between 1990-2019. As syphilis rates increased among people of childbearing age, congenital syphilis cases increased as well to an alarming 446 cases in 2019. This is included cases of fetal demise and stillbirths, which are preventable and should never have happened. California also bears a significant burden of chronic hepatitis B and C based on the most recent data. From 1989 to 2016, the cumulative total of chronic hepatitis B cases newly reported to CDPH was 287,087. From 1994 to 2018, the cumulative number of chronic hepatitis C cases reported to CDPH was over 700,000. This does not take into account the many people living with hepatitis B or C who remain unaware of their infection, meaning that these are probably underestimated. STI testing volume decreased during the COVID-19 pandemic, which highlighted the need for alternative testing options.

Within that context, there has been interest in creative strategies that can be used to increase all hepatitis testing. Two bills were signed into law, Senate Bill (SB) 306 (Pan, Chapter 486, Statutes of 2021)²¹ and Assembly Bill (AB) 789 (Low, Chapter 470, Statutes of 2021)²² that healthcare providers (HCP) in California are now required by law to follow. Effective January 2, 2021, California law now requires syphilis screening in pregnancy per CDPH guidelines. This includes third trimester screening in pregnancy. SB 306 also provides liability protections for prescribers and pharmacists dispensing expedited partner therapy (EPT) for chlamydia and gonorrhea. This is very exciting, given that prescriber concerns about liability have been a barrier for a number of years. California also had stricter laws related to the use of Clinical Laboratory Improvement Amendments (CLIA)-waived rapid tests. SB 306 now will allow HIV test counselors who are trained and certified to use CLIA-waived rapid tests. AB 789 requires primary care facilities to screen adults for hepatitis B and C, which was modeled after the law in New York and appears to be the first law that requires screening for both.

SB 306 also requires health plans to cover at-home STD tests, which is particularly important due to the increased use and comfort that arose with home tests for COVID-19 that could help pave the way for at-home tests for other diseases. The SB 306 definition of at-home STD tests is, "A product used for a test recommended by CDC guidelines or USPSTF that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting." CDPH has spent a lot of time examining each word in this definition, given that it is somewhat cryptic. It has been reported that FDA is working closely with companies to help them achieve FDA approval standards for at-home tests. The SB 306 at-home STD testing coverage requirement is complicated. Specific coverage requirements vary by payer depending on which state agency regulates their products. Medicaid (Medi-Cal) does not have to reimburse for at-home STD tests until specific billing codes are created, including American Medical Association (AMA) Common Procedural Terminology (CPT) Codes and CMS Healthcare Common Procedure Coding System (HCPCS) Codes.

²¹ SB 306 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB306

²² AB 789 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB789

In terms of next steps, CDPH is in the process of developing fact sheets to summarize various aspects of SB 306 and AB 789 for dissemination to HCP, payers, local health departments, and CBOs. The fact sheets are now going through the clearance process. They also are monitoring testing company efforts to request new CPT and HCPCS codes that will be needed for at-home test reimbursement. CDPH has a formal evaluation plan in place and is exploring options for how to evaluate the impact of these bills.

Louisiana's HCV Elimination Plan

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Mr. James reported on the progress that has been made on Louisiana's HCV Elimination Plan that was launched in July 2019 and is rooted in several strategies. One of the primary strategies is the establishment of an innovative payment model. The plan also seeks to expand provider capacity to treat hepatitis C; educate the public related to the availability of a cure; expand screening and expedite linkage to HCV treatment; strengthen surveillance systems to identify and diagnosis; and link those who are identified to care and treatment as part of Louisiana's "Big Bet." As part of the Big Bet, Louisiana Department of Health (LDH) has undertaken several large-scale projects to improve health conditions within Louisiana. Since the launch of the Big Bet in 2019, a total of 10,759 persons have access to treatment for hepatitis C. That includes 9,302 persons within the Medicaid population and 1,457 persons who are incarcerated.

In terms of the breakdown of characteristics of Louisiana's Medicaid and corrections populations, the majority of folks (60%) who have access within the Medicaid population are male and 40% are female. In the incarcerated population, 96% have been male and only 4% have been female. While there is a fairly good distribution race and ethnicity, approximately 59% of those accessing Medicaid treatment are white and 60% of those within the incarcerated population are Black. It is important to have that historical context to understand that a disproportionate number of persons of color are incarcerated compared to those who identify as White. The largest distribution of those accessing treatment within the Medicaid population are between 30-59 years of age, with a similar trend within the corrections population.

As everyone knows, even the best laid plans have hiccups. Since the launch of the plan in 2019, one of the biggest hiccups has been COVID-19. Being a Southern Gulf state, hurricanes also impact Louisiana significantly. Hurricanes Ida, Laura, and Zeta and an ice storm all had major impact on the Southwestern portion of the state in 2020 and 2021. Prior to this prescription model, about 61 persons on average were accessing a hepatitis C treatment. That number increased significantly to about 390 persons on average. Due to COVID-19 spikes, that average decreased to about 290. It is important to note that for persons on Medicaid, treatment is calculated using DAA claims data. Due to delays in reporting of claims data, numbers from recent months are preliminary and are an undercount.

Since July 15, 2019 over 9,300 persons have accessed treatment for HCV through Medicaid; 9,133 persons have started treatment for HCV through Medicaid for the first time; 7,930 persons who have accessed treatment have completed it; 6,394 persons have accessed treatment because of Medicaid Expansion; 612 providers have written prescriptions for DAAs for the first time; and last HCV RNA was positive for 585 persons who did not complete treatment. In order for all of this to work, it was necessary to examine some policy changes.

Several of those dealt with Medicaid in terms of lifting provider restrictions and the sobriety and fibrosis requirements.

It is important to understand that while over 9,300 individuals have been treated, others have been identified who are currently enrolled within the Medicaid group who are accessing one of the 5 managed care organizations (MCOs), which helps fulfil Medicaid's charge. Close to 16,000 persons with a positive RNA have been identified who are currently enrolled but who have not been treated. In terms of the last 2 years of this iteration of the statewide elimination plan, a lot of energy and attention will be placed on examining this group in more detail and on examining additional strategies that can be put in place to help lead these folks to a cure.

Based on data from July 15, 2019 through August 31, 2021, over 8,100 individuals in Medicaid had started treatment. Of those, over 7,000 (87%) completed treatment and over 5,200 (65%) had sustained virologic response (SVR) testing performed. Of those, approximately 4,700 (90%) achieved SVR and 514 (9.8%) had a failed SVR. Examining the Medicaid population by birth sex, 88% of females who started treatment completed treatment and 87% of the population of who started treatment completed treatment. There was a larger rate of SVR failure within the male population (10.5%) compared to the female population (8.7%).

By race and ethnicity, 93% of American Indian/Alaskan Natives (AI/AN), 87% of Blacks, 83% of Hispanic/Latinx, and 8% of Whites who started treatment have completed treatment. Of those who failed treatment, 10.2% were White, 9.3% were Black, 9.3% were Hispanic/Latinx, and 7.7% were AI/AN. By age, 80% of persons 18-29 years of age, 84% of persons 30-39 years of age, 89% of persons 50-59 years of age, and 88% of persons ≥60 years of age completed treatment and achieved SVR. Among those who experienced failure, the highest failure was among persons 18-29 years of age at 19%, followed by persons 30-39 years of age at 11.6%, persons 40-49 years of age at 9%, persons 50-59 years of age at 8.9%, and persons ≥60 years of age at 6.6%.

Assessing completions and failures by regions helps LHD prioritize regions that may be experiencing more difficult challenges. Also of interest is that 653 providers have prescribed for the first time. Determining where those providers sit within the state and using provider details can help identify and work with the regions with slower increases in new providers prescribing DAAs for the first time. From a regional perspective, Region 9 (13.7%), Region 2 (11.9%), and Region 1 (10.8%) had the highest rates of failure. Regions 4 (6.6%), 5 (6.9%), and 6 (6.5%) are doing somewhat better. Region 7 (3.7%) has had the most success, which is the Shreveport/Monroe area. Among persons who have identified as having an opioid use disorder (OUD), 84.9% have completed treatment versus 93.2% with no OUD. The completion rates for males and females seem to be fairly consistent, while there is slightly variation in terms of race and ethnicity and by age group. There are some variations from a regional perspective as well.

To summarize, Louisiana has made significant progress in addressing that HCV epidemic. If not for COVID-19 and severe weather conditions, it is anticipated that more people would have been treated. Based on data received earlier in the day, the number of individuals accessing treatment from the Medicaid and corrections populations is close to 11,000 combined.

Transitions Clinic Network

Shira Shavit, MD

Family Physician
Executive Director & Co-founder
Transitions Clinic Network

Dr. Shavit explained that the Transitions Clinic Network (TCN) is a national non-profit organization that supports health system transformation for primary care clinics that are serving communities disproportionately impacted by incarceration. In San Francisco in 2006, TCN developed an evidence-based model of primary care for people returning home from incarceration. All of the community health centers employ CHWs with histories of incarceration within primary care teams to address the health and well-being of people returning from incarceration. To date, they have worked with 48 primary care clinics in 14 states and Puerto Rico.

People who are incarcerated are disproportionately impacted by a variety of chronic medical conditions, HIV, and substance use. People who are incarcerated have 3 times the prevalence of HIV, a much higher prevalence of hepatitis C with rates approaching 30% to 40%, and increased risks of STIs of 30% to 40%. Incarcerated people also have higher rates of chronic medical conditions and high rates of SUD and mental health conditions. With 95% of people returned home, the primary care system is a natural place to think about providing care to these individuals since they have multiple, complex, comorbid conditions. It is important to remember that in terms of cross-sector collaboration and working across systems, the carceral system and the health system have very different cultures and that really dictates a lot of what can be done and how. The punitive aspect of the carceral system sometimes plays out significantly and can impact what is known to be best practice for caring for people in the health system.

While people may not receive great care while they are incarcerated, people's health actually worsens when they are released from incarceration. Their HIV or SUDs may become worse, their viral loads may increase, they are more likely to be hospitalized post-incarceration, and they are more likely to die. A seminal study showed that people were 12 times more likely to die in the first 2 weeks post-incarceration from drug overdose, cardiovascular disease (CVD), suicide, or cancer. While great strides have been made on a policy front via ACA and Medicaid Expansion, many people who previously did not get Medicaid now have Medicaid and are eligible for services upon release. Having that Medicaid card is not always enough to get people in the door to treatment and it does not always translate to increased engagement or use of services.

That is because people face tremendous barriers when they come out of incarceration that are not just about access to care or having insurance. There is little continuity of care between systems. People may not even get medications or if they do, they get a shortened supply of medications that is not enough to bridge them to the health system. They have competing priorities, with all of the SDOHs evident (e.g., housing, employment, food on the table, stigma and mistrust with the health system due to negative experiences prior to incarceration, et cetera). These are Black and Brown communities that have experienced discrimination at the hands of health systems and then have negative experiences in the carceral system, so it is no wonder that they have a healthy mistrust of systems when released. They also face a lot of challenges in navigating complex services and services in the community that may not meet their needs.

The TNC Model of Enhanced Care was created to try to build capacity in the community health side. While it is easy to point the finger at the carceral system as not being a robust health system, the outside health system also was not meeting the needs of people returning home. Services need to be enhanced in community health systems to provide patient-centered services and engage people into care. In collaboration with communities, the TNC Model of Enhanced Care was created. This model is based on existing primary care clinics where each clinic hires CHWs who have experienced incarceration in prison or jail, most of whom have felony convictions. TNC also works with the clinics to ensure that they are providing patient-centered services like treatment of hepatitis C, HIV, OUD, behavioral health conditions, et cetera. They also work with the clinics to build cross-sector collaboration with the criminal legal system, as well as many other systems to address SDOH (e.g., re-entry organizations, community networks, faith-based networks, family systems, behavioral health system, public health system, tertiary care system, housing system, et cetera). This forces clinics to open their walls and be more contiguous with these important systems in supporting the care for people who are coming home.

This model has been successful because it follows what the community dictated as being needed. They have iterated on the model and have studied it, which has shown that this is an evidence-based model of care. Hiring CHW with lived experience in incarceration and embedding them into clinics has reduced urgent care utilization. For instance, a randomized control trial (RCT)²³ was conducted in San Francisco that assessed 200 people with chronic medical conditions or >50 years of age just released from prison. All of them were engaged into care by CHWs with lived experience. They were then randomized to either staying in the TNC or receiving primary care in the remainder of the system. They found that patients in the program had 50% fewer ED visits in the first 12 months post-release, and that having CHWs engaged study participants at much higher rates into primary care than is seen in the community.

Some information has come from unpublished administrative data from one of TNC's programs in Santa Clara County in California that works very closely with their jail.²⁴ Their health system is part of the jail health system as well, so they were able to make appointments in the jail for people pre-release, but only 33% of people were going to their appointments. When CHWs with lived experience go inside and meet people in the jail, the appointment attendance rates increased to 70%. This demonstrates that the CHW component is critical in bridging systems and engaging people in care.

A propensity-matched study²⁵ in Connecticut of enhanced primary care on contact with the criminal justice system among individuals recently released from prison to New Haven compared to individuals who were released to Hartford where there was no transition clinic program. This study found that individuals in the TNC program had fewer preventable hospitalizations and fewer probation and parole violations. They were spending 25 less days re-incarcerated in the first year post-release. The takeaway from this is that when investments are made in the health system to support these populations, costs can be reduced and outcomes can be improved in other sectors.

²³ E.A. Wang, et. al. AJPH 2012 Jul 19

²⁴ Data provided by Dr. Ari Kriegsman, Santa Clara Valley Health & Hospital System 2017

²⁵ E.A. Wang, et. al. BMJ Open 2019

The last 2 years have laid the groundwork for the opportunity to build more bridges between carceral systems and health systems. Because of COVID-19, correctional leadership for the first time really understood what it meant to the importance of bridging these systems. Like everything else in the pandemic, many of these disparities and the need to address them became evident. Many of the statewide systems within TCN built stronger bridges with their carceral systems to be able to connect with people pre-release and provide care coordination systematically from those systems back to community health systems, and back to networks of patient-centered services in the community.

The timing of that groundwork has been fortunate in that some major policy shifts are emerging in the country, such as policies to waive the Medicaid inmate exclusion policy. When people are incarcerated, they are excluded from using Medicaid for their routine services. The idea would be to turn on Medicaid 30, 60, 90 days, pre-release from incarceration to allow health systems or other entities in the community to help provide care coordination from one system to the other. Another policy opportunity relates to providing targeted services to people returning home from incarceration. In California, individuals returning from prison or jail are eligible for enhanced care management services, which is a team-based approach to support people in navigation of the health system and around SDOH. Recent legislation that was passed and pending supports the idea of Section 1115 Demonstrations that would allow for states to turn Medicaid on at some point pre-release to bridge the carceral system and the community health system.

On paper this sounds feasible, but it is important to recognize that it requires a lot of system transformation. The primary care system requires tremendous system transformation to successfully care for this population. In the carceral system, there are many barriers to cross-sector collaboration and a lot of transformation is needed there as well. It is important to recognize that some of the barriers are structural. For instance, having 35 prisons across a very large geography could be a major barrier for local entities that support individuals coming out in terms of meeting with patients and supporting them in the transition home. Other barriers that may play a role include the leadership in place, lack of discharge planning services, lack of meaningful health information exchange, absence of timely identification/access to patients, lack of telehealth services, limited access for all types of community service providers, the siloed nature of carceral systems, patient mistrust, and/or isolation from/lack of community partners. Much remains to be done to build better capacity within the carceral system to enable partnerships with health systems.

The TCN has demonstrated that the policy strategy of supporting the integration of CHWs into health systems who have lived experience of incarceration means that these individuals can give back to their communities to make a difference to improve health outcomes, and health systems can contribute to reversing the harms of mass incarceration by providing job opportunities for people who normally are excluded from health systems because of their criminal record. This really is a win-win.

CHAC Member Discussion Panel 2

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 policy changes are needed to improve access to care and prevention services and tools for HIV, other STIs, and viral hepatitis among populations disproportionately affected by these infections?
2. What policy-making partnerships should CDC/HRSA establish or expand to improve care and prevention among these populations?
3. What are the opportunities for CDC/HRSA to inform and collaborate with states on evidence-based policies that establish enabling environments to decrease HIV, other STIs, and VH?

The following questions, observations, and suggestions were raised:

- Regarding non-viral hepatitis and hepatitis C, Dr. Mehta said it is clear that barriers are disproportionately faced by PWID and other marginalized populations. Related to the barriers pertaining to testing, genotyping, and pharmacy pick-ups described, a recently published study demonstrated that in a global population, people with chronic hepatitis C can be treated with minimal initial monitoring and providing all 84 tablets with little in-person contact. The study demonstrated that it was safe and that SVR rates were comparable to other real-world studies of persons with hepatitis C. This is important to think about in terms of policies going forward and data collection on barriers and acceptability of providers on such an approach.
- Dr. Dowler emphasized that getting Medicaid Expansion in every state would be amazing and that establishing CPT and HCPCS codes for at-home testing is critically important in terms of billing and reimbursement. CHAC probably could have some influence on this effort and perhaps could make a recommendation about this.
- Dr. Mermin asked what advice Dr. Simmons and Ms. Harvey could give to CDC and CHAC about how the agencies could help states and local jurisdictions do X, Y, and Z to make a major difference in terms of helping them make the changes recommended.
- Ms. Harvey emphasized that there are many reasons why policies changed over the last 5 to 7 years. For instance, prices have changed, the Center for Health Law and Policy Innovation brought litigation in a lot of states based on the fact that the restrictions were illegal, and there has been a ton of very forceful patient advocacy around these issues. Thinking about the specific questions Dr. Anderson read is that federal guidance in this space would be very valuable. Thinking back to the 2016 Bulletin that was jointly put out in the HIV space around treatment and prevention by CDC, HRSA, and CMS has been an essential tool in some of her other work to help move the needle on Medicaid access. There is an opportunity for a similar initiative in the Hepatitis C space as well.
- Dr. Simmons added that another helpful tool states had over the last few years was the HHS Hepatitis C Medicaid Affinity Group (Affinity Group), which engaged in collaborative efforts between Medicaid, departments of health, corrections, et cetera to discuss innovative payment models. Many have cited this group as a catalyst for demonstrating that evidence-based policy change and evidence-based programming can make major impacts.

- Dr. So noted that it would be beneficial to know how many state Medicaid programs are covering hepatitis C treatment among incarcerated populations, particularly given that over 20% of incarcerated populations are estimated to have hepatitis C. It is clear that evidence-based policy change has made an impact, such as requiring pregnant women to be screened for syphilis, hepatitis B and C screening law, and linkage to care law. He emphasized the need to address health disparities/inequities and incentives/laws for providers to incorporate recommendations from various bodies (CDC, HRSA, USPSTF) into health records, waivers, and screening recommendations/requirements. CDC and HRSA should reach out to electronic medical record (EMR) providers to incorporate recommended screenings, linkage to care, and clinical support/decision tools to ensure that patients are identified and receive appropriate treatment.
- Dr. Anderson agreed that while there may be guidance or policies in place, in hectic daily 10- to 15-minute visits with patients, it is difficult for this to rise to a priority. Also, there may be issues related to lack of knowledge. Having decision aids in the EMR is invaluable.
- In terms of Dr. Shavit's comments about the policy suggestion Dr. Wester made during her presentation about ensuring the best price restrictions in Medicaid do not preclude access of strategies for incarcerated populations at the state or county level justice-involved populations, particularly for hepatitis C treatment and other expensive medications. Louisiana has used 340B pricing, but she asked whether there are any examples of jurisdictions that have successfully been able to put waivers in place for that.
- Dr. Shavit clarified that in the study in which they were assessing cost savings for patients who were receiving care in their program compared to other programs, they did a propensity match for another city in Connecticut and found that they had a reduction in preventable hospitalizations and parole probation violations. The cost savings was primarily on the criminal legal side with 25 days or less incarceration. While she was not specifically talking about pharmaceuticals, investments in Medicaid saves costs in other sectors. No states have successfully waived the Medicaid exclusion policy yet. CMS had a listening session and is developing some guidance based on that. Multiple states have applied, including California, but none have been approved yet to her knowledge. However, it is an emerging opportunity.
- Dr. Wester asked whether there has been any integration of a requirement for hepatitis C screening among pregnant persons. Through claims data, they are seeing about a 30% uptake of hepatitis C screening among pregnant persons and they would like to see that increase quickly.
- Dr. So indicated that the California law is based on recommendations from the USPSTF, which recommends screening for all adults for hepatitis C. Because universal screening has become the law in California, it makes it much easier to implement screening in EMRs. He has been trying to convince Kaiser and other large groups to introduce all of the USPSTF recommendations into EMRs. As of this month, Stanford has incorporated universal hepatitis B and C testing, even though the USPSTF recommendation is not quite universal for hepatitis B.
- Dr. Ramos indicated that they started a pilot project in Orange County, California to provide medication to individuals who are HIV-positive within that county incarceration system. It is paid through the CDPH AIDS Drug Assistance Program (ADAP), which is a mixture of general funds versus HRSA funds. They are currently going through an estimate package.

It looks like they will be able to expand to more counties if they are interested in participating in the program. Some of the more conservative counties were not testing everyone for HIV as they entered some of the jails. To ensure that screening is done, treatment for those found to be positive will be paid for by CDPH versus using the county's general funds. The hope is to expand to at least 6 more counties that have shown interest.

- Dr. Anderson said she was impressed with the recent state laws in California and their innovations have moved this topic along. She observed that one barrier seems to be that there are so many different county and state laws. While it is not clear if/how CDC/HRSA could impact that, perhaps a central compilation of innovative strategies as laws arise could be beneficial. Access to knowledge about innovations in some states might be very appropriate in terms of pushing the discussion forward in other states.
- Mr. Williams indicated that NCHHSTP funded the National Conference of State Legislatures (NCSL) to create a Legislative Data Tracking System.²⁶ That is exactly what the system is designed to do, and the system refreshes every 2 weeks. As states introduce pieces of legislation that fit certain key words across all of these areas, including laws that affect healthy youth and sex education curriculum, these will be displayed. It is easy to ask NCSL to make adjustments to the system to ensure that everything is captured.
- Dr. Dowler pointed out that even when there are laws, they are very hard to track and enforce. She noted that the Guttmacher Institute maintains a good listing.
- Dr. Mermin said he was intrigued by the differential aspects of the pharmacy program for PrEP that Dr. Ramos described. Based on the examples presented, it seems that the emergency aspects of receiving PrEP through pharmacies is harder than receiving PEP. The ongoing benefit of having a pharmacist as a provider is lost if they can give only a starting dose. While receiving a starting dose can be helpful, he wondered why the PrEP restriction of 30-60 days once every 2 years was included and whether it could be changed.
- Dr. Ramos indicated that there is a history. Originally, there was a push from some of the clinics that had a pharmacy within their organization since it would be easy for someone to present, be started on PrEP, and then go next door to see their PCP. While she did not have the data, PrEP has been under-utilized from what she has seen. However, the specialty pharmacies within those clinics would not like it to go away because they can administer and at least start PrEP. Implementation has been slow. The state is seeing more dispensing for PEP than for PrEP. Because of COVID-19, this was averted to do the training that is required.

Wrap Up Day 1

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

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Dr. Anderson observed that it had been a tremendous day with a lot of information that began with reports from CDC and HRSA. They heard some statistics on continued increases in syphilis and congenital syphilis, as well as increases in adolescent mental health concerns and

²⁶ <https://www.ncsl.org/research/health/state-public-health-legislation-database.aspx>

the need to find ways to address these. Some of these negative statistics were offset by the data CHAC heard about the dramatic improvement in viral load suppression overall and in key populations; demonstrable reductions in disparities; and very impressive successes reported in CDC-funded programs in schools to decrease risky sex behaviors, safety concerns, and sexual assault. She congratulated CDC and HRSA for their work and deep thinking in terms of integration and collaboration strategies and the use of the syndemic approach to deal with these interrelated problems, which is critical. In the afternoon, they heard about innovative models of care and continued challenges. Some of the innovations and the ability to address challenges are constrained by state- and county-level policies and legislation, funding, and lack of time or knowledge on the part of physicians. They also heard about a lot of flexibility and innovation during the COVID-19 pandemic and in many cases inspired by it. They heard about the role of integration of different relevant infections, as well as issues related to SDOH.

Dr. Gayles expressed his gratitude for the great presentations and for the work everyone does on a daily basis in order to be able to present the data that you provide. He further emphasized the continued notion of evolution in terms of the need to be modern and think outside the box moving forward with regard to funding to sustain programs and to continue to pivot to keep efforts moving. This includes the ability to speak fluently to young people to make sure that they are engaging and they are able to effectively communicate their needs in safe spaces. With regard to engaging in conversations about increasing services that folks need, it is important not to use mental health as a crutch to not do the necessary work to root out racism, systemic issues, bias, transphobia, and all of the other things that significantly influence the potential success of projects in the future in terms of being able to sustain funding and considering the significant variability in terms of the differences in geography and the level of services available. A lot of tremendous work has been done but there are still many headwinds in the way moving forward.

Adjourn

Dr. Mermin officially adjourned the meeting for April 26, 2022 and CHAC stood in recess until 11:00 AM ET on April 27, 2022.

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
Centers for Disease Control and Prevention

The proceedings were called to order at 11:00 AM 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 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 27, 2022.

Special Presentation: Turning the Tide on Self-Testing and Sample Collection

Moderator: Elizabeth DiNenno PhD; Division of HIV Prevention, NCHHSTP, CDC

FDA Regulation of HIV Self-Testing Devices and Self-Collection Kits for HIV Diagnosis

Julia Lathrop, PhD

Associate Deputy Director
Division of Emerging and Transfusion-Transmitted Diseases
US Food and Drug Administration

To lay the groundwork Dr. Lathrop explained that in vitro diagnostic devices (IVDs) are medical devices per Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) [21 CFR 809.3] that defines medical devices as: “Reagents, instruments, and systems used in the diagnosis of disease or other conditions . . . in order to cure, mitigate, treat, or prevent disease intended for use in collection, preparation, and examination of specimens from the human body.” Clearly, self-testing and self-collection kits are considered to be medical devices. As such, they are subject to the provisions of the FD&C Act. It also means that regardless of whether a device is regulated either in the Center for Biologics Evaluation and Research (CBER) or the Center for Devices and Radiological Health (CDRH), it is subject to the provisions of the FD&C Act.

The review of all IVDs, regardless of where they are reviewed or what their use is, is based on the balance of the benefit and risk to the individual and that the data provide a reasonable assurance of safety and effectiveness of the device. A risk for an IVD is providing an incorrect result to the individual. For an HIV diagnostic, that would be a false positive or false negative. Risks from receiving a false negative could be that an individual is denied life-sustaining treatments and could transmit a life-threatening disease. The risk for having an incorrect result, especially a false negative for HIV, is very high. One element of assessing for reasonable assurance of safety and effectiveness and the balance of benefit/risk pertains to whether the device does what it is intended to do.

All IVD reviews begin with a review of the intended use because this is where the determination of the risk lies. Intended use pertains not only to the HIV diagnosis, but also the sample type, population, conditions (e.g., professional use only or self-collection). The risks all lie in the intended use and it is from the intended use that the review logically flows. It is important to keep in mind that one device may have more than one intended use and those uses can have different risks. For example, HIV diagnostics and viral load monitoring have very different risks

associated with incorrect results. The risk involved and what is necessary to mitigate the risk determine whether a device is categorized as a Class I, Class II, or Class III. Colloquially speaking, those mean low, moderate, and high risk, respectively. However, that is not entirely accurate because there can be a high-risk device like an HIV diagnostic that can be safely regulated as a Class II device. FDA is in the process of reclassifying HIV diagnostic supplemental and viral load tests from Class III to Class II. The risks associated with an incorrect result have not changed; these are still high-risk devices. Having approved many devices over many years allows FDA to establish special controls, which are provisions associated with the demonstration of the safe and effective use of the device. Establishment of special controls allows for successful mitigation of the risks in order for FDA to safely review these as Class II devices requiring a PMA. Special controls can be requirements such as performance criteria, post-market reporting, et cetera, that are necessary to provide reasonable assurance of safety and effectiveness of the device. Because reviews are based on intended use, there is no expectation that all Class II devices should have the same special controls since the risks associated with each intended use differ.

Turning specifically to FDA regulation of HIV self-testing devices (HIVST), HIV devices are Class III devices that require approval of a PMA before they can be marketed. There is one approved self-testing device on the market, the OraQuick® HIV self-test approved in 2012. HIVST devices were not included in the reclassification of HIV diagnostic, supplemental, or viral load tests due to a lack of sufficient experience with these devices to write special controls that will safely mitigate the risks so that they can be regulated as Class II devices. FDA does agree wholeheartedly that there is an urgent need to improve access to self-testing for HIV. To that end, FDA is working with manufacturers to consider alternative validation strategies and streamlining of the review and approval process to expedite entry into the market. When the OraQuick® HIV self-test was approved, the process was very laborious and very careful because there were a lot of concerns, even with the whole concept of self-testing, but HIVST has since been demonstrated quite clearly to be safe and effective. Thus, many of the concerns that caused the original process to be so laborious have been mitigated through experience with the devices. FDA has been working with manufacturers to determine ways they can use existing data, for example, especially if it is an already approved point-of-care device, and adding a self-testing claim to that. This differs from a manufacturer who is submitting a brand-new device never approved before.

HIV self-collection kits also require FDA approval. All self-collection kits are medical devices that require FDA authorization before they can be distributed regardless of their intended use, but the review pathway can vary based on the intended use of the device. For example, a device might be intended for home use or use in a clinic for self-collection that is supervised or unsupervised based on disease indications. The reason that FDA needs to review these devices is that adequate and appropriate sample collection is essential for device to meet performance expectations. Self-collection means that an untrained individual is collecting their own sample, so there is no automatic assurance that collection has been performed properly when the sample arrives at a laboratory. FDA reviews instructions for sample collection and the device's performance with the intended sample type to ensure a reasonable assurance of safety and effectiveness of the device.

In terms of the current landscape, FDA recognizes there is a need for self-collection kits for HIV diagnosis for individuals who are unable or unwilling to attend a clinic. However, HIV self-collection kits require approval of a PMA or clearance of a 510(k) following reclassification of HIV diagnostic device to comply with the FD&C Act. Distribution of unapproved HIV self-collection kits is a violation of the Act. There are no FDA-approved HIV self-collection kits that use blood samples currently on the market. FDA's goal is to bring unapproved/uncleared

devices into compliance with the law and regulations. In the interest of public health, FDA is committed to working with device developers to meet the requirements.

Turning the Tide on Self-Testing and Sample Collection Background and Need

Michele Owen, PhD

Associate Director of Laboratory Science
NCHHSTP, CDC

To ensure that everyone was on the same page, Dr. Owen first shared the following terminology and definitions:

- **Point-of-Care Test (POC):** Conducted near an individual also referred to as point of contact or rapid tests administered by trained staff or health care providers
- **Self-Test:** A complete test conducted by an individual for their own knowledge—also referred to as an over-the-counter test (OTC) or direct-to-consumer test (DTC).
- **Self-collection (self-collected test):** A scenario where an individual collects their own sample, and hands it off or ships the sample to a laboratory for testing

There are many considerations for self-testing and self-collection testing. It is very important for populations where clinic or laboratory testing is difficult or not feasible. However, it is very important to provide clear information regarding assay limitations. For example, the oral fluid assays will detect some early infections.²⁷ These are never the final diagnosis. They are used in conjunction with clinical testing for a definitive diagnosis. Ideally, these tests should be available at a price point that will allow wide access for many people to have the ability to use them. As noted, OraQuick® is the only FDA approved HIV self-test. This is an oral fluid test that costs about \$35 to \$40 retail. It is important to note that this test does not detect acute HIV infections (e.g., up to 90 days for positive result post infection) and there are limitations for its use in the context of PrEP. Based on delayed reactivity shown in PrEP trials, this test is not optimal for prescribing PrEP. There are currently no cleared self-tests for STIs or viral hepatitis.

In terms of HIV self-testing data in the US, CDC in conjunction with Emory University conducted a longitudinal randomized control trial (RCT) known as eSTAMP²⁸ that demonstrated the feasibility, acceptability, and benefit of distribution of self-test kits. The study used the FDA-approved OraQuick®, a fingerstick test under IDE (Sure Check®), and a dried blood spot (DBS) test. Infection was identified in first time testers and social contacts and no harmful adverse events (AEs) were reported. A partnership with CDC's Let's Stop HIV Together Campaign-to launch TakeMeHome distributed approximately 100,000 HIV self-test kits through a portal on the CDC website.²⁹ This event demonstrated that self-testing serves people who might be reluctant or unable to seek clinic- or community-based testing. This tool was identified by 80% of jurisdictions that are part of the EHE as being very important for their community EHE plans.

The World Health Organization's (WHO's) stance of self-testing is informative. WHO has made recommendations twice that self-testing should be part of eliminating HIV or identifying people and getting them into treatment. The first recommendations were in 2016. After reviewing the data in 2019, the WHO updated their recommendations to make a strong recommendation for HIV self-testing. They also pointed out that testing in this manner reaches high-risk people who

²⁷ Stekler et al, JCV 2013 and 2016; Luo et al JCV 2013

²⁸ MacGowan et al. JAMA Intern Med, 2019

²⁹ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7038a2.html>

might not test otherwise, so it should be an ongoing approach for testing services.³⁰ There are a number of HIVST products available outside of the US with WHO pre-qualification.³¹

As mentioned earlier, there are no FDA-cleared self-collection test for HIV and Home Access is no longer on the market. Commercial laboratories have set-up laboratory-developed test (LDT) services, primarily because of testing during COVID for HIV, STIs, and PrEP initiation because it was known that people were not getting tested. This also was done for hepatitis B and C antibody tests. Multiple studies have been conducted on STI self-collection inside and outside the US. WHO also funded a meta-analysis of STI self-collection tests³² after which they published recommendations for self-collection testing for STIs. Similar to HIV self-collection, WHO pointed out that self-collection of samples for *Neisseria*, gonorrhea, and chlamydia are very important and reach people who might not normally be tested.

In the US, various institutions have set up programs for self-collection for STIs.³³ One of the most well-known program is I Want the Kit³⁴ that came out of Johns Hopkins where they are doing chlamydia and gonorrhea testing. Originating in Baltimore, this testing has now been expanded to Maryland, Alaska, and Arizona residents. The District of Columbia (DC) conducted a similar type of project called GetCheckedDC.³⁵ This is a mail-in STI testing program. Both programs have reached priority populations and data indicate that the methodology is feasible.

CHAC Member Discussion on Special Presentation

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 important is self-testing and self-sample collection to overall public health efforts?
2. Are there specific analytes (e.g., antibody or antigen tests for HIV, HCV or treponemal/non-treponemal test for syphilis) that CHAC would consider a priority?

The following questions, observations, and suggestions were raised:

- Dr. So emphasized that there is a lot of value in having rapid tests for home use and use at outreach events for HIV, STIs, and hepatitis. He asked whether one reason for not having more approved rapid tests and self-tests was because industry is not submitting applications and if FDA should be sending out notices to welcome industry to submit applications.
- Dr. Lathrop indicated that FDA has engaged in increasing outreach to manufacturers to encourage them to submit all of these devices. There tends to be a lot of mythology around what FDA will and will not consider in terms of data. Some of that is because that is the way it used to be and some of it is because people talk amongst themselves and have decided this, or they may have gotten an unhappy answer and then decided that FDA would never consider using data from outside the US. In some cases in the past, that might have been true. However, FDA has been working hard to open up alternative validation strategies that might not have been considered in the past, and is trying to engage outreach to get people

³⁰ WHO recommends HIV self-testing. (2016) World Health Organization. <https://apps.who.int/iris/handle/10665/251549>; Consolidated guidelines on HIV testing services. <https://www.who.int/publications/i/item/978-92-4-155058-1>

³¹ Latest list of WHO prequalified products: https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

³² Ogale et al. BMJ Glob Health 2019

³³ Kersh et al: J Clin Microbiol, 2021

³⁴ <https://iwantthekit.org/>

³⁵ <https://www.getcheckeddc.org/>

to come in. Fundamentally, FDA can only review what people submit. People also can simply start conversations with FDA regarding what is/is not required. There is a pre-submission process that is simple and can be informational. They want people to talk to them about what they have and what the expectations are. There is no penalty or user fee to clarify what is needed. In a pre-submission, FDA's feedback is binding. If they say that a study design is acceptable, they cannot change their mind later unless the science changes. It also is confidential on the part of FDA.

- Dr. Anderson observed that there seemed to be no question about the need for self-testing and self-collection devices for various infections. Perhaps the barrier at this time is that more data are needed for validation. She wondered whether manufacturers and laboratories do not have the protocols, are not interested, et cetera. Obviously, the need for more data has cost implications. While FDA is reaching out to individual manufacturers for technologies that are already developed and being used abroad, she wondered what realistically could be done to move this along in the US such as some sort of incentive structure. It sounded to her like a lot of data already have been generated, at least in a global setting, some of which may be useable for US approval. She clarified that when she said "incentivize," she was not suggesting that they pay manufacturers. She just wondered what outreach mechanisms might be available.
- Dr. Lathrop said she could not speak to whether FDA has the ability to incentivize manufacturers and they do not sponsor trials. Manufacturers may assume that the barriers are so high that they could not possibly get approved, but validation is validation. FDA recognizes Clinical and Laboratory Standards Institute (CLSI) standards for measuring assay precision. These are voluntary standards, but they are best practices developed by the device manufacturers. CDC and FDA are on the panels for some of the standards and follow those principles. Good device validation follows the CLSI standards to be properly validated in many cases. FDA has a number of roundtables that are designed specifically to engage in open discussion with manufacturers. She agreed that finding ways to reach out to various manufacturers who are developing these tests is crucial.
- Dr. Owen added that CDC also has tried very hard to engage in outreach with manufacturers by interacting with the Advanced Medical Technology Association (AdvaMed) to discuss the needs for HIV, STI, and HCV tests. In addition, CDC recently convened a diagnostics conference that they have had for many years. Most manufacturers either attend and/or have booths. Manufacturers have said that they will not bring a test to the market if they do not see a market share for that. They are private companies and they want to make money. It is important to continue to emphasize the need for these devices and that there will be a market for them.
- Dr. Dionne-Odom inquired about the role of clinical investigators who design RCTs. In order to reach this vulnerable population who is at-risk and not accessing care, self-testing for HIV and STIs is critical. If researchers receive funding for trials from NIH to conduct this type of research with donated kits from companies that have told them the bar is high for validation through the FDA, she wondered whether that would be the type of data that would be compelling or if the real work needs to be done at the level of the company to put their specifications and QI in place.
- Dr. Lathrop indicated that the clinical data is part of the package, but someone has to actually sponsor and submit the application. There is nothing that says a clinical laboratory or a university cannot do that, but they have to have all of the information that supports the analytical validation for the device as well. That can be challenging. A kit can be made that

works on an already approved instrument, and that a laboratory or university could submit that as their test and take responsibility for it. It does not have to be the manufacturer. While there are some risks associated with that, it can be done. It is difficult when someone is just doing the trial component, because they may not have access to all of the information needed. That would have to be acquired from the manufacturer or the researcher working with the manufacturer to provide that for an FDA application. The data generated in those kinds of studies, if well-designed and potentially can be submitted to FDA in the end, speaking very generically, should be usable.

- Dr. Mermin observed that while the efforts to reach out to manufacturers are appreciated, it is extremely expensive to put forward an application for PMA for a Class III device. For a university to want to conduct the clinical trials is not an easy process, for HIV in particular.
- Dr. Lathrop indicated that the user fee for a PMA is substantial. One benefit for reclassification is that when diagnostics are 510(k), it is a much lower user fee. At the moment, a self-collection kit is a PMA because the assay is a PMA. Once the assays are reclassified as Class II, the self-collection kits can come in as a 510(k). FDA is awaiting the finalizing of the reclassification, but when that occurs, it should lower the financial cost. The clinical studies still need to be done with performance criteria that are in the special controls, but certainly the submission and maintenance of that application are much lower.
- Dr. Markham reported that the IWantTheKit program from Johns Hopkins has made an incredible impact in reaching Native American and Alaska Native communities working with colleagues at the Alaska Native Tribal Health Consortium (ANTHC) and the Inter Tribal Council of Arizona, Inc. (ITCA). They are expanding their work to the Southern Plains Tribal Health Board (SPTHB) in Oklahoma. This has been a phenomenal program and working with the Johns Hopkins team has been outstanding. Testing is only one part of it. There also is a need for funding the culturally sensitive outreach and marketing, because those testing kits are only as good as the folks that they reach. It also is important to have support to linkage to care in local communities. For remote tribal communities where youth do not want to go see their Auntie at the local clinic because that is not going to be confidential, the importance of having that self-testing and anonymous/confidential access and linkage to care is critical.
- In terms of the mention earlier that different centers within FDA have adopted different approaches, Dr. Mermin asked whether thought has been given to aligning the requirements of both centers so that there is more consistency.
- Dr. Lathrop clarified that they do not have different interpretations. They have different intended uses. The requirements for an HIV diagnostic will differ from the requirements for an HCV diagnostic because the risks associated with the intended uses are different. Both centers are assessing them in the same way in terms of the potential impacts of the incorrect results to the individual. For instance, the risk from an incorrect result for a viral load monitoring test versus a screening test are very different. The centers talk all of the time and try to align as much as possible.
- Dr. Mermin indicated that CHAC, CDC, and HRSA have discussed that they do not believe the distinction between hepatitis C and HIV diagnostics at the point of use are different. They talked with FDA about that as well. They are left with a situation in which they are an organization trying to get testing out to the people who need it, but see different routes being required by different centers in the FDA even when it is not clear why one is being treated differently than the other.

- Dr. Lathrop said she understood why it appears that way sometimes. FDA's feeling is that the risks from a wrong result for HIV are not the same as the risk of a wrong result from HCV, especially in terms of a false negative and a person believes they are not infected and go about their life. HIV is treatable when people know they are infected.
- Dr. Dowler expressed an interest in understanding from the payer perspective how they can pay for these tests so that companies will invest the resources to go through the process. No Medicaid program is going to pay for a self-collected test with no incentive to do that. There is an opportunity for CHAC to assess the rigor of going through the approval process, incentives for industry to want to do that, and making sure that tests are equitably distributed and accessible to various communities in terms of being offered and the payment structure.
- Dr. Daskalakis shared a resource for HIV self-testing:
Issue Brief: <https://www.cdc.gov/hiv/policies/data/self-testing-issue-brief.html>

Panel 3: Applied Syndromic Approach to HIV, VH, and STIs: Focusing on People

Moderator: Demetre Daskalakis, MD; Director, Division of HIV Prevention, NCHHSTP, CDC

Comprehensive Harm Reduction Supports Navigation to Curative Hepatitis C Virus (HCV) Treatment and Syphilis Services

Andrew Gans, MPH

HIV, STD and Hepatitis Section Manager
New Mexico Department of Health

Josh Swatek

Hepatitis and Harm Reduction Program Manager
New Mexico Department of Health

Mr. Gans and Mr. Swatek presented on comprehensive harm reduction supports navigation to curative HCV treatment and syphilis services provided by New Mexico Department of Health. Typically, when speaking about harm reduction and high-volume, high-quality, low-barrier harm reduction programs as a great access to services, it is normal to assume that there will be hepatitis C, maybe HIV testing, and syphilis services to build trust in the community. Unfortunately, with the release 10 days ago of the STD surveillance data for 2020, New Mexico is number one in congenital syphilis. Small number, high rate, and very alarming.

New Mexico is able to do navigation because they have such a high-volume harm reduction program. While previously they were performing rapid HIV and hepatitis C testing, they have moved away from rapid hepatitis C testing because they have clients who have been antibody tested repeatedly over a decade or more, but it does not actually get them into care. It is expected that all harm reduction includes navigation to substance use services. New Mexico's enhanced model is about navigation to services rather than just referrals. As part of the hepatitis C elimination plan, it is necessary to get people into curative treatment. This involves getting them insurance, getting them into primary care, getting them medication opioid use disorder (MOUD) treatment, syphilis services, and ensuring that the DIS who are involved in a lot of these services can be doing partner services, testing, and linkage to STD or hepatitis treatment as well.

New Mexico wants to be among the first, if not the first, to eliminate hepatitis C as a public health threat by 2030 meeting national and international goals. New Mexico has 5 wins and innovations in the state that really place them ready to do this:

1. Project ECHO, which was founded in New Mexico at the University of New Mexico specifically to increase access to HCV treatment.
2. New Mexico Corrections Department (NMCD) is actually providing STD treatment actively and was doing antibody testing upon entry for almost a decade, switched to do confirmatory testing as well, and now has funding in the legislature to do curative treatment for about 2,800 inmates.
3. New Mexico has one of the most progressive Medicaid policies, which opened up for hepatitis C treatment without pre-authorization, fibrosis restrictions, or sobriety restrictions in 2015. The consultant who pulled off this amazing feat is now their Cabinet Secretary for Health.
4. New Mexico has an innovation with a high-risk pool, which they have been using to ensure that everybody living with HIV has insurance coverage, even if they are categorically ineligible due to immigration. The New Mexico Medical Insurance Pool (NMMIP) was approved at the end of 2019.
5. Comprehensive harm reduction services are available statewide.

Project ECHO has a peer education program working with state corrections, which does a lot to promote referral to hepatitis C treatment. They have the funds now and the 340B discount, which has allowed them to increase from about 150 inmates being treated for hepatitis C prior to this innovation to an average of about 600 a year. They have to motivate people to ask for it. It is not just for people with advanced disease, fibrosis, et cetera. It is for everybody, but not everybody knows they need it. NMCD has a plan for HCV elimination and received a very large allocation of funds. Project ECHO is a key part of that in terms of consultation and includes the NM Peer Education Program that educates the population on HCV screening and treatment. Partnerships are highly essential in New Mexico. New Mexico's innovative policies for hepatitis C treatment that began in 2015 increased access to treatment for Medicaid recipients. They have good coordination that is constantly improving with Medicaid MCOs, which helps somebody who leaves corrections who did not start or complete treatment get community treatment as well. A lot of people are cycling through jails where there is less excellent coverage, state prisons, and then back into the community for Medicaid.

New Mexico's innovative high-risk pool has done very well with wrap around insurance. Before ACA, New Mexico was a state that never had an HCV drug assistance program waiting list, because with this high-risk pool, they were ensuring everybody with HCV who could not get insurance 10 years ago. When ACA rolled out and there was Medicaid expansion, a lot of folks with HCV moved to Medicaid or to an ACA plan. Others still have employer insurance. The NMMIP is still the last option. There are only about 200 people with HCV in the state, but the hope is to be able to serve 50 to 100 people with hepatitis C who cannot get any other insurance. The exciting part is that they thought this would be a treatment model where the state health department and public health offices would be the wrap-around safety net. In some communities, one of the few providers in the county is the Department of Health Public Health office. Even in some of the larger communities, there may not be a lot of providers who are willing to provide hepatitis C treatment, so they hope to ramp this up. While they got set back about 2 years by the pandemic, they have a protocol for hepatitis C simplified treatment and can serve a lot of people who do not have advanced disease right in their health offices to be that safety that helps people get access to MOUD, which is essential for a lot of the population. New Mexico has comprehensive harm reduction program services available statewide. More than 18,000 unique people were provided with syringe services in 2021. An important piece of

that is that 87% of people have been tested for hepatitis C, but only 24% have had access to treatment. Harm reduction programs are a key place to provide services for viral hepatitis. Component 3 through the 2103 CDC DVH grant has allowed New Mexico to expand its services, which is essential for preventing reinfections.

Some of the strengths of the New Mexico model are negotiated exchange, which allows tailoring to client needs while still striving to maximize collection of used syringes. Services are comprehensive. Locations at NMDOH Public Health Offices offer HIV, HCV, and STD testing and services, WIC (Women, Infants, and Children), family planning, et cetera. Many sites are within FQHCs or other health care providers. Services are low threshold, meaning that new clients can enroll with just a brief interview. The program is confidential, but unique client identification codes can be used to ensure immunity from prosecution for possessing syringes. Program sites were an ideal venue to provide hepatitis A vaccines during an outbreak among persons experiencing homelessness.

This is a comprehensive model that provides new, sterile syringes. Safe disposal of syringes can be done through both program interactions and community drop boxes. Small sharps containers are provided to participants to return to the program. There also is provision of other “works” needed to prevent the spread of infectious disease, as well as overdose prevention services. Referrals and navigation are provided to substance use services, public health interventions, and social services. Some people might not be ready for treatment because of the circumstances of their lives (e.g., lack of childcare, food insecurity, lack of housing, et cetera). Active navigation helps to address those gaps first, with the eventual goal of getting people into treatment.

In terms of messaging, New Mexico’s older campaign had 6 messages for people in their services who may not have thought of PrEP, PEP, curative treatment, or rapid testing. The new campaign is being rolled out as harm reduction across the state around maternal testing for syphilis, which is very important for responding to congenital syphilis. The issue with New Mexico’s congenital cases is that a lot of people are not in prenatal care, very often due to substance abuse.

The New Mexico Harm Reduction Act passed in 1997. It authorized the Department of Health to compile data to assist in planning and evaluation, provided immunity for exchange or possession of hypodermic syringes from the Controlled Substances Act for both participants and providers, and approved community providers across the state. Program operations started in 1998. There were a lot of problems with the original policy. Original state rules were detailed in terms of data collection and reporting. This necessitated long intake interviews and some irrelevant questions (i.e., sexual behaviors). Eligibility is only for state residents aged 18 and over. Some educational messages that became outdated (i.e., use of bleach) were written into initial regulations. Exchange was one-for-one only with a limit of 200 syringes per interaction (hindering secondary exchange). However, policy changes have increased the scope of harm reduction services. House Bill 52 passed in the 2022 legislative session, with a lot of bipartisan support. It allows NMDOH to promulgate rules that reduce negative health outcomes associated with drug use such as overdoses and infectious disease and reduce harm by improving participant engagement in harm reduction.

Harm reduction is now being used to respond to maternal and congenital syphilis. New Mexico has a lot of moms who are not accessing prenatal care due to immigration status, using substances, experiencing homelessness, engaging in transactional sex work, et cetera. They fear that if they get connected to a system of care, they will lose custody of their baby. A lot of training is being done for providers to make sure those who do come in are tested. Harm reduction efforts include strategies to engage at-risk persons in harm reduction, including meth users and those who do not inject; rapid and conventional syphilis testing; incentives for testing, including for male partners of persons of child-bearing age; social network strategies (SNS) to recruit; and integration with DIS to ensure treatment, disease investigation, and better quality services.

Corrections Health is Public Health for the Justice-Involved Community!

John J. Hagan, MD

State Correctional Health Authority

North Dakota Department of Corrections and Rehabilitation

Dr. Hagan noted that he has the privilege of leading a small but mighty team of medical and psychiatric professionals who provide care to a unique and vulnerable population. Together, they change the lives of residents in the North Dakota Department of Corrections and Rehabilitation (DOCR). There is an epidemic of incarceration, with 1.43 million adults held in federal or state prison facilities currently. There are about 735,000 persons in jails. Across the country, about 0.7% of the adult population are held in jail or prison. The North Dakota State Prison system houses 0.3% of the adult state population. That does not include folks on parole or probation. North Dakota is a very rural state of 774,000 total humans. The adult count in the prison system is very small at 1,685. They are happy to be small and are trying to go out of business if they can. Their average turnover is 1,500 admits per year, the median length of stay about 16 months, and the recidivism rate has been about 40% over 5 years.

North Dakota residents are a vulnerable and underserved population. People of color are over-represented in prison in probation and on parole. Someone who is Black in North Dakota is 4.2 times as likely to be under DOCR control compared to their White counterparts. Latino North Dakotans are 1.8 times as likely and Native Americans are 5 times as likely to be incarcerated. Residents arrive uninsured with very fragmented medical care. They suffer significantly higher rates of hepatitis C, SUDs, serious mental illness, diabetes, and hypertension. The goal is simple. The mission of the North Dakota DORC is to transform lives, influence change, and strengthen the community. They work hard because they believe the work is worth doing. They practice dynamic security, the goal of which is to create a humane, normalized environment to the extent possible. They have security available if having issues, but they found that when their patients are treated normally, they respond normally. They are trying to get folks ready to head home by creating an environment in which residents attain and practice prosocial skills in a setting where they are safe.

DOCR's plan for success in treating STIs, hepatitis C, and HIV is straightforward. DOCR is tremendously well-supported by the North Dakota Department of Health (NDDOH). DOCR partners with NDDOH to bring screening and treatment service to the DOCR system, and they form a large platform for DOCR's more comprehensive treatment programs. DOCR would have no opportunity to do this without the superb NDDOH, which underpins everything DOCR does.

One of the things that drives DOCR's programming at every level of operations and security is that their residents are going to become their neighbors. Of the individuals in DOCR's care, 98% will be discharged to North Dakota, South Dakota, or Minnesota. They ask themselves with their programming what kind of neighbors they want. They are very much person-centered rather than diagnosis-centric. DOCR considers what these folks need to be successful in the community, and challenge their clients to work to remodel and revitalize themselves. The testing and treatment programs that they offer are concrete actions that convey to the residents that DOCR is heavily committed to investing in their future. This is a great place to find and treat folks. Upon arrival, 31% of DOCR residents identify themselves as PWID. It is suspected that the numbers are higher. About 15% of the residents suffer from chronic hepatitis C with elevated viral load. In the last 10 years, DOCR has had 2,388 unique patients arrive with hepatitis C antibodies and 80% of them are typically HIV-positive. Only 0.6% of DOCR residents test positive for HIV. The chlamydia rate is 20.7/1000.

The goal is to build trust from day one. In the first 30 days, there is an orientation program during which the DOCR Nurse teaches health-related issues and answers questions. The result of offering a stable and humane environment is that residents asked for treatment on arrival. There is an opt-out program for testing. Virtually nobody opts out. For the first time in 6 months, only one individual in the state of North Dakota asked not to test, so the environment definitely is right for this. The only reason DOCR succeeds with this program is because of the unwavering support of the NDDOH. This translates to 20% of adult men on arrival are antibody positive and 15% overall have active virus, while 37% of women are antibody positive and 25% have active virus. This is known due to the ability to perform universal testing on arrival. The reason they can do this is because their cost for HCV antibody is \$26 underwritten by the NDDOH. The HCV RNA/Genotype is \$55. The average screening cost for hepatitis C is \$37 dollars per arrival. DOCR cannot come close to that anywhere in the private world, so that helps them a great deal. That turns out to be important because NDDOH reports that 15% of individuals in North Dakota who have an HCV positive laboratory result reported to NDDOH each year have at least one HCV associated laboratory report in a correctional setting.

DOCR cures hepatitis C. They have the support of leadership and their legislature. DOCR treats and cures 43% of the people who come through the door who are infected and they test everybody. Because we partner with the NDDOH and have access to 340B pricing, their average cost is \$12,560. Their 2021-2023 budget is \$1.9 million. For an additional \$2.4 million for a joint program, they can get to micro-elimination and treat everybody they see. This is a great opportunity to impact the state. Since NDDOH steeply discounts their laboratory costs through Section 318 of the Public Health Service Act (PHSA), DOCR's GC and chlamydia tests are \$10 and HIV tests are \$10. They treat by protocol for GC and chlamydia. As soon as they are notified, their staff completes Level I contact tracing on behalf of NDDOH. They also are the first to notify patients on HIV results on a regular basis. People have wanted testing, they have feared testing, but they feel safe at DOCR. Fortunately, they have immediate counseling, psychiatry, psychology, primary care, and infectious disease services available.

Prisons face challenges in treating justice-involved individuals. Most states do not have a unified system. Jails and prisons look the same on television, but they are not at all the same in real life. They are separate organizations. They speak to each other and about each other, but they are not in the same organizations. Jails are funded by county budgets and prisons are funded out of state budgets. The scope and breadth of services differ by county and by state. Some counties have comprehensive services, while some counties have no services. DOCR does not have direct control over prisons. They have a relationship, but programs written for jails and prisons may not work in one setting or the other.

It is important to note that justice-involved individuals are ineligible for Medicaid, Medicare, VA, or private insurance as soon as they are incarcerated—even if they are still paying premiums. States pay cash for all DOCR services. They negotiate and pay out of the general fund. Public funding opportunities for these services is fragmented and separate programs exist for hepatitis C, GC and chlamydia, HIV, SUD, serious mental illness, and wraparound services. For all of the issues that this vulnerable group is expected to have, support disappears when the door is slammed shut by law. Another challenge is attracting and retaining providers. Medical staff are state employees who are underpaid compared to the community. State medical and mental health case management for transition is badly underfunded in most states, so they do not have the services that are known to have a high impact. Jail resources for education, screening, and treatment are very sparse and jails are unable to shoulder the burden as a result.

The next step is to expand the import model. The ultimate goal is to engage the community and patients. That is working well. DOCR partner with federal, state, and local agencies to bring services that already exists into the prison system. The advantages include a steady and predictable volume for agency partners, a solid source of reliable care for this vulnerable population, and continuity of care on release. A great example is DOCR's cooperation with the UND Family Medicine Residency Program, which runs the Center for Family Medicine and also takes care of Custer Family Planning, which is the public health STD treatment programs. For its residents, DOCR also uses the HerCare clinic to bring in onsite prenatal/obstetric care and reproductive health services (e.g., LARC, reversible contraceptives, education). There also is continuity of care, in that those leaving DOCR's care are plugged into that service and they continue to work. Another example like this would be the use of methadone and opioid treatment providers in the community to perform services. DOCR's goal is to expand this important model.

The takeaway messages are that prisons and jails are ideal settings intervening in the syndemic of HIV, STIs, and VH. Justice-involved individuals are a vulnerable population at high-risk for these conditions and are eager to accept treatment. Corrections health is community public health in its purest form. It is important to remember that these individuals are not always in prison or jail. There are actions that can improve the health of justice-involved community members dramatically. While DOCR has 1,685 folks in prison and 800 in jail currently, the total count is 7,500 to 8,000 who are in prison or jail and on parole or probation. It is important to envision justice-involved individuals as a community, and jails and prisons as an ideal location to deliver impactful programming. Further developing programming to discount the cost of syndemic testing in jails and prisons has been highly effective. It is entirely the low cost that allows them to be universal. It is no longer risk-based, there is no stigma, and people are very accepting of it. Allowing flexibility to unify and align existing programs to meet the unique needs of this vulnerable population is very beneficial. Restoration of the HRSA/HPSA special designation for determining workforce shortages for jails and prisons that is independent of the surrounding community represents a major need. This is an incredibly effective way to add staff.

Providing Comprehensive Sexual Health Services to SFUSD Youth

Rosalia Lopez, M.Ed

Student Family Services Division
San Francisco Unified School District

Dr. Lopez shared information on how comprehensive sexuality education and how sexual health services or appointments outside of the school system work in the San Francisco Unified School District (SFUSD) in the context of policies and mandates that support programs, community partnerships, and the tier systems of support. It is extremely important to have intentional policies and mandates that support programs at the state, local, city, and school district levels. Several policies and mandates are highlighted below:

- **Health Education Content Standards for the State of California**³⁶ for which 2 examples of interest are: 1) 1.9.G, which explains laws related to sexual behavior and the involvement of minors; and 2) 3.2.G, which identifies local resources concerning reproductive and sexual health, including all FDA-approved contraceptives, HIV/STD testing, and medical care.
- **The California Healthy Youth Act (AB 329)**,³⁷ which went into effect in January 2016, requires that schools provide comprehensive sexuality education for students in grades 7-12 at least once in middle schools and at least once in high school.
- SFUSD Board Policy **6142.1 Sexual Health and HIV/AIDS Prevention Instruction**³⁸ requires comprehensive sexual health education and HIV prevention education shall be offered to all students in grades 7-12, including at least once in junior high or middle school and at least once in high school.
- **Sensitive Services/Minor Rights: California Family Law Code Section 6920-6929**³⁹ Parental/guardian consent is not required for minors under the age of 18 to access sensitive services. These services may include treatment having to do with drugs/alcohol, reproductive health, sexually transmitted diseases, and mental health.
- **Condom Availability Program - SFUSD Board Policy 5141.25, California Education Code 19-24- Sp1** requires a Condom Availability Program at all SFUSD Middle and High Schools; delineates guidelines, parent/guardian notification, exclusions, education component, and abstinence message; and creates alliance with schools and community health care providers.
- **Meeting the Needs of LGBTQ Students - SFUSD Board Policy 610-8A6, California Bill AB537** prescribes a variety of activities, interventions, accountability, and support to ensure that schools are a safe place for LGBTQ youth; and ensures that sexual orientation and gender identity be included as protected categories in all non-discrimination policies and procedures applying to all SFUSD students, teachers, staff, administrators and other employees.

³⁶ <https://www.cde.ca.gov/be/st/ss/documents/healthstandmar08.pdf>

³⁷ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB329

³⁸ <https://go.boarddocs.com/ca/sfusd/Board.nsf/goto?open&id=BDVSWC74A618>

³⁹ <https://law.justia.com/codes/california/2005/fam/6920-6929.html>

In terms of partnerships, SFUSD has a cooperative agreement with CDC-DASH, San Francisco Department of Public Health (SFDPH), and other CBOs to implement programs that support sexual health, education, sexual health services, and safe and supportive environments. SFUSD uses a multi-tier system of support, including health education, wellness programs, and LGBTQ student services programs. Because of the partnerships with the SFDPH and other CBOs, SFUSD has been able to support comprehensive sexuality curriculum to ensure that there is a common language (Be Ready, Be Real for High School; Healthy Me, Healthy Us for Middle School; Healthy Me Resource Guide). Staff training is provided on policies and procedures to providing youth-friendly services; providing sensitive services and referring students to local clinics if needed; and logging services and follow-up one-on-one services to youth when needed.

The SFUSD team work closely with the Wellness Program and the LGBTQ Student Services Program for consistent assessment of the health education curriculum to determine where it needs to be updated to meet the needs of LGBTQ and all other students. One example would be if the topic of human trafficking is being discussed, a social worker is in the classroom in case students need services beyond just awareness. Because of policy, schools are not allowed to pass out condoms and the role of the teacher is just awareness. The nurse in the Wellness Center would provide students with condoms. Because a student would need to go to the Wellness Center to complete a quick needs assessment and receive condoms, there is relationship-building between the teacher, the nurse, and the students in terms of where students receive services. Those who need further services beyond what the Wellness Center can offer are referred to a local teen clinic.

SFUSD's Sexual Health Services & Multi-Tier Systems of Education has 3 tiers: Intensive, Targeted, and Universal. Health education is considered Tier 1, given that it is for everyone. Tier 2 is for those who need smaller social groups. Tier 3 is for those who need more support (e.g., testing, mental health services, medical issues, et cetera) for which students are referred out to partner organizations. This year more than ever, there is a lot going on in schools and the help of CBOs and health clinics has been key. Though it has been somewhat difficult to reconnect during the pandemic, this is a work in progress.

These innovative collaborations have yielded some excellent expected and unexpected results, including fantastic lessons, connecting classrooms to services, and increased collaboration of SFUSD partners with over 50 CBOs. The top 5 types of services based on number of students served include general counseling, case management, medical services, behavioral health counseling, and sensitive services.

Advancing Syndemic Approaches Through Cluster Detection and Response

Alexa Oster, MD, CAPT USPHS

Acting Chief, Detection and Response Branch
Division of HIV Prevention, NCHHSTP, CDC

Dr. Oster pointed out that cluster detection and response offers a framework to guide tailored implementation of proven HIV prevention strategies where transmission is occurring most rapidly. After an outbreak, detection helps to identify when HIV is spreading quickly and to work to stop that spread. The presence of a cluster or outbreak indicates a failure of care and prevention services that needs to be addressed to improve access to services, such as antiretroviral therapy, PrEP, and sub-transmission. This is an opportunity to identify the needs of affected communities and generate ideas for improving services, because cluster and outbreak response involves curating care and prevention services to be more accessible to the

people who need them most. Cluster response is an opportunity to identify gaps in services and curate tailored treatment and prevention interventions where standard population interventions have failed. Importantly, cluster detection and response involves adapting resources for those who use them rather than expecting people to adapt to access services in a system that has failed them.

Concurrent with the opioid crisis, there have been a number of HIV outbreaks among PWID in the US over the past several years, beginning with a large outbreak in Scott County, Indiana that was detected in 2015. PWID experience numerous syndemic conditions, including HIV, STDs, VH, SUD, and mental health challenges. In addition to these medical issues, they often face unstable housing, food insecurity, and other needs for social services.⁴⁰ Clusters and outbreaks affect a variety of populations, and these principles apply to sexual transmission as well as injection-related transmission.

In an example from Kanawha County, West Virginia, HIV diagnoses among PWID drugs increased rapidly beginning in 2019.⁴¹ As a result, the West Virginia Bureau for Public Health requested CDC assistance with an HIV outbreak investigation. CDC built its team with syndemics in mind. The CDC team, led by DHP, also collaborated with HRSA's HAB and the Department of Housing and Urban Development (HUD), both of whom have become very important partners for response support. This team collaborated to support the state and local health departments in conducting an investigation that included a medical record review and a rapid assessment with qualitative interviews. At the local level, a diverse set of partners from the state and local health departments and multiple other healthcare CBOs were involved.

To highlight some findings from qualitative interviews with 26 PWID and 45 key community members, many people described using substances to cope with feelings of hopelessness and despair associated with a confluence of health and social challenges, such as unstable housing, depression and anxiety, and unemployment. Among the numerous health and social conditions PWID faced at the time, HIV and SUD were just a couple of the many issues. This constellation of challenges underpins the complex needs of the populations served, as well as the challenges that can slow progress in implementing holistic approaches.

The medical record review, which included 496 healthcare encounters among 65 people with HIV, showed missed opportunities for prevention and care for a wide range of conditions, including low provision of naloxone and medication for OUD. Medical encounters for overdose and STIs were infrequent. Hepatitis C diagnosis was common and preceded HIV diagnosis by about 4 years. Most people were covered by Medicaid and housing instability and incarcerations were prevalent.⁴² Surge DIS staff from the Division of STD Prevention brought a syndemic approach to partner services, going above and beyond to ensure appropriate testing, treatment, and linkage to care for various syndemic conditions and working to meet a variety of other food and social service needs. The findings mentioned informed one of the team's recommendations, which was to improve access to HIV, hepatitis C, substance use, and mental health services through service integration by co-locating services and cross-training service providers to improve access to effective infectious disease prevention efforts. Co-location of services, along with multidisciplinary teams and intensive case management, can help to address important barriers to care for multiple conditions. Low barrier, one-stop-shop models can help. It also is important to involve people with lived experience in the development, implementation, and monitoring of programs.

⁴⁰ Lyss SB et al., JID 2020

⁴¹ Hershov R et al. MMWR 2022

⁴² Bonacci R et al. CROI 2022; Hudson A et al. CROI 2022; https://oeps.wv.gov/hiv-aids/documents/data/EpiAid_Report.pdf

In terms of challenges to syndemic success, integrating data sources from multiple conditions can be difficult, but is essential to understand the various needs of the people served. Silos in data systems can reflect silos in programs, and bridging those programs silos can be critical to facilitating integration of data. Policy barriers also can be a major challenge. For example, expanding harm reduction services and SSPs was a primary recommendation of the investigation. Although SSP policies were changed where possible, state laws and city ordinances related to SSP limited the ability to expand these services to meet the need. Likewise, limitations to eligibility for hepatitis C treatment for people covered by Medicaid meant that testing and linkage ended up being deprioritized. Limited eligibility led to misconceptions that affected the care-seeking behaviors of even those who were eligible for treatment. Program and funding silos are an important consideration. This is relevant at a macro-level, including how federal funds are distributed, but also applies to how health departments are structured with separations between infectious diseases and behavioral health and also at a micro-level where providers and systems have incentives to only address immediate needs, including in EDs and correctional settings. Finally, health department capacity limitations also were a challenge. Even when funds are available, health departments sometimes have difficulty hiring and retaining staff, and this limits their ability to perform recommended activities, including partner services for every new diagnosis of HIV and syphilis. CDC can provide surge support to help address a backlog of cases or additional cases during an outbreak, and federal support provides an opportunity to build program and systems capacity, but this can be limited by other capacity issues at that health department.

It is important to note that although outbreaks among PWID have been highly visible due to concerns about rapid transmission in these populations, most clusters of rapid transmission are related to sexual transmission. Among 144 clusters first identified through molecular analysis in 2018-2019, 82% were primarily among gay and bisexual men. Among the largest clusters that had grown to more than 25 people as of September 2021, 72% were among gay and bisexual men. These clusters were typically small when they were first detected, but grew to be just as large as the concerning outbreaks seen among PWID. Many of the same syndemic issues and others apply to gay and bisexual men, who also face homophobia and other systemic injustice.

To share an example of a cluster related to sexual transmission that resulted in response to syndemic issues, Michigan identified a molecular cluster of rapid transmission in 2021 in Wayne County affecting a network that included Black or African American transgender women. About half of the network members indicated participating in sex work or having partners that engaged in sex work. The health department immediately began engaging with community partners that serve trans communities to talk through potential gaps in services and how to improve them. Over a few months, 13 meetings were held with these community partners. The health department also spoke with members of the network, who were supportive of the response efforts and willing to share information about the community's needs and also helped to indicate additional people in need of services. They indicated that there were not enough providers who provide gender-affirming care. As a result, Michigan has created a mobile services initiative to offer gender-affirming care that includes general health and wellness checks, immunizations, a food pantry, and HIV and STI testing. Michigan is also developing community-oriented social media and messaging campaigns developed with input from the trans community.

Although value and opportunity have been demonstrated in advancing syndemic approaches through cluster detection and response, there are a number of needs and considerations, most of which are not unique to cluster and outbreak response. Those at the federal level can support syndemic approaches by communicating the priority of a syndemic approach from federal funders to state and local recipients consistently across all federal funding programs

and partners. This work cannot be successful if driven by a single program. This includes working to minimize silos between federal funding that serves as a disincentive to collaboration. Teams need to be designed with syndemics in mind, modeling at the federal level what is thought to be needed at state and local health levels. This collaboration cannot occur only when there is an escalated response, but must involve long-term work to integrate and align programmatic guidance and technical assistance.

Additionally, policy issues are often at the heart of the most stubborn barriers and where possible, state and local partners must be supported to address these policy issues. It also is important to build systems to meet the needs of the people served rather than expecting people to adapt to systems. To do so, it is necessary to listen to people with lived experience. Qualitative interviews have been a powerful tool to identify what is broken in systems and get ideas for how to fix them. Often the barriers to delivering seamlessly integrated services are issues like funding, training, separate service organizations, time, or physical space. Funding and program requirements can help to dismantle these barriers. That core set of integrated services should be a primary goal and not a bonus or afterthought. Solutions need to address syndemic health conditions that people are facing, but that is not enough. Intervening only on health concerns may not be effective if social conditions are not considered and addressed.

Identifying partners well-equipped for syndemics is key to success. Local health departments, health centers, or community organizations that receive broader funding that is not siloed or who receive funds from various sources already are well-positioned to support this work. Likewise, providers that recognize their clients' holistic needs and meet clients where they are have the most success in linking and engaging them in services. Community outreach workers and partner services staff can embody this approach and this trust is so critical for populations stigmatized on many levels. Moving from the current systems to a gold standard syndemic approach, while an important goal, will take time, so it is important to be prepared to accept incremental progress. Setting expectations too high can sometimes have the unintended effect of disincentivizing staff from initiating response efforts and other work that can unmask the many changes that are needed. Syndemic approaches rely on building cross-cutting teams that can best support this work and the people served.

CHAC Member Discussion on Panel 3

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 priority policies and actions should be considered in operationalizing a syndemic approach to service provision?
2. What settings should be considered for the highest public health impact?
3. How can CDC and HRSA make syndemic strategies and programs more common and effective?
4. What are the best practices for integrating non-HIV-specific services into HIV systems?
5. What strategies would better link youth to clinical services through school health programs with collaboration with public health departments?

The following questions, observations, and suggestions were raised:

- Dr. Anderson noted that one of the fun aspects of these meetings is hearing about all of these impressive programs that a lot of them would not hear about otherwise.
- Mr. Driffin said one of his finals for ethical consideration for one of his DrPH classes is on HIV sequencing and non-positive response. He wondered whether the presenters could share additional insight on racial and ethnic demographics that have been observed in response to the cluster response teams.
- Dr. Oster indicated that they looked at people who were in clusters of rapid transmission nationwide and found that about a third were White, about a third were Black or African American, and about a third were Hispanic or Latino. Rapid transmission is occurring in a variety of populations, and it is important to ensure that they are assessing the gaps that are driving this and supporting changes in programs and services along with those populations. In the analyses that assessed large clusters among gay and bisexual men, they found that most were in the South and West.
- Mr. Lindsey noted that a key barrier to syndemic approaches has been segregated funding streams in the past, which also was a barrier to personnel or workforces who are unable to work together because of segregated funding streams. He wondered whether it is all state funds or if there is anything else that can be done to address ideological or financial barriers to allow more of these population focuses and syndemic approaches to flourish.
- Mr. Gans responded that New Mexico integrated HIV, STD, hepatitis, and harm reduction into one section in 2015. Because they are a centralized health department, having all programs under one roof and operating on the statewide and local levels gives them a lot more flexibility. New Mexico is unique in a couple of ways. First, they have a lot of state support for a variety of programs and second, they have a lot of flexibility as long as they meet performance measures globally. For instance, they have had a long-term shortfall in their harm reduction budget, but they have about \$1 million in state funds in harm reduction. When he started it was \$4 million or \$5 million a year and now it is closer to \$12 million. It has dipped somewhat as people moved to fentanyl and smoking rather than injecting. While they could not afford that out of that budget, they could use state general funds in HIV prevention, HIV care, STD, et cetera. The other thing is that they have other revenue sources. They generate pharmacy revenue, which sustains a lot of HIV PrEP programs around the country, including community health centers. They do something similar with their direct services. Generally, they do not have a huge amount of flexibility in federal grants but when there is flexibility, they use it. They always have had fully integrated DIS who are largely funded in HIV and STD, and they are all cross-trained in HIV, hepatitis, harm reduction, and other navigation along with STD as the focus. New Mexico is always looking for ways to be creative. It is easier to have a syndemic approach at the local level, when they are all located in the same building and talk about their budgets all of the time across the agency.
- Dr. Hagan responded that they have syndemic issues with treating different illnesses. More importantly, most of their program availability begins and ends at their doorstep. There is a sharp cutoff when folks are detained or when they are incarcerated. When incarceration ends, the transition of services is a particularly weak section for them. That is where the natural silos have occurred as people try to create programs for incarcerated folks and folks in the community. That crossover is missing for them because there is not longitudinal thinking. They have the same problems in prisons and jails. When the door slams or opens,

programs begin or end and they are not well-connected. A lot of efficiency is lost that could be capitalized on. We track data out into the community and have tremendous longitudinal data for parole, probation, and recidivism, and recognize the continuum of care. We are taking actions based on the data. Prisons have the infrastructure, and it is shocking how much data they have, but do not crunch it. He can say which of his residents bought FUNYUNS® last week and other incredible data. They have to be careful with it, but they do have incredible data. They just do not use it as well as they might.

- Dr. Lopez stressed the importance of working together in order to provide universal services for everyone and to avoid duplication of efforts.
- Dr. Greene said she was hearing themes throughout about meeting people where they are, low barrier and low thresholds to care, flexibility, and how self-testing could help facilitate people where they are. As someone who works in geriatrics, she pointed out that this is very relevant to older adults, people with mobility limitations, and people with other issues that affect their access to care across all of these systems.
- Dr. Hagan replied that their approach in jails has been largely to try to get services. For instance, for some of the large local jails, they have worked hard to bring the university residents on site. These folks need customers, need to meet people, and need to understand their population. They do have folks with serious mental illness (e.g., schizophrenia, bipolar psychosis, major depression) who come off of their medication and cannot operate well within the social system. Once someone has had a single felony, they become felonized. He thinks there should a DSM-5 diagnosis called “felonized” because they never again will go to public health or mental health care. They will go to prison or jail. The first thing is linking work and bringing folks on site, irrespective of the ability to pay. In jails the focus is largely on getting patients what they need most and establishing trust. Some folks will be up to a year in jail depending on the jail, but most are not. The focus in jails is to get them basic services.
- Dr. So congratulated Dr. Hagen for running such a great program in the prison system. It is a model program. He asked whether they test their prisoners for hepatitis B and whether they are offered hepatitis B vaccination. Some prior CDC studies showed that about 2% of the incarcerated population have chronic hepatitis B and as many as 6% will develop acute hepatitis B infection in this country who have a history of prior incarceration.
- Dr. Hagan said that while they do not do universal testing, they do offer universal immunization. On arrival, they check everybody in the immunization registry, which is very complete in North Dakota. They are proud to be the state’s number one provider of adult hepatitis B immunizations. They have lost their funding for hepatitis A immunizations. The American Correctional Association’s goal is to fully immunize everybody for hepatitis A and B and fully test everyone for C. They do not do the testing unless there is a question clinically, but immunization is offered to everybody on arrival as a public health function.
- Dr. So suggested considering testing before vaccination, because the Medicare cost of a 3-panel hepatitis B test is only \$30. If they had prior infection or already have a chronic infection, it would save on vaccine cost since the vaccines are still very expensive. They also would pick up those who have chronic hepatitis B and may need antiviral therapy.
- Dr. Mermin said he was struck by the fact that in some ways, they were doing too good a job. Each of the presenters showed so much of what could be done with screening, comprehensive SSPs, comprehensive student health services, et cetera. He wondered

whether there were policies that would need to be put into place that would prevent people from getting hepatitis C, HIV, STDs, TB, et cetera—something that would have an effect even more upstream to make the work easier.

- Mr. Gans indicated that New Mexico wanted to get ahead on hepatitis C curative treatment to move towards elimination because they had some of the highest prevalence in the country. They are working to improve their surveillance system because the quality of active risk factor and race/ethnicity surveillance in hepatitis C is not the quality of HIV because it has not been funded as well. It is probably too late for the upstream changes, but they are probably a good model for all of the best policies He wished Medicaid expansion was universal, but it is not.
- Dr. Lopez said that while California has some of the strongest policies, the problem is that they are unfunded policies. That is well-intentioned, but it becomes challenging to address the policies.
- Dr. Hagan said he would like to see much better availability for needle exchange, which is still a taboo subject in his state. The state is really good at taking care of incarcerated folks. The rationale is simple. Everybody is someone's brother, cousin, uncle, daughter. Everyone knows somebody. He also would like to see better access to SUD treatment in the community. One place to focus is on jails since many people enter and cycle out of jails a number of times. Before they ever get to prison, they have been to jail 10 or 15 times.
- In terms of specific policies, Dr. Guilamo-Ramos said that from his point of view, the "low-hanging fruit" is to look at the workforce. The example shared about limitations on pharmacists and PrEP could be applied to other disciplines. The largest segment of the healthcare workforce is nurses, yet they have many regulatory limitations around the country that do not make any sense and limit the ability to improve access to prevention and treatment. Another thing that was striking to him in terms of settings was that he had not heard a lot about the important role of families, biological or non-biological. Families are an important setting, particularly for young people. Thinking about SDOH is impressive in terms of trying to integrate services, co-locating, and cross-training. Consideration must be given to how particular groups or communities thrive and overcome adversity despite significant challenges. He is a little concerned about the narrative, given that it has been focused on vulnerability but does not provide a path forward in terms of how to use the science of how people overcome and what has worked as being important to understand.
- Mr. Driffin suggested that more consideration be given to additional community engagement strategies that can continue to be lifted between CDC, HRSA, and other federal partners to ensure that communities move along with them to beef up strategies.
- Dr. Oster indicated that they are collaborating on some sessions with HRSA HAB for the Ryan White conference that relate to cluster detection and response. Some of the topics include community engagement, partnering with community organizations and providers, how everyone can come together to ensure that they are responding to clusters in a way that helps to make services better for these populations, et cetera. Community engagement around this topic is a major focus. She and Dr. Daskalakis have been spending a lot of time together working to have discussions with lots of different partners, community organizations, policy partners, healthcare organizations, and public health partners over the past few months.

- Ms. Hayes indicated that PACHA is hosting an HIV molecular surveillance small group think-tank that will include their community and federal partners.
- Dr. Anderson indicated that there is a current ECHO program related to the intersection of HIV, substance abuse, mental health, and intimate partner violence (IPV) for which she could share information.

Telehealth/Telemedicine WG Report

Dr. Shannon Dowler, Lead CHAC Telehealth WG

Dr. Dowler reported that the Telehealth WG had engaged in several meetings since its launch during the last CHAC meeting. The first thing the WG did was dig into the benefits and risks of telehealth and summarized their findings into potential areas of interest for CHAC. In terms of benefits, telehealth broadly has the potential to improve various types of access (e.g., geography, transportation, provider limitations, et cetera). Particularly in the sexual health space, telemedicine offers a unique opportunity to reduce stigma. It results in decreased costs, such as non-emergency transportation, lost work time, and practice infrastructure. It has the potential to close care gaps and improve health equity. Telemedicine also has the potential to improve retention in care, empower folks who are receiving services to take control of their healthcare, be more patient-centered, and increase provider productivity. There are many reports showing that patient no-show rates using telehealth are improved and that the barriers that keep people from getting to a scheduled office visit are mitigated with virtual care. As an example, North Carolina Medicaid wanted to know what was happening with its beneficiaries, so they added an adult experience and child experience with telehealth into their Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. They found that people were generally as happy with their care whether they had telehealth or in-person care. There was not a statistically significant difference for adults or children. Beneficiaries/patients seem to be happy with this modality of care.

There also are risks and challenges to telehealth. The WG found that there is disparity in terms of access to technology and broadband access depending upon where someone lives and the ability to pay for technology and services. Maintaining confidentiality and privacy in the home setting can be a risk and challenge. Not everyone has a large home in which they have the benefit of spreading out or going somewhere private for telehealth visits. There is a loss of ability to identify IPV. There is a risk of influence or manipulation by people who are not seen in the visit, which has significant implications. It takes time and energy to train people to use telehealth technology. There is a potential to break up services and have multiple visits, which may not be ideal. From the standpoint of fragmentation of care, there is always the risk of breaking up the medical home experience, not having good communication, and creating challenges in continuity of care—particularly when there is not shared documentation. There is a risk of losing some of the components of in-person care. This raises questions about the percentage of visits using technology versus in-person visits so that critical pieces of care are not lost. The issue of language barriers comes up repeatedly. In terms of the payment and integrity standpoint, there is a risk of fraud and abuse, particularly in the telephonic arena where it is not possible to confirm someone's identity.

Another challenge in the field pertains to the fact that everyone is using different terms and has different rules. Until everyone can come together nationally and agree on certain terms and on what is/is not covered, there will continue to be of mixed-metaphor of what people are saying. When the terms telehealth, telemedicine, or virtual health are used, everyone is saying and

allowing for different services or benefits. North Carolina Medicaid has 2.8 million beneficiaries. They began an evaluation to determine what was happening. There was a huge plummet in visits when the stay-at-home order was issued by the Governor. Simultaneously, there was an exponential and steep rise in telehealth. There were essentially no services prior to the pandemic, so the baseline was zero. The dramatic improvement in access would have been lost if people had relied on in-person visits, because it completely dropped off the radar.

After studying these data for over 2 years and looking at the relative probability of adults using telehealth services as a function of race, ethnicity, and geography, Black and Hispanic persons and those living in rural areas were less likely to engage and there was not a tremendous amount of improvement over time. While there is a lot of discussion about all of the great opportunities Telehealth offers to improve health equity and access, the lived experience in North Carolina is that the odds are still against closing those gaps. On the other hand, people with chronic conditions leaned in hard and fast to use telehealth early in the pandemic. Over time, that number decreased. In the rural/urban space, there has been an increase in the last 6 months with people beginning to use the technology more consistently in rural areas.

Looking at some specific codes, North Carolina assessed child developmental services to decide what would be kept as permanent policy versus what would not. Consideration was given to a service as a function of whether it changed geographic, racial, or ethnic equity. Consistently, the findings did not identify changes. They found that urban individuals were more likely to engage in telehealth even though they have more child development centers than in rural areas. The same patterns were observed by ethnicity in that someone who was not Hispanic was more likely to engage in child development virtually. The same difference was seen in terms of whether someone was Black or White. Gaps were not being narrowed in this area, and this pattern was reproduced across multiple codes. The data show that the same people who are using telehealth are the same people who are using in-person care, and that new patients are not being entered into care.

The WG talked specifically about opportunities to improve sexual healthcare in the context of modernization of technology and proposed a few areas they think are the most important. One opportunity is with home or alternate testing for STIs. The conversations over the last 2 days of the CHAC meeting aligned nicely with these recommendations. Consideration should be given to ways to normalize home testing and increase home delivery of medications, which could reduce the stigma of going into a pharmacy to ask for something. PrEP access could be enhanced to have a more patient-centered approach. Inequities around access to PrEP are significant and broad across the country, and PrEP is just not getting to people in an equitable way.

With this background information in mind, the WG developed the following recommendations and invited input regarding any priority areas for which CHAC thought proposals might be made to CDC, HRSA, or both.

- **Build on the PrEP letter that went out early in the COVID-19 Pandemic (CDC):**
 - Recommend that CDC launch a formal campaign to teach providers how and where virtual services can assist in the EHE goals specific to PrEP
 - Recommend the potential for the same initiative related to retention in care for HIV

- **Explore how virtual services can enhance routine STI screening for all populations (CDC):**
 - Recommend that CDC fund pilot home testing service delivery models broadly to seek to understand the impact of this model
 - Award sites based on factors such as poverty indicators, payer mix, population and geographic disparities
- **Study health equity as it relates to telehealth service provision (CDC/HRSA):**
 - Early data suggest that telehealth has not overcome barriers to access to care
 - A formal study could spawn interventions that might impact equitable service delivery more effectively
- **Deploy a Tele-PrEP initiative for FQHCs (HRSA):**
 - Recommend that HRSA fund a Tele-PrEP initiative for FQHCs to pilot focused on areas with high need to PrEP ratio

CHAC Member Discussion and Vote on Telehealth/Telemedicine WG

Dr. Gayles noted that while he and Dr. Anderson would moderate this discussion, they both recused themselves from participating in the discussion and any related votes due to COIs related to telehealth.

The following questions, observations, and suggestions were raised:

- Dr. Driffin said the only thing he would add, especially for others as they begin, was that the processes address the nuts-and-bolts questions around what success looks like for communities. This means ensuring that Black and Brown people have access to the internet, tablets, and/or whatever other vehicles are necessary to get them to the option of telehealth/telemedicine.
- Dr. Mermin noted that the data presented were very impressive and showed that a smaller proportion of certain populations participated in telehealth during the pandemic. He wondered whether they still participated in health visits and if those using telehealth were the same as those presenting in-person. He thought it would be beneficial to understand whether people who did not participate in telemedicine dropped out of care entirely or continued care through in-person visits.
- Dr. Dowler indicated North Carolina found that the same people who are using telemedicine are the same people who are presenting in person. The Duke-Margolis Center for Health Policy also performed a data analysis and came to the same conclusion that the same people who are using telehealth are the same people that are presenting in-person and new patients are not getting into care. People who are engaged in health care are engaging in health care maybe in more convenient ways or in different ways, but access to care is not actually being broadened. The exception to that seen in North Carolina was in primary care homes. Rapid adopters picked up telehealth really quickly and made it a large part of their practice, increased the number of patients they saw overall and improved access to care. Generally, the beneficiaries who are accessing care are just accessing care differently. In terms of whether people who did not participate in telemedicine dropped out of care entirely would have to be analyzed specifically. While they saw overall engagement, the beneficiaries did not change. North Carolina Medicaid

maintained a lot of telehealth services, but their commercial partners have not been as clear. The things that they are keeping would allow people to use their smartphone. In the sexual health arena, there are many positive opportunities because of stigma in that people will feel more comfortable in using self-collected tests and it would feel more patient-centered.

- Dr. Mermin emphasized that technologies are increasingly being seen as tools for helping people stay healthy. Perhaps providing someone with a smartphone and software might make a difference in people participating. Consideration would have to be given to whether there could be reimbursement by Medicaid or private insurance. The upfront investment could be prohibitive for both providers and individuals unless it was covered by insurance, but this could eliminate some of the obstacles for people—particularly those with limited resources.
- In terms of the idea of a more formal campaign to teach providers how/where virtual services can assist in the EHE goals specific to PrEP, Dr. Daskalakis indicated that NCHHSTP’s Capacity Building and Technical Assistance Branch has materials⁴³ for providers that focus on telemedicine around PrEP, which probably could be nuanced more to specifically identify places where telemedicine may be more or less appropriate.
- Dr. Greene suggested that perhaps the proposed recommendation to study health equity as it relates to telehealth service provision should be elevated to the first bullet.

CHAC Action

Mr. Riester made a motion to approve the proposed Telehealth/Telemedicine letter, with the suggestion of moving health equity to the top bullet in terms of prioritization. Dr. Markham seconded the motion. CHAC approved the letter with 8 affirmative votes and 2 abstentions.

Public Comment Period

Mark Misrok

Executive Director

National Working Positive Coalition

I am Mark Misrok. I’m Executive Director of the National Working Positive Coalition (NWPC), which works to strengthen responses to the long-ignored employment needs of people living with or at greater vulnerability to HIV. I’m a person living and aging with HIV and a member of the Steering Committee for the US People Living with HIV Caucus (US PLHIV Caucus). Last Summer, the CDC released their most recent data report from their ongoing collection of surveillance data of people living with HIV in the US from their MMP, or Medical Monitoring Project, surveillance data. This latest data report is for 2019, the last full year before the impacts of the COVID-19 pandemic in this country. This most recent data report presented 41% of people living with HIV as unemployed prior to the impact on employment and the job market of the pandemic. This extraordinary high unemployment rate among people living with HIV in this era of care and treatment reflects the profound lack of access to employment-related

⁴³ <https://www.cdc.gov/hiv/effective-interventions/library/telehealth/implementation-materials/cdc-hiv-ei-telehealth-practitioners-guide.pdf>

information, services, and resources within HIV supportive services that has continued unchanged across all areas of the epidemic. We know that communities most vulnerable to HIV and most impacted by COVID and a host of health crises are always also communities with long histories of unequal access to quality education and to employment and economic opportunities. Meanwhile, the HIV/AIDS Bureau has kept directives in place since the 90s that ban use of supportive services dollars by Ryan White HIV/AIDS program grantees to provide employment or job readiness services, suppressing growth of responses to the employment needs of people living with HIV, that could grow organically and community-based programs most trusted and often most committed to communities not prioritized in mainstream workforce development or vocational rehabilitation initiatives. It is time that our leaders, and advisory bodies, and government agencies shaping the US HIV response end the cruel abdication from understanding and addressing the employment-related needs of people living with or at greater vulnerability to HIV that has been our long-sustained pattern. Thank you.

Amy Killelea

Killelea Consulting (PrEP for all)

Hi everyone. My name is Amy Killelea. I am a consultant and for the purposes of what I'm going to talk about today, I've been working with Johns Hopkins University over the past about 12 months working on a proposal for a national PrEP program. Thank you for the opportunity to speak to you all today. I want to highlight that we have got an opportunity presented to us in the President's Budget for FY23, which was released a few weeks ago. It includes an incredible opportunity to expand access to PrEP in this country and includes a call for Congress to enact a new \$9.8 billion 10-year national PrEP program for the uninsured and underinsured, coupled with significant reforms to ensure that people on Medicaid who need PrEP can easily access it. I want to focus my remarks on both the opportunity before us with the new momentum from the Administration as well as what I think is a growing and should be a growing sense of urgency around PrEP. PrEP uptake, as I am sure this body has discussed in meetings prior, continues to be very low in the US, with only about a quarter of folks who could benefit from PrEP actually taking it and growing disparities among Black, Hispanic, and Latino communities in particular. I think it is becoming more and more apparent that we will not end the HIV epidemic without a drastically different approach to PrEP. A few things to really highlight in terms of the systems failures when it comes to PrEP. One is that we have a system for PrEP access, particularly for those who are uninsured and even those on Medicaid that is fragmented, that is confusing, and that is incomplete. For those who are uninsured, the medication is often available through a different program and mechanism than the lab services, which may also be separate from the ancillary services for PrEP. We also have put our thumb on the scale of a largely clinical approach to PrEP heavily dependent on primary care, on community health centers, and 340b entities who are big and savvy enough to navigate the complexities of PrEP financing. And let me be clear, because we heard from the previous presentation about community health centers and telehealth clinical entities are necessary for PrEP access, but they are nowhere near sufficient. And so the opportunity before us, I think, is to re-envision what a national PrEP program and functioning system for PrEP access could look like. What was submitted in the public comment was a sign-on letter from over 20 national, state, and regional organizations that really outlined a set of principles that provide a foundation for a national PrEP program, so I want to highlight just a few of those. First is that the program has to prioritize equity, has to invest in mechanisms that increase access to Black and Brown communities, trans folks, cisgender women, folks in the South, and others who are currently failed by our current PrEP delivery systems. The program has got to be simple and it has got to be accessible and include medication, labs, and the ancillary services needed to support PrEP access. I think the accessibility part means that it has to be available through a greater range of community-based access points outside of just clinical delivery sites and community health centers. By expanding

those touch points, the goal is also to increase PrEP demand in communities who are not well-served by, and not touching frankly, traditional healthcare delivery sites. Finally, a PrEP program has to be sustainable and it has to be based on evidence. We have got a generic form of Truvada, TDF/FTC, that is safe. It is highly effective. It is incredibly cheap. It is clinically appropriate for the vast majority of folks. But we aren't maximizing that potential to open the floodgates for PrEP, largely because we have a current system that incentivizes brand name drugs at every turn. We are also going to fail to maximize some of the newer forms of PrEP like long-acting cabotegravir if we don't insure that that drug and the drugs that are coming down the pipeline are available at fair public health prices and through a much broader network of public health providers. I will close with just saying that this is an opportunity and it's a challenge. We have a tough political environment to get this ambitious proposal through Congress, but I hope that through the CHAC and the folks on this call today that we can harness the momentum that we have with the President's Budget and build a better system for PrEP access. Thank you.

Chris Jowett

Chief Commercial Officer
Visby Medical

Good afternoon. Thank you for the opportunity to summarize our recommendations committee. I'm Christopher Jowett and I represent Visby Medical. I am the Chief Commercial Officer with Visby Medical based out of San Jose, California. Accurate STI point-of-care tests can revolutionize patient care. The "CDC's 2021 STD Treatment Guidelines" recommend nucleic acid amplification testing (NAAT) for the detection of chlamydia and gonorrhea and specifically call out chlamydia and gonorrhea in symptomatic women. In the "STI National Strategic Plan," there is a recurring theme requesting innovative solutions and approaches to address the ongoing and emerging challenges in STI prevention and control. Specifically, it calls out the need to develop point-of-care diagnostic tools. Visby Medical has developed such a tool which delivers PCR results in less than 30 minutes in the palm of your hand and received FDA clearance and CLIA waiver in August 2021. Visby Medical developed this rapid point-of-care platform with substantial support from the NIH and yet there remains significant hurdles to deliver these tests equitably nationwide. The CDC and other government agencies can help in the following ways. Support implementation science studies to assess clinical adoption in various settings. Implement policies and funding to provide equitable access to technologies that can improve patient health. Understand the true prevalence of trichomonas, a silent epidemic and not yet reportable. Support reimbursement incentives to promote breakthrough innovations. Breakthrough technologies come at a cost. Extraordinary pressure to reduce testing costs comes at the expense of patient care. Rather than reimbursement based on reagent and operational costs, CMS should consider the value that rapid and accurate point-of-care diagnostics provide to the patient and to public health. Visby has engineered out the need for highly trained lab personnel to interpret and operate the results. This and enabling specific targeted treatment based on PCR diagnostic results at the point-of-care is better for the patient, reduces the risk of antibiotic resistance, lowers operational costs, and reduces spending over the long-term by preventing more expensive sequelae, like pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. As the CDC is focused on advancing health equity and insuring access to diagnostic innovations, the Visby medical sexual health test is designed to support that goal and can fundamentally transform patient care and the public health. This point-of-care test platform is patient-centered and convenient, which in-turn can address access and equity concerns across the country. We asked the committee to focus on the value of point-of-care diagnostic testing and consider how to incentivize its use to address the STI epidemic. We are eager to serve as a resource for you at the CDC, HRSA, and HHS to reduce and prevent STIs moving forward. We look forward to continued opportunities for collaboration

with the Visby medical sexual health preventive care product and our future direct-to-consumer STI product offering. Thank you.

Jules Levin

Executive Director/Founder
National AIDS Treatment Advocacy Project

Hi, everybody. This is Jules Levin. I'm the Executive Director and Founder of the National AIDS Treatment Advocacy Project (NATO). I come to you as a person today living with HIV for 40 years. I'm now 72. I've been an advocate for 25 years. I am HIV aging and am now what I call "elderly." I think the CDC, Jonathan, calls people over 65—that's the category "elderly." Over 50 is "aging." I also come to you as a person cured of hepatitis C 21 years ago with pegylated interferon and ribavirin. I'm going to discuss 2 things today, hepatitis C and aging and HIV in 3.5 minutes. Number one, hepatitis C. I think it's disgraceful that here in the United States where we have had a cure for a number of years for hepatitis C, where you can cure hepatitis C in an inexpensive, safe manner with 8 or 12 weeks of therapy that we don't have a national hepatitis C elimination program. It's beyond talk. It's beyond speech. The discussion over the past 2 days around hepatitis C at this CHAC meeting has not been fully comprehensive. The needs for people living with hepatitis C have not been adequately discussed or addressed. Curing hepatitis C requires, in my opinion, a program, a Ryan White Care Act type program, that can be done in 5 or 6 years of limited time or \$5 or \$6 billion dollars, which is in the full scheme of things nothing. A drop in the bucket for the federal government. We need full funding for screening. We need to use electronic health records. We already have new models of care that provide support services for IDUs that could be utilized. The CDC is not working. They are not doing their duty. They are not providing and meeting the needs of this community and what is needed. The CDC is not working with local departments of health, many of whom already have elimination plans. We need funding and the CDC does not seem to be working with the local and state DOHs to develop and push these programs forward and help support them further. They're not providing resources and collaborations. Yesterday, somebody said DAAs are expensive. Are you kidding? They're \$15,000 for a course of treatment. To treat someone like me with HIV for 20 years is \$400,000. Syringe exchange programs and needle exchange programs is only one issue in the full framework that needs to be addressed to eliminate hepatitis C. Aging and HIV. The response has been completely inadequate. It's also a disgrace that this CHAC meeting at CHAC meetings have not had a panel on aging and HIV. We are experiencing more comorbidities than people without HIV. We have reduced life expectancy. We're getting bad care. The 20-minute visit does not work. African Americans get the worst care. Suffice it to say and in summary, it's just really unfortunate and a disgrace that aging and HIV is not adequately addressed and is not part of the discussion in almost every circle that participates in that is a discussion amongst the leaders at the NIH, CDC, many circles around leadership and HIV, our federal government, and state governments as well. Thank you.

Lorren Sandt

Executive Director
Caring Ambassadors Program, Inc.

My name is Lorren Sandt. I am the Executive Director of the Caring Ambassadors Program in Portland, Oregon. We do education and advocacy for people living with hepatitis C and lung cancer since 1997. Dr. Mermin opened the meeting discussing the Center's equity initiative strategy to achieve equity and eliminate health disparities, and the need to address some syndemics. You said you wanted to become as holistic as possible and asked what you could do better. Well, with all due respect, funding holistically, break it down, break down the silos, include reimbursement silos across all agencies. If these funding silos are not broken down,

hepatitis and STIs, health disparities, and health equity will never come to fruition in our country. The \$40 million in funding is frankly something everyone at CDC should be ashamed of. One program highlighted yesterday gave 36 community-based organizations \$400,000 dollars in funding to address one part of HIV. The average funding each state receives in hepatitis funding is \$315,000 dollars. The last professional judgment from the CDC and 2016 called for closer to \$400 million in funding each year for 10 years. This is a finite number so we can reach our elimination goals. We have an elimination plan like HIV, but we have no implementation plan and we have no funding. In Oregon, we have 7600 people living with HIV. We have dozens of case managers and a room full of epidemiologists. We have 90,000 people living with hepatitis C, 1 case manager at 1 HIV organization, and 1 state epidemiologist that we just got after 15 years of no epi. Funding must be commensurate with the impact of the disease. Almost every presentation we've seen, and they've been great, has been a call to break down silos so programs can meet people where they are. We are missing too many opportunities to help people when they reach out for care to help them. There is a cost-savings when people are tested and treated for the disease they present with rather than sending them down the road to test for something else or go somewhere else for care. Every time someone is denied, we are telling them they are not worthy. Hepatitis care and treatment is cost-saving to our health system. I respectfully ask every member of CHAC to be bold. Consider asking the Administration and Congress for an expansion of Ryan White programs to fully integrate hepatitis care and treatment and STI care and treatment, and the CDC to fully integrate the Center with your programs and your funding. We're done PCSIs. We're done with demonstration projects. We know what works. We need the political will to change the policies that keep these funding and silos and place. Thank you very much. And one final comment. I never heard what the outcome was on the discussion of whether the CHAC should weigh in on the mental health of our children. I firmly believe that it is your duty to weigh in on that. I hope that you guys voted to do that and will be weighing in and helping our children to live fully as they grow. Thank you very much.

Daniel Raymond

Director of Policy

National Viral Hepatitis Roundtable

I'm Daniel Raymond. I'm the Director of Policy for the National Viral Hepatitis Roundtable (NVHR). You heard from my colleague yesterday, Adrienne Simmons, with our colleague from Harvard Law School, Julia Harvey, on the current state of Medicaid access to hepatitis C direct-acting antiviral. I just want to go back to their remarks and note that, John, when you asked for guidance that there was a recommendation that more guidance to state Medicaid programs would be enormously helpful. My colleague Adrienne specifically called out the value in recent years of the HHS Medicaid Affinity Working Group, which the Office of Infectious Disease Policies led, but wrapped up its work last year. That Affinity Working Group was really instrumental in aiding states, not only in removing barriers to coverage, but also serving as a catalyst and incubator for discussing innovative payment and financing models for comprehensive care, including elements like case management and peer patient navigation that can be especially vital for achieving health equity goals, but also for analyzing administrative data to construct care cascades for states' Medicaid beneficiaries. This kind of work has become even more important. As some of you may be familiar, the manufacturers of hepatitis C therapeutics have recently imposed greater restrictions on 340B-covered entities. The need for strategizing about ensuring access and scale-up of care is vital. I would encourage CHAC to consider opportunities for making recommendations to further that work through concerted efforts. And then secondarily, I wanted to note the release last week of the White House Office of National Drug Control Policy's "Drug Control Strategy," which included very strong discussion of harm reduction, including support for syringe services programs and

specifically in their performance measures, committed to increasing the number of counties with elevated overdose rates that had an operational SSP by 85% between a 2020 baseline and 2025. I would suggest that there's an opportunity here for CHAC to make recommendations that CDC and HRSA, as part of broader efforts, provide guidance, technical assistance, and policy development on accelerating SSP implementation. I would call attention particularly to opportunities through federally-funded facilities, including Ryan White-funded providers and clinics, STD clinics, and Federally Qualified Health Centers. As we heard earlier today in terms of, for example, the West Virginia experience with clusters and outbreaks, this work has taken on an increased urgency. With the leadership of the Biden/Harris Administration and the new drug control strategy, there is ample opportunity to dive in and make meaningful progress. Thank you.

Recap Day 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson emphasized that CHAC heard some incredible presentations and some very important topics covered. Reflecting on those and high-level messages, they started the morning with a special presentation from FDA and CDC about self-testing and self-collection of specimens in the diagnosis of HIV, HCV, and STIs. There was broad agreement on the needs and advantages of these tools now more than ever. The technology is available. Many of these are available globally. However, there are some barriers that they learned more about during the day in terms of meeting regulatory requirements. Some of the barriers identified include a possible need for additional validation for some tests, the high cost to seek regulatory approval, perhaps the lack of incentives for manufacturers regarding return-on-investment (ROI) in putting in the time, effort, and funding. The take-home message is that there needs to be concerted outreach, which to some degree already is being done, to key players and key stakeholders. It seems like the first step is to discuss with FDA avenues to reduce cost and consideration of where and when manufacturers can be incentivized to provide these critical tools. In the afternoon, CHAC heard about exemplary programs from New Mexico, North Dakota, and San Francisco. All of them exemplify a syndemic approach. They also heard a presentation on CDC cluster response and interventions. The take-home messages include the fact that in New Mexico, North Dakota, and San Francisco, the local or state policies enabled some of these programs and were able to breakdown silos and address things in a cross-cutting way. The issue of silos has been a recurring theme of this meeting and every CHAC meeting in which Dr. Anderson has been involved. The issue of the importance of meeting people where they are intersects with the discussion on self-testing and self-collection. There is a need to link to care and to pay attention to certain high-risk key populations, including incarcerated individuals and pregnant and post-partum women in terms of congenital syphilis, mental health disorders, and SDOH. There also was mention of some of the workflow issues that brought to mind some of the work that has been done in low- and middle-income countries on task-sharing and task-shifting and how the US could do a much better job of that.

Dr. Gayles indicated that in addition to Dr. Anderson's very thorough and comprehensive summary of the day, he had only a couple of points to add. Everything that Dr. Anderson mentioned was a reminder of the importance that all of this work takes into consideration the whole person and not just one aspect as they continue to think through access to testing, access to healthcare, and the full picture of what people face in terms of being able to access

and fully utilize all of the available resources needed to be successful. Regarding a comment raised during the public commentary about looking into the issue of children’s mental health, particularly in the face of different legislative efforts occurring across the country specifically tied to sexual and gender identities, he assured everyone that CHAC is looking into that and would be addressing that as a group during the next day’s Business Session. CHAC does believe this is an important issue, does take their role as a committee seriously, and hopefully will be able to utilize this role to raise further awareness to the relevant parties who may have an opportunity to fill some of the gaps or address some of the issues that are secondary to the various efforts underway.

Adjourn

Dr. Mermin thanked everyone for another day of outstanding presentations and discussions. He then officially adjourned the meeting for April 27, 2022 and CHAC stood in recess until 10:00 AM ET on April 28, 2022.

Day 3: 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
Centers for Disease Control and Prevention

Dr. Mermin called the proceedings to order at 10:05 AM ET and welcomed participants to the third day of the CHAC meeting. He conducted 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 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 28, 2022.

Recap of Days 1 and 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles provided some high-level highlights from the previous 2 days. The first day began with updates from colleagues at CDC at HRSA describing the fantastic work that they continue to do, including efforts to better understand the increased presence of mental health concerns among children, the increased work at CDC regarding health equity and infusing equity into all aspects of their work, and the great work underway at HRSA and introductions to new key staff members there. There is a lot of great innovation and it is important that CDC and HRSA continue to lead the way at the federal, state, and local levels. One of the key issues that arose during the morning session regarded the role CHAC might play in terms of commenting on or putting forward recommendations to offset some of the political efforts that are putting the great work at CDC and HRSA have invested in at risk, as well as creating obstacles and challenges for communities in being able to take advantage of the programs and opportunities that result from the work of these agencies. Programs from Mississippi, New York, and Minnesota highlighted innovative strategies they are implementing to increase utilization and access to testing, such as using the school space to increase access to young people and leveraging some of the technologies and strategies that were put in place during the COVID-19 response to modernize the public health infrastructure. These programs underscored the importance of using COVID-19 pandemic innovations as models for securing and sustaining funding to continue to support these efforts and codify that work moving forward in a post-COVID world.

During the second day, CHAC heard presentations highlighting how impactful self-collection kits could be in communities that have historically not utilized traditional brick-and-mortar structures. As a result, the availability of self-collection kits increased testing practices in a number of communities. It is known that when people are tested more frequently, the incidence of new cases is reduced. Self-testing also can be used as an opportunity to connect people to clinical care, social-emotional support, and other services such as those that address SDOH. There were discussions with colleagues from FDA regarding the pipeline and approval process for self-collection kits, given concerns that arose with regard to how FDA views HIV versus HCV self-collection kits. CHAC wondered if/how manufacturers producing self-testing kits could be incentivized to increase production in the variety and availability of self-test kits. There are authentication methods domestically and internationally that could serve as models to increase the self-test kit approval process. CHAC also engaged in discussion related to key topics in syndemic analysis, which continues to underscore the need for all work to take a whole person

approach with respect to the various issues that influence an individual's ability to access resources that are being put forward, utilize them effectively, and have successful health outcomes. Exciting and impressive syndemic approaches were presented, along with limitations many jurisdictions will have in moving those creative ideas forward due to financing challenges, particularly in under-resourced districts that do not have significant financing outside of the federal government. While this may not lend itself to a letter at this point, this topic deserves further discussion and consideration in future CHAC deliberations. The Telehealth WG put forth an excellent letter, which was approved and will be sent out following the meeting. Suggestions were made for potential development of 2 letters, one to the Secretary of Health regarding LGBTQ youth and one to FDA regarding the pipeline and approval process for self-collection kits.

Business Meeting

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 2021 CHAC minutes for review. No errors or omissions were identified, no questions or concerns were raised, and no edits were suggested.

CHAC Action

Dr. Mehta made a motion to approve the November 2021 CHAC minutes, which Dr. Greene seconded. CHAC members unanimously approved the minutes with no changes or further discussion.

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

Ada Stewart, RPH, MD, FAAFP, AAHIVS, HMDC

PACHA Liaison Representative for CHAC

Dr. Stewart reported that PACHA last met virtually on March 14-15, 2022 for its 73rd full council meeting where they had an opportunity to bring back "PACHA-to-the-People." When PACHA was re-established in 2019, the goals of the Co-Chairs recognized the importance of reaching out to the people on the ground—the individuals working in, living with, or at risk for HIV and AIDS—to help guide the work of the PACHA. She expressed gratitude to PACHA's current Co-Chairs for allowing "PACHA-to-the-People" and thanked them for a very successful virtual meeting. The first day consisted of a welcome from Dr. Rachel Levine, Assistant Secretary for Health at HHS, and Harold Phillips, Director of the White House Office of National AIDS Policy regarding NHAS and their commitment to EHE. Reports were presented from PACHA's Stigma and Disparities, EHE, and Global Subcommittees and the Stigma and Disparity Subcommittee's WG that prioritizes molecular surveillance and cluster detection issues. PACHA took this on as a priority due to the growing number of responses they have heard from individuals living with HIV and others regarding the application of this response tool, especially in terms of criminalization of HIV and other social justices.

During the PACHA-to-the-People interactive community engagement session, community members provided feedback in breakout sessions focusing on 2 main topics. The first breakout session focused on HIV prevention in the context of EHE. This group focused on prevention of HIV in women and adolescent girls, those 55 years of age and over, persons living with substance use and mental health disorders, the LGBTQ+ community, and PrEP assistance programs. In the NHAS and EHE Initiative breakout, community folks provided input about how the strategy is working in their states, cities, and territories and how PACHA can help. During these community engagement sessions, there were passionate and robust discussions from communities highlighting the need for whole person care; addressing QOL issues; the need to address aging with HIV; the need to address persons with physical and/or mental health issues, and/or SUDs; the importance of elevating U=U and recognizing the needs of all women, cisgender and transgender; ensuring that there is a national comprehensive program to address barriers to prevention and making sure that rural communities are engaged; and the importance of advocacy in terms of funding.

There was an update on the President's Emergency Plan for AIDS Relief (PEPFAR). PACHA's Global Subcommittee has worked diligently to ensure that HIV/AIDS is elevated from a global perspective, making sure that future guidance is sought from global and domestic lessons learned. There was an important panel discussion related to HIV amongst women and adolescent girls and why representation matters in response to HIV in this population. There was an emphasis on the importance of women, especially women of color, being part of clinical trials and addressing the bias that exists in prescribing of PrEP to women. There was a call to action to shift the narrative to ensure that all women living with HIV need to have a seat at the table and that IPV and QOL must be addressed for both cisgender and transgender women.

There was a panel discussion regarding PrEP for the nation and how to get PrEP to everyone who wants and needs it. There was discussion and approval of a draft letter to the HHS Secretary with PACHA's recommendation on scaling up PrEP to the nation. There also was a panel discussion on strengthening the HIV workforce. Dr. Wendy Armstrong and Vincent Guillermo-Ramos presented as part of the panel about how this important goal can be accomplished. They discussed the importance of removing regulatory barriers that place restrictions on practice at the highest level of training and licensure to ensure that the talents of Advanced Practice Nurses (APN), Nurse Practitioners (NPs), and Social Workers can be leveraged to the fullest of their ability to increase the HIV workforce; ensuring that CMS offers reimbursement for decentralized, team-based, whole person, HIV prevention and care services; supporting a shift toward education and training for the future health workforce that emphasizes key competency of team-based, whole person, HIV care; providing training for those not only pursuing full-time HIV work, but also those who are intimately involved in that; having the knowledge to be able to address co-morbidities using training tracks, residency programs, access to experts, et cetera; investing in infrastructure; developing decentralized and differentiated HIV prevention and care such as telehealth and community-based services; and allocating funding toward HIV using specific demonstration projects.

CHAC Member Observations/Suggestions: PACHA Update

The following questions, observations, and suggestions were raised:

- Dr. Guilamo-Ramos noted that this speaks to the issue of meaningful engagement of people living with HIV in the workforce and expanding definitions of the workforce beyond the clinical to think about a range of important actors who could help to end the epidemic in the country.
- Mr. Lindsey pointed out that there is a community health worker apprenticeship program that came out of the broader HRSA environment.
- Dr. Armstrong indicated that HRSA established and put many resources behind a Community Health Worker Training Program (CHWTP). More programs such as this are needed, but do require additional resources for childcare, transportation, and other supports peers will need to take advantage of such opportunities.
- Dr. Driffin emphasized that it is important to be mindful of diversity, equity, and inclusion in the workforce so that there is racial and gender diversity in key health departments along HIV jurisdictions and such that the community sees more people who look like them in key leadership and executive decision-making roles.
- Dr. Gayles said that he was hearing that perhaps it would be beneficial to stand up a CHAC Workforce Development WG. There previously was a CHAC HIV and Aging WG. Perhaps it would be beneficial to hear an update on this WG and the status of its efforts.

Action Item #1: Potential Letter Regarding LGBTQ Children/Youth

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson reminded everyone that the work that CHAC does and the advice they can give to CDC and HRSA is somewhat limited between meetings. The reason they chose the 2 action items for this business meeting was because they felt that there was some sense of urgency for these topics and that some bullet points could be created that CHAC could vote on during this meeting, which could then be developed into a letter over the next few weeks. She then reviewed the proposed components for the letter:

- Background:
 - In December 2021, the Surgeon General warned of a “devastating mental health crisis among adolescents.”
 - There was a 60% increase in major depressive disorders from 2007 to 2019 (National Survey of Children’s Health. HRSA October 2020).
 - Suicide rates increased nearly 60% in youth 10-14 years of age from 2007-2018 (National Vital Statistics Reports September 2020).
 - These problems are magnified among LGBTQ youth (CDC Adolescent Behaviors and Experiences Survey (ABES) 2021).
 - More than 60% of LGBTQ students experiencing poor mental health during the pandemic, which is over twice that seen in heterosexual students.

- LGBQ students were more than 3 times as likely to have attempted suicide in the past year.
 - Three-quarters of LGBTQ students experienced emotional abuse at home during the pandemic.
- For youth to thrive in schools and communities, they need to feel socially, emotionally, and physically safe and supported.
- There are ample data showing that LGBTQ students experience more bullying, harassment, and physical assault as compared to heterosexual students (2015 National Youth Risk Behavior Survey).
 - Young gay/bisexual men are at increased risk for HIV infection (**need update**). In 2014, they accounted for 8 of 10 new HIV diagnoses among youth (HIV Surveillance Report 2014).
- LGBTQ-supportive school policies and practices support all youth with decreases in depressive symptoms, decreases in suicidal thoughts and behaviors, and decreases in suicide attempts—especially among LGBTQ students (National YRBS 2015 & 2017; CDC School Health Profiles 2014 & 2016).
- From 2015-2019, over 200 pieces of anti-LGBTQ legislation were proposed in 35 states. In 2022 alone, over 300 bills have been introduced in state legislatures, often focusing on restricting school curricula, access to books or other educational materials relating to gender identification/gender-affirming care, or sexual orientation (<https://childtrends.org/publications/anti-lgbtq-policy-proposals-can-harm-youth-mental-health>; NYT 4/27/22)
- Implications/Concerns:
 - These legislative efforts send a clear message to LGBTQ youth that they are not okay.
 - Legislative efforts at the state level likely will create significant gaps in access to health care and social support services critical to these youth, including mental health services.
 - These legislative actions also can cause significant anxiety and depression that can further impact adherence to and engagement in medical care.
 - These legislative efforts will put HRSA and CDC efforts (demonstration projects, funding mechanisms) at risk and will impair successful delivery of services.
 - These gaps in care introduce spaces for the federal government to step in and provide a connection to support services that fill that void.
 - Recommendations:
 - Develop and disseminate resources at the federal level for youth and their families, as well as teachers and school counselors, to try to mitigate the potential harmful effects of any LGBTQ legislation.
 - Develop and disseminate resources at the federal level targeted to healthcare providers to better educate them about LGBTQ health and mental health and risk reducing strategies, and to provide information about assistance when problems are identified.
 - Develop public service messages (PSAs) and social and other media to educate the public about these harms and the need to reduce/prevent stigma and discrimination for these vulnerable youth.
 - PSAs also should be developed to target social media and other electronic platforms most utilized by youth, including LGBTQ youth, to provide information and resources.

CHAC Member Observations/Suggestions: LGBTQ Letter

The following questions, observations, and suggestions were raised:

- Consider forming a CHAC WG around these issues.
- Be explicit about promoting ways to encourage healthy sexual behaviors.
- Be specific about risk reduction strategies for at-risk adolescents, such as availability and provision of PrEP.
- Recognize the importance of school counselors at the state and county levels, and support school connectedness in general.
- Thinking particularly about youth who are in the foster care system, target information to social service providers outside of the schools.
- Discuss the potential need for housing assistance, which often goes unnoticed as part of their lived experience.
- Discuss the lack of gender-affirming care and the lack of provision of services/information that involves gender identity, and be more explicit about the mental health challenges that entails. There are efforts to prohibit conversations about sexual or gender identity, some of which is legislative and is actively seeking to bring child abuse charges against anyone who provides gender-affirming services and/or information.
- Perhaps there should be something about starting earlier than the education system. For instance, Oklahoma wants to ban any markers of non-binary gender identities on birth certificates. This seems to be going even further in an effort to erase identities that have been long and hard fought for.
- Highlight the importance of safe spaces, including safe spaces in which families can receive high quality and accurate information. For youth who already feel isolated or for whom the online space or social media is exacerbating their mental health issues, perhaps there could be some opportunities for in-person convening or collective healing through safe spaces or similar avenues. Parental consent was raised during the presentations. Sometimes, parents may be the bullies. Youth need to have safe places where they can speak freely about bullying from one or both parents, as well as school and/or social bullying that is occurring.
- Willful disinformation campaigns should be mentioned in the background section.
- Discuss funding.
- Perhaps there could be a leading bullet point before getting specifically into LGBTQ youth to recommend enhanced effort across the board to increase access to mental health services for all children, particularly around connectedness, coping mechanisms, access to therapy in a timely manner that addresses their mental health needs. That could be the big take home since all youth are currently behind the metaphorical 8 ball. Then it could go on to say, because of everything Dr. Anderson laid out, there needs to be special attention to

LGBTQ youth given particular legislative efforts and include the data showing the implications and connections within all of that.

- Dr. Cheever noted that the topic pertains to LGBTQ issues. If the letter and recommendations are made more general, this topic could be swept into a more general set of discussions around mental health for children. While this is critical as well, it would not focus specifically on the needs of trans and LGBTQ youth who are in places where there have been specific political movements to make it more complicated for them.
- Dr. Mermin added that there are data that support the idea that not only is there a disproportionate effect on mental health among LGBTQ youth, but also there is a fairly large proportion of youth who identify as LGBTQ and, therefore, this has public health importance in this political and social environment that CHAC has been discussing. It is possible to make a difference and it seems like a very important issue, particularly because for STDs (though maybe less) and HIV, there is a highly disproportionate rate among gay and bisexual youth, males particularly. This is a strong rationale for the focus. Based on the discussions, it is very hard for parents, youth, and teachers to obtain information about how to deal with this. The idea for the first bullet to focus on dissemination and access to credible resources is the next generation. CDC/HRSA and other partner organizations have a responsibility to get information out that can be useful and there is also the legal/policy level.

CHAC Action

Dr. Anderson made a motion to approve the letter for LGBTQ youth, which will be developed and circulated for review by CHAC before sending it out, including the 4 original recommendations presented and the addition of the following 4 recommendations:

- Increase efforts across the board to develop and disseminate information and resources for youth and their families, as well as teachers/school counselors addressing the mental health crisis in adolescents.
- Develop and disseminate messages about healthy sexual behaviors and resources to improve access to PrEP and other preventive services to at-risk youth.
- Encourage development of safe spaces for youth in general and LGBTQ youth specifically to access accurate information and support.
- Ensure that resources for LGBTQ youth are available to address disparities in care related to social determinants of care (including homelessness, domestic violence, and racial/ethnic discrimination).

Dr. Dowler seconded the motion. CHAC unanimously approved the LGBTQ letter.

Action Item #2: Letter on Self-Collection and Self-Testing

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles noted that while this proposed letter to the FDA was not fully fleshed out, the CHAC discussions prompted them to put this forward, recognizing that data will need to be identified in order to further shape the letter before it is ready to move forward. Some of the highlighted

points discussed as key areas of concern pertaining to self-collection testing included the following:

- There is a differentiation in how HCV and HIV are viewed, particularly around the impact of results.
- Criteria required for the authentication process domestically versus internationally. One of the major issues was that there are similar tests that are utilized internationally that are not accessible in the US.
- There is a need for incentives and an increased sense of urgency to foster and facilitate a production pipeline. This may involve proactive outreach to manufacturers to encourage them to seek approval for tests, beginning with a discussion with FDA to explore how to decrease the costs associated with premarket approval (PMA). As raised the day before, the cost is just shy of \$400,000 for that process. Consideration needs to be given to how to remove barriers, as well as the existing data related to the impact of self-collection in terms of increased testing in certain groups. It is important to figure out ways to increase the pipeline and help foster a smoother process to move things forward in order to increase access to these testing modalities for certain groups.

CHAC Member Observations/Suggestions: FDA Letter on Self-Collection Testing

The following questions, observations, and suggestions were raised:

- This seems like a critical place for CHAC to focus its efforts to intervene.
- It is important to remember that payers cannot pay for self-collection tests without CPT HCPCS codes for home tests. This was done for COVID-19, which opened the door for other tests. Perhaps someone could reach out to the AMA to discuss this.
- There are some incentives already. Companies would like to market their products and have them widely used, which is why they develop them. Some companies have said the barrier is too high at the FDA level to get approval. FDA spoke about the risk-benefit comparison, but that does not align with the true risks and the true benefits of home testing. A high-level conversation is needed with FDA to come to an agreement that everyone needs to work together to make self-collection kits available to the people who need them. Regulatory barriers were put in place 10 or 20 years ago and need to be revisited.
- There are larger issues to consider when tests are brought to market pertaining to affordability, awareness of availability among communities who need the tests, linking people to services, payer issues, et cetera. With that in mind, perhaps CHAC should consider standing up a Self-Collecting Testing WG to further explore the issues.
- Dr. Mermin asked CHAC to consider whether a very specific, short-targeted, single-pointed letter could be more effective than one that tries to redress all of the comprehensive issues related to testing, which may be better suited for ongoing discussions. The first and part of the third bullets contain the major points. Based on the CHAC discussions throughout the meeting, FDA is aware that the marketing in Europe is different than in the US. While articles have been written about Europe's more efficient process, it is not going to change the US approach to approval processes. While it has been explicitly stated that HIV is exceptional in that it is much more dangerous for someone to have a false negative HIV test than it is to have a false negative hepatitis C test, there are theoretical arguments

against that view. Many years of HIV self-testing are already in place, so the rationale is unclear about the danger. High-quality thoughtful letters are more effective than ones that have not been thought out as well.

- Dr. Akolkar, FDA, clarified that the user fee is not determined by FDA. It is legislatively determined by the Congress. There are also regulations FDA has to abide by, even though they may want to do something for both HIV and HCV. HCV approval was basically done on the basis of persons with signs and symptoms, which is different than for HIV. It is not just a simple equation that HIV and HCV are the same—there are historical nuances. FDA has learned a lot from the self-test experience for HIV and is working with the sponsor, but it is important to remember that the sponsor must approach FDA before a process can begin. They are open to have preliminary discussions with sponsors who believe they have something of value and some data to support that.
- There was CHAC support for the idea of crafting a pointed letter that addresses and engages on the first bullet point specifically, plus/minus some language around asking for the deeper conversation to revisit the processes and how they can be updated to match current thinking versus the thinking of 20 some years ago when self-collection reviews were beginning.
- Some CHAC members wondered if perhaps they were rushing this and that it might be better to establish a WG rather than trying to litigate everything during this meeting. It was noted that an alternative to a WG would be to convene an interim business meeting, which would allow time to assemble the facts and develop a draft letter. Establishing a WG could prolong the process.
- Dr. Gayles recapped that they were hearing that there is still much to be clarified in terms of what would best fit into such a letter, which would take more time to flesh out into more detail. There are 2 mechanisms for moving forward that could work, which are to: 1) convene an interim business meeting that probably could not be scheduled until September; or 2) create a WG to study the key points, with specific tasks of differentiating the bullet points, determining whether the letter to FDA should focus on one point or be more general, and then reporting back to the full CHAC during its November meeting. Given the timeframe, the reality seemed that creating a WG would offer more time to further explore the issues and develop action items.

CHAC Action

Dr. Gayles made a motion to create a Self-Testing and Self-Collection WG to study this issue with the specific task of obtaining more information on: 1) differences in risk classification of HCV and HIV; 2) criteria required and data available for the FDA approval process; and 3) downregulation to Class II diagnostics. The WG will then propose messaging that should go into the letter related to self-collection, including the development of a set of recommendations to be presented during the November 2022 CHAC meeting. Dr. Dowler seconded the motion. CHAC unanimously approved the motion to create a Self-Testing and Self-Collection WG.

Action Item #3: Stand Up a Workforce Development WG

Dr. Anderson reminded everyone that a suggestion was made during the meeting to consider standing up a Workforce Development WG with several specific tasks.

CHAC Action

Dr. Gayles made a motion to create a Workforce Development WG to study this issue with the specific tasks of: 1) formulating a potential panel for the November CHAC meeting in order to have a larger discussion on this topic; 2) liaising with PACHA to ensure that CHAC is not duplicating and is supportive of their efforts that are already ongoing in this space; and 3) exploring the role of other health-related professionals and CHWs to enlarge the workforce and to task-share when appropriate. Dr. Guilamo-Ramos seconded the motion. CHAC unanimously approved the motion to create a Workforce Development WG.

Next Meeting / Proposed Agenda Items

The next CHAC meeting is scheduled for November 1-3, 2022. The following future agenda items were proposed:

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

Recap and Closing

Dr. Gayles expressed his personal gratitude to everyone for their thoughtful input, continued and consistent engagement across 3 days of Zoom meetings, and great input and work. He recognized that the work they all do on regular basis contributes to their expertise and membership on CHAC. He thanked Dr. Anderson for keeping the meeting moving along and for being the epitome of comprehensiveness and thoroughness.

Dr. Anderson echoed that this had been a tremendous meeting in terms of the topics covered, the work done, and the exciting future topics identified. She complimented Dr. Gayles on his amazing abilities not only to summarize, but also to draw out all of the implications. She also expressed gratitude to their CDC and HRSA support.

Adjournment

Dr. Cheever thanked everyone, recognizing that very good panels had been assembled with excellent presenters who brought forward important information. Secondly, she recognized the CHAC members for their ability to listen carefully and reflect on the information presented and engage amazing discussions. She expressed her gratitude for Drs. Gayle and Anderson for their leadership as Co-Chairs and their wonderful abilities to synthesize the information and discussions.

Dr. Mermin expressed his gratitude, emphasizing that he had learned a great deal. At its best, an advisory committee provides useful advice that can help influence the thought process on various topics. CHAC's did exactly that over the past 2.5 days with their thoughtful input, which raised important issues for CDC and HRSA to think about as they consider many issues of importance. He recognized that it is time-consuming and that everyone is very busy. Especially in the time of COVID-19 when site visits have been reduced, it is very difficult to understand what is occurring. It is great to have input from people who are thinking about the issues and want to make a positive difference in these areas of diseases that are of great public health importance and that experience a lot of inequity. He thanked everyone for their time and effort and emphasized that he was looking forward to the November 2022 CHAC meeting.

Certification

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

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

Date

Jean R. Anderson, MD, Co-Chair
CHAC Co-Chair, HRSA Appointee,

Date

Attachment A: Participant List

CHAC Members Present

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

CHAC Members Absent

Mr. Venton Hill-Jones
Ms. Gloria Searson

CHAC Ex-Officio Members Present

Dr. Pradip N. Akolkar
US Food and Drug Administration

Dr. Maureen Goodenow
National Institutes of Health

Dr. Neerja Gandotra
Substance Abuse and Mental Health
Services Administration

Mr. Richard Haverkate
Indian Health Service

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

Dr. Richard Wild
Centers for Medicare and Medicaid
Services

CHAC Ex-Officio Members Absent

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

CHAC Liaison Representatives Present

Dr. Ada Steward
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

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

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

Attachment B: List of Acronyms

AAA	Area Agency on Aging
ABES	Adolescent Behaviors and Experiences Survey
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living
ADAP	AIDS Drug Assistance Program
AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ANTHC	Alaska Native Tribal Health Consortium
APN	Advanced Practice Nurses
ART	Antiretroviral Therapy
ARV	Antiretroviral
BPHC	Bureau of Public Health Clinics
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBER	Center for Biologics Evaluation and Research
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CDRH	Center for Devices and Radiological Health
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHOW	Community Health Outreach Worker
CHW	Community Health Workers
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CMO	Committee Management Office
CMS	Centers for Medicare & Medicaid Services
COI	Conflicts of Interest
CPT	Common Procedural Terminology
CRUSH	Community, Restoring, Urban Youth, Sexual, Health
CVD	Cardiovascular Disease
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DBS	Dried Blood Spot
DC	District of Columbia
DDID	Deputy Director for Infectious Diseases
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DHP	Division of HIV Prevention
DIS	Disease Intervention Specialists

DOCR	Department of Corrections and Rehabilitation
DSTDP	Division of STD Prevention
DTC	Direct-to-Consumer Test
DVH	Division of Viral Hepatitis
EHE	Ending the HIV Epidemic
EIS	Epidemic Intelligence Service
ELEVATE	Engage Leadership through Employment, Validation, and Advancing Transformation & Equity
EMR	Electronic Medical Record
EMR	Electronic Medical Record
EOB	Explanation of Benefits
EPT	Expedited Partner Therapy
ET	Eastern Time
FACA	Federal Advisory Committee Act
FD&C Act	Food, Drug & Cosmetic Act
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
GS	General Schedule
HAB	HIV/AIDS Bureau
HCP	Health Care Provider/Practitioner
HCPCS	Healthcare Common Procedure Coding System
HCV	Hepatitis C Virus
HHS	(United States Department of) Health and Human Services
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Tests
HOPWA	Housing Opportunities for People with AIDS
HPV	Human Papillomavirus
HR	Human Resources
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
IHS	Indian Health Service
IPV	Intimate Partner Violence
ITCA	Inter Tribal Council of Arizona, Inc.
IVD	In Vitro Diagnostic Devices
LARC	Long-Acting Reversible Contraception
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Questioning
MCH	Maternal and Child Health
MCO	Managed Care Organization
MFPP	Minnesota Family Planning Program
MIEP	Medicaid Inmate Exclusion Policy
MMP	Medical Monitoring Project
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MOUD	Medicated Opioid Use Disorder
MSM	Men Who Have Sex With Men

MSW	Men Who Have Sex With Women
NAAT	Nucleic Acid Amplification Testing
NAAT	Nucleic Acid Amplification Test
NACCHO	National Association of County and City Health Officials
NACCHO	National Association of County and City Health Officials
NASTAD	National Alliance of State and Territorial AIDS Directors
NATO	National AIDS Treatment Advocacy Project
NCHHSTP	National Center for HIV, Viral Hepatitis, STD and TB Prevention
NCIPC	National Center for Injury Prevention and Control
NDDOH	North Dakota Department of Health
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance
NHRC	National Harm Reduction Coalition
NHRTAC	National Harm Reduction Technical Assistance Center
NIH	National Institutes of Health
NMCD	New Mexico Corrections Department
NMMIP	Mexico Medical Insurance Pool
NOFO	Notice of Funding Opportunity
NP	Nurse Practitioner
NRWC	National Ryan White Conference
NVHR	National Viral Hepatitis Roundtable
NWPC	National Working Positive Coalition
NYC	New York City
NYC Health	NYC Department of Health and Mental Hygiene
OAA	Older Americans Act
OIDP	HHS Office of HIV/AIDS and Infections Disease Policy
OMB	Office of Management and Budget
OMB	Office of Management and Budget
ONAP	Office of National AIDS Policy
ONAP	Office of National AIDS Policy
OTC	Over-The-Counter
ODU	Opioid Use Disorder
PACHA	Presidential Advisory Council on HIV/AIDS
PACHA	Presidential Advisory Council on HIV/AIDS
PCSI	Program Coordination and Service Integration
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMA	Premarket Approval
PN	Peer Navigators
POC	Point-of-Care
PrEP	Pre-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
PWID	People Who Inject Drugs

QOL	Quality of Life
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SB	Senate Bill
SDOH	Social Determinants of Health
SFUSD	San Francisco Unified School District
SHCs	Sexual Health Clinics
SNS	Social Network Strategies
SPPS	St. Paul Public Schools
SPTHB	Southern Plains Tribal Health Board
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
SUD	Substance Use Disorder
SVR	Sustained Virologic Response
TA	Technical Assistance
TAP	Technical Assistance
TB	Tuberculosis
US	United States
US PLHIV Caucus	US People Living with HIV Caucus
USPSTF	United States Preventive Services Task Force
VH	Viral Hepatitis
WG	Working Group
WGS	Whole Genome Sequencing
WHO	World Health Organization
WIC	Women, Infants, and Children
YAB	Youth Advisory Board
YRBS	Youth Risk Behavior Survey

Attachment C: Public Comment Letters

everly health

April 18, 2022

CDC/HRSA Advisory Committee on HIV, Viral
Hepatitis and STD Prevention and Treatment
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop US8-6
Atlanta, GA 30329-4027

Submitted by email to nchstppolicy@cdc.gov

Subject: Spring CHAC Public Comment Registration

Dear Advisory Committee Members:

Thank you for the opportunity to submit written comments to the upcoming meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). Founded in 2015, Everly Health is an Austin, TX based company offering modern, diagnostics-driven care. Our goal is to meet the consumer where they are by leveraging our national clinical network composed of hundreds of physicians, nurses, genetic counselors, pharmacists, and member care specialists along with our digital platform and fully-owned CLIA certified, CAP accredited laboratories. We provide services both directly to the consumer through Everlywell as well as complete solutions for diagnostics-driven virtual care at scale to health plans and enterprises through Everly Health Solutions.

Everly Health is an industry leader in facilitating telehealth and at-home services for laboratory testing. In total, we offer over 2500 tests with our partner laboratories in addition to the thirty tests across six key categories within our own diagnostic laboratories. Our demonstrated success in at-home collection and testing enabled us to mobilize quickly and early in the pandemic to provide nationwide access to testing for COVID-19. We were the second company to receive emergency use authorization (EUA) from the Food and Drug Administration for our at-home collection kit and since March 2020, we have provided clinical oversight, care coordination, and physician services for tens of millions of tests for COVID-19. Everly Health Solutions' 50 state provider network can facilitate test ordering, follow up with patients who test positive, and offer assistance with accessing treatment.

Just released this month, the Centers for Disease Control (CDC) preliminary report on 2021 surveillance of sexually transmitted diseases (STDs) shows that rates of syphilis continue to increase, with a 34% increase among women.¹ The agency also reported that the pandemic led to underreporting of infections and increased transmission in 2020 due to reduced screening as healthcare clinics either closed or restricted in-person visits to limit spread of COVID-19.² Additionally, public health departments are already facing limited resources needed to move

¹ <https://www.cdc.gov/std/statistics/2020/preliminary2021.htm>

² <https://www.cdc.gov/std/statistics/2020/impact.htm>

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personnel from STD prevention and control efforts to the pandemic.³ Recognizing this shift in access to STD prevention, in its 2021 update to its Sexually Transmitted Infections Treatment Guidelines, the CDC identified an opportunity to build upon the lessons learned from the response to COVID-19 including the use of at-home collection for STDs.⁴ The pandemic clearly illustrated the critical role at-home testing plays in responding to and controlling infectious disease outbreaks and for these reasons, we were very pleased to see that the agenda for the upcoming CHACHSPT meeting included a focus on self-testing and self-sample collection for STDs.

We currently offer a direct-to-consumer testing channel for men and women to self-sample within the comfort of their own home to test for chlamydia, gonorrhea, hepatitis C, HIV, syphilis, trichomoniasis and herpes simplex virus type 2. For those who test positive, we provide access to providers who can initiate access to appropriate treatment. We have found that patients prefer privacy when testing for sensitive conditions and the seamless access to treatment to quickly resolve their infection and symptoms. In 2021, we had 77,800 sexual health kits ordered and registered to 47,400 unique users. Of those, 6202 tested positive for one or more STD, and 8,604 consults were scheduled. We have surveyed our customers about their at-home testing experience and they consistently report high levels of satisfaction.

We hope that our experience in providing access to laboratory testing directly to consumers will help inform future policy recommendations that support self-testing and self-sample collection for testing for STDs. Our own experience has proven that the sampling technology and digital platforms exist to successfully enable at-home collection and testing for STDs. Not only will it remove major barriers to access, including during public health emergencies, but our data show that people prefer and desire this testing option. Now we just need proactive policy to support the delivery of these critical and innovative prevention and treatment tools directly to those at greatest risk.

Thank you for your consideration of our comments and we hope that you will look to Everly Health as a resource and partner as you consider the role of self-testing and self-sample collection in preventing STDs. Please do not hesitate to contact me at marisa@everlyhealth.com if I may be of further assistance.

Sincerely,

Marisa L. Cruz, MD

Marisa L. Cruz, MD
EVP Regulatory and Clinical Affairs
Everly Health

³ Ibid.

⁴ https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm?s_cid=rr7004a1_w

April 4, 2022

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

Dear Secretary Becerra:

We, the undersigned national, local, and state-based health, education, and civil rights organizations, outline our support for a national program to finance and distribute medications that prevent HIV infection, known as pre-exposure prophylaxis, or PrEP. A key goal of a national program is to scale up access to PrEP substantially in order to help end the HIV epidemic. A national PrEP program should be guided by these principles: accessibility, equity, simplicity, affordability, sustainability, and adaptability. We were pleased to see the historic investment in a national PrEP program included in the President's 2023 budget. We believe systems-wide reforms and innovative policies are needed to end the HIV epidemic in the U.S., and we look forward to working with the Administration to help make this ambitious proposal a reality.

HIV in the United States (U.S.)

In 2019, nearly 37,000 people in the U.S. were diagnosed with HIV. Black and Latinx/Hispanic individuals comprised 42 percent and 29 percent of new diagnoses, respectively. Every person living with HIV requires a lifetime of treatment at an estimated individual cost of about \$501,000, with potential adverse effects that include liver toxicity and insulin resistance. HIV was the underlying cause of death for more than 5,000 people in 2019 in the U.S.

A major gap in U.S. efforts to address HIV is the under-utilization of medications that can virtually eliminate the acquisition of HIV. Fewer than 25 percent of people who could benefit from PrEP actually receive it, with large and growing disparities by race, ethnicity, gender, and geography. In 2019, the CDC found that 63 percent of White Americans recommended for PrEP received a prescription, compared to 14 percent of Latinx/Hispanic Americans and just 8 percent of Black Americans.

The current role of the federal government in HIV prevention

In 2019, the federal government launched a major new initiative called *Ending the HIV Epidemic*, investing more than \$500 million in HIV prevention, treatment, and research programs. The goal is to reduce new HIV infections in the United States by 90 percent by the year 2030. Though achievable, success will require substantial improvement over the modest 9 percent decline in new infections from 2015 to 2019.

The recently updated National HIV/AIDS Strategy for 2022-2025 recognizes the need for much greater use of PrEP. The major reasons for poor access include high prices, expensive and inaccessible laboratory tests, complex and confusing eligibility requirements to access PrEP services, limited provider availability in many parts of the country, and stigma. The Department of Health and Human Services (HHS)'s *Ready, Set, PrEP* Program, launched in 2019, aimed to reduce this gap by providing free PrEP medication for those without prescription drug coverage; however, the program does not cover the required associated clinic and lab costs for PrEP. The program also relies on high-cost, brand-name oral medications from a single manufacturer, despite the fact there are currently 12 manufacturers marketing generic PrEP in the U.S as well as a new long-acting injectable form of PrEP approved in December 2021.

Benefits of a national PrEP program

To scale up PrEP as part of an effective, sustainable strategy to end the HIV epidemic, a national PrEP infrastructure must move away from the current reliance on high-cost, brand-name drugs that have resulted in overly complex, difficult-to-navigate programs for the un- and under-insured and a relatively small number of access points in the Medicaid program. The [proposal from Killelea and colleagues](#) provides one potential path for a national PrEP program focused on these populations. A call for a national PrEP program builds off of recent efforts to secure congressional and Administration support for expanded access to PrEP. Any new funding must be strategically invested to ensure that scarce dollars are stretched to help the most amount of people and focused on reversing growing inequities in PrEP access. A multi-pronged approach will be needed to create a system in which individuals and providers can equitably and sustainably access PrEP.

To reduce the growing inequities enabled by our fragmented PrEP financing system, we seek your support for a national PrEP program which:

- Expands access to PrEP medications and lab services for people who are uninsured and on Medicaid
- Allows the federal government to negotiate with manufacturers and labs for fair public health prices
- Scales-up access to generic PrEP medication as a safe, effective, and cost-effective option for the majority of those indicated for PrEP and provides access to other PrEP options when indicated
- Creates an expansive provider network of non-clinical community-based PrEP providers and local health departments serving the uninsured and Medicaid that are paired with clinical providers via telehealth partnerships
- Works in tandem with existing PrEP funding and programs to supplement, not supplant programs and activities that are working
- Creates a platform for the effective and rapid deployment of novel PrEP medications

- Provides new opportunities to effectively raise awareness and combat stigma by enrolling and educating a new, broad network of providers and building community-led campaigns that connect key populations to this new PrEP infrastructure

A national PrEP program would help put the U.S. on track to end the HIV epidemic.

If you have any questions, do not hesitate to reach out to Jeremiah@prep4all.org

Sincerely,

Advocates for Youth
 AIDS Alabama
 AIDS Foundation of Chicago (AFC)
 AIDS United
 Amida Care
 AVAC
 Black AIDS Institute
 Callen-Lorde Community Health Center
 Center for Health Law and Policy Innovation, Harvard Law School
 Community Education Group
 COVID Clinic, Inc.
 Equality California
 Fenway Health
 Friends For Life Corp - Memphis, TN
 Georgia AIDS Coalition.
 Georgia Equality
 HealthHIV
 HIV Medicine Association (HIVMA)
 Housing Works
 International Association of Providers of AIDS Care (IAPAC)
 John Snow, Inc. (JSI)
 Latino Commission on AIDS
 NASTAD
 National AIDS Housing Coalition (NAHC)
 National Association of City and County Health Officials (NACCHO)
 National Coalition for LGBTQ Health
 NMAC
 PrEP4All
 San Francisco AIDS Foundation
 Silver State Equality-Nevada
 Southern AIDS Coalition
 The AIDS Institute
 The Aliveness Project, Inc.
 The Reunion Project
 Treatment Action Group
 Vivent Health

National Center for HIV, Viral Hepatitis, STD, and TB Prevention
U.S. Centers for Disease Prevention and Health Promotion
[1600 Clifton Road NE](#), Mailstop US8-6
Atlanta, Georgia 30329-4027
Attention: Marah Condit, MS, Committee Management Lead

Re: Written Comments for the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)

Dear Members of the CHACHSPT:

On behalf of Visby Medical, Inc. (Visby), a medical diagnostics technology company headquartered in San Jose California, and the patients and providers we seek to support with our point-of-care (POC) testing, we appreciate this opportunity to submit comments for consideration during the spring meeting. Our mission is to “empower anyone to test for any infection anywhere with near-100% accuracy.” As such, we very much support the CHACHSPT’s focus on activities related to the prevention and control of sexually transmitted infections (STI) and stand ready to be a resource and partner with you in your important work.

About Visby

Visby Medical is transforming the order of diagnosis and treatment for infectious diseases so clinicians can test, talk with, and treat the patient in a single visit. The Company’s proprietary technology development program culminated in the world’s first instrument-free, single-use PCR platform that fits in the palm of your hand and rapidly tests for serious infections. Originally developed for sexually transmitted infections, the Company’s FDA-cleared, CLIA-waived Sexual Health Click Test for women returns accurate results within 28 minutes. The Visby Medical technology is also helping to fight the global pandemic via the Visby Medical COVID-19 Test, and its robust pipeline includes tests for other infectious diseases. Visby Medical is accelerating the delivery of fast and accurate, palm-sized PCR diagnostics to the point of care, and eventually for use at home. Visby Medical has received Federal funding from NIH and BARDA to support the development and validation of the PCR platform. For more information, visit www.visbymedical.com.

Accurate POC Tests Can Promote and Protect Public Health

The nation is in the sixth year-over-year increase in chlamydia and gonorrhea cases and this silent – and neglected – epidemic will not wane unless we become more intentional as a nation in how we deploy accurate, rapid test modalities. The Centers for Disease Control and Prevention’s (CDC) 2021 Sexually Transmitted Disease (STD) Treatment Guidelines recommends Nucleic Acid Amplification Tests (NAATs) for detecting chlamydia and gonorrhea. The 2021 STI National Strategic plan includes a recurring theme of the need for “innovative solutions and approaches to address the ongoing and emerging challenges to STI prevention and control” and specifically calls out the need to develop “point of care diagnostic tools.”

Visby has developed and introduced such a test to the market. We have the first FDA-cleared and CLIA-waived instrument-free PCR platform that can detect and distinguish

April 19, 2022

between three of the most common and curable STIs – chlamydia, gonorrhea, and trichomonas. This test provides lab-accurate results in less than 30 minutes without the need for trained laboratory technicians to operate or interpret test results. These tests can be used in any POC setting that has a CLIA-waiver, including STI clinics, OBGYN offices, emergency departments (EDs), urgent care settings (UC), and mobile vans. Because this platform does not require an extra instrument, it lends itself well for use in resource-constrained and remote settings. Many tests can be run in parallel to meet surge capacity.

The standard of care (SOC) practice is to send-out STI test samples for PCR testing, which typically does not return results for at least 24 hours, oftentimes longer. In the absence of real-time test results, patients are presumptively treated based on symptoms and sexual history. While this generally no longer happens in any other disease-state, it is common practice for STIs. Often the initial diagnosis is incorrect, meaning that the patient will need to be contacted with the right diagnosis and a new prescription for treatment or the patient may have to return for a second appointment to get the appropriate treatment. Women bear the greatest burden of this delay in accurate treatment, where untreated STIs can result in pelvic inflammatory disease (PID), ectopic pregnancies, and infertility. Moreover, STI infection increases the risk of HIV transmission. In sum, the current SOC practice delays accurate treatment, inconveniences the patient, can burden providers, and increases costs – and decreases efficiency – within the health care system.

The reality is that we are treating patients before test results are available. The rates of overtreatment (e.g., patient is treated for chlamydia, but laboratory results show she is not infected with chlamydia) can be as high as 80%, especially in settings such as EDs and UCs where staff fear patients will be lost to care. The Visby STI test can prevent overtreatment thus reducing the unnecessary use of antibiotics and promoting antibiotic stewardship. Conversely, undertreatment (e.g., patients are not given treatment, but laboratory results show they are infected with chlamydia) are also high. The consequences of undertreatment are detrimental to both individual and public health as untreated STIs can lead to PID and other severe sequelae, and patients can continue to spread disease. Importantly, clinic staff spend time calling the patient back with their test results and, in many settings, can never get in contact with the patient. The patients lost to care can be as high as 40%, posing a risk to public health by continuing to spread untreated disease.

Because Visby test results are available during the span of a patient's clinic visit, this enables:

- Accurate treatment informed by real-time PCR results
- Patient education (treatment and how to avoid future infections)
- Expedited Partner Therapy (EPT) (this is permitted in most states)

POC STI testing is better for the patient because:

- Patients are accurately treated based on what they have. This in turn improves their outcomes directly and helps reduce the spread of STIs.
- Treatment in a timely fashion means chlamydia infection does not progress to pelvic inflammatory disease (PID), which if left untreated can result in infertility and

April 19, 2022

ectopic pregnancies, which can be devastating for patients and expensive for the health care system.

- Accurate treatment means the patient does not receive an unnecessary antibiotic (and not subject to unnecessary side effects from the antibiotic).
- Unnecessary additional clinic visits are avoided and clinician effort spent trying to reach patients for follow-up is eliminated.

Taken together, these advantages reduce costs and decrease the burden on the health care system.

Visby's STI Test Helps Advance the 2021 STI National Strategic Plan

Deploying a test like the Visby sexual health test supports all of the goals in the STI National Strategic Plan that was released in 2021.

Goal 1: Prevent new STIs

- By treating patients with the right drug in the initial clinic visit patients are not at risk of transmitting disease to other sexual partners; this provides timely, appropriate care to the patient directly and results in a better outcome for public health
- The provider has an opportunity to educate the patient face-to-face in real time. This will help increase awareness of STI prevention and sexual health.

Goal 2: Improve health of people by reducing adverse outcomes of STIs

- By providing test results within a patient's clinic visit, morbidity is reduced:
 - Patients are accurately treated based on what they have, not the best guess of the physician.
 - Timely treatment will reduce morbidity and in turn, improve outcomes and reduce costs. As noted above, timely treatment means chlamydia, gonorrhea, or trichomonas infections do not progress to PID, which, if left untreated, can result in infertility and ectopic pregnancies. Because infection with these STIs can increase the risk of HIV transmission, it is important to test, educate, and treat patients quickly.
 - Accurate treatment means the patient does not receive an unnecessary antibiotic and is not subject to unnecessary side effects from the antibiotic: Antibiotic Stewardship.

Goal 3: Accelerate progress in STI research, technology, and innovation

- By using an innovative diagnostic like the Visby Sexual Health STI test, the government can support shifting the paradigm from syndromic treatment to 'test, talk, treat'. Evidence-based treatment and decision-making is strengthened by POC accurate testing.

Goal 4: Reduce STI-related health disparities and health inequities

- Making a POC test like this available as standard of care can help advance equity, reduce health disparities, and decrease implicit bias that may be a component in syndromic treatment and diagnosis.

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- Innovations in diagnostic testing, like that of the Visby STI test, can fundamentally transform the patient experience, making it more patient-centered and convenient, which in turn can address access and equity concerns.
- STIs disproportionately affect women, and particularly minorities. For example, even though the population/clinic-based prevalence for trichomonas is 0.2%, black women bear the highest burden of disease (9%).
- The newly released 2020 STD Surveillance Report showed that while STDs are increasing across many groups, some racial and ethnic minority groups, gay and bisexual men, and our nation's youth continue to experience higher rates of STDs.

Goal 5: Achieve integrated, coordinated efforts that address the STI epidemic

- A key attribute of the Visby test is that it does not rely on a separate instrument, meaning that it is deployable almost anywhere, and lends itself well for surge capacity; as many people as possible can be treated contemporaneously.
- These tests can easily be deployed in the community and utilized in mobile clinic vans. For example, Visby is supporting a study to assess how this test can be used when deployed into a harm reduction mobile van that reaches rural individuals with substance use disorders.
- As a POC test the Visby test facilitates the delivery of integrated, coordinated care; all within one visit, the patient will be tested, diagnosed, educated about their infection, and prescribed a treatment pathway.

Call to Action

The potential for innovative, game changing POC STI tests to have a significant, positive impact on the STI epidemic is enormous. However, a number of barriers preclude the test becoming available to all who need it. As such, we respectfully call upon the CHACHSPT to support and recommend to Department of Health and Human Services (HHS), CDC, and the Health Resource and Services Administration (HRSA) the following:

1. *Implementation science studies* to assess clinical adoption in various settings, especially those settings where health inequities can be improved, such as with underrepresented groups, rural populations, novel health care delivery settings (e.g, mobile vans), and others.
2. *Policies, programs, and funding for equitable access to innovative technologies.* Access to innovative technologies should not be limited to those with means; innovation, especially that funded with taxpayer dollars, should be available to everyone. HHS should advance policies, programs, and funding that facilitate equitable access to technologies that can improve individual and public health.
3. *Efforts to uncover the true prevalence of Trichomonas* in all geographies and demographics. Trichomonas, as with other STIs, is a silent epidemic. Currently, Trichomonas is not required to be reported, so the true prevalence is unknown. Some clinics in the South report 30% prevalence in women and 10% in men, but in other geographies it appears to be less prevalent; however, this could be

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because people are not being routinely tested for Trichomonas. Knowing the true prevalence will help guide CDC treatment and reporting guidelines.

4. *Adequate coverage and payment policies for breakthrough innovative technologies that can make a difference to patient outcomes.* Patients and providers want, need, and deserve access to accurate, POC testing. However, reimbursement for such tests can be so low that it thwarts utilization of the technology when and where it is needed most. Moreover, the current federal coverage and payment system – as operationalized by the Centers for Medicare and Medicaid Services (CMS) – is built around laboratory-based testing and not POC. As many commercial payors and Medicaid often follow CMS, the adverse impact on the adoption rate for new diagnostic technology can be significant. The Visby test was built intentionally to engineer out the need for highly trained laboratory personnel to operate and interpret the test results so that it could be used nimbly in a variety of care settings to have the maximum positive impact on public health. Unfortunately, without improved coverage and payment policies, the test will not be adopted, and its promise will not come to fruition.

Conclusion

Again, on behalf of Visby and the patients and providers we seek to support with our POC testing, we thank you for your consideration of our views and recommendations. With sufficient reimbursement and intentional deployment, we feel strongly that our POC STI test has the potential to make a significant difference in addressing the STI epidemic. We are eager to serve as a resource to you, CDC, HRSA, and HHS to reduce and prevent STIs.

Sincerely,



Christopher J. Jowett
Chief Commercial Officer

visby medical™

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