

**U.S. 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
March 5, 2020**

Table of Contents

Opening of Meeting and Roll Call	3
Recommendation Letter on Recency Assay-Based Incidence Estimation Pilot Project.....	5
Recommendation Letter on HIV and Youth.....	6
Adjournment.....	7
Attachment 1: Participant List.....	8
Attachment 2: Recommendation Letter on Recency Assay-Based Incidence Estimation Pilot Project	10
Attachment 3: Recommendation Letter on HIV and Youth	14



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION HEALTH RESOURCES AND SERVICES ADMINISTRATION

**CDC/HRSA ADVISORY COMMITTEE ON
HIV, VIRAL HEPATITIS, AND STD PREVENTION AND TREATMENT
VIRTUAL MEETING
March 5, 2020**

Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, 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 virtual meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHAC). The proceedings were held on March 5, 2020.

The CHAC is a committee that is 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.

The meeting was open to the public (*Attachment 1: Participant List*). Information for the public to attend the CHAC meeting remotely via teleconference was published in the *Federal Register* in accordance with FACA rules and regulations.

Opening of Meeting and Roll Call

Laura Cheever, MD, ScM
Associate Administrator, HRSA, HAB
CHAC Designated Federal Officer (DFO), HRSA

Dr. Cheever called the proceedings to order at 3:12 p.m. ET. Dr. Cheever announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record.

Dr. Cheever conducted a roll call to determine the CHAC voting members and ex-officio members (or their alternates) in attendance. She reminded the CHAC voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and to recuse themselves from voting or participating in these matters.

CONFLICT OF INTEREST DISCLOSURES

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of funding from HRSA/RWHAP and has stock in Gilead.
Marvin Belzer, MD, FACP, FSAM (University of Southern California, Keck School of Medicine)	Recipient of funding from CDC, HRSA/RWHAP, Substance Abuse and Mental Health Services Administration (SAMHSA), National Institutes of Health (NIH) and is medical editor for the American Board of Pediatrics.
Jodie Dionne-Odom, MD (University of Alabama Birmingham)	Research funding from the NIH and royalties.
Debra Hauser, MPH (Advocates for Youth)	Recipient of CDC and Gilead funding, on Trojan Sexual Health Advisory Committee
Venton Hill-Jones (Southern Black Policy and Advocacy Network)	Organization receives Gilead Sciences funding.
Devin Hursey (U.S. People Living with HIV Caucus)	Recipient of funding from HRSA/RWHAP.
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts disclosed.
Greg Millet, MPH (amfAR)	No conflicts disclosed.
Michael Saag, MD (University of Alabama at Birmingham, School of Medicine, UAB Center for AIDS Research)	Recipient of funding from HRSA/RWHAP and CDC and a consultant for BMS, Merck, Gilead, and VIVE.
Bradley Stoner, MD, PhD (Washington University School of Medicine))	Recipient of funding from CDC.
Lynn E. Taylor, MD, FAASLP (University of Rhode Island)	Recipient of funding from CDC.

Ex-officio members in attendance included: Pradip N. Akolkar, PhD; Paul Gaist, PhD, MPH; Richard Haverkate, MPH; Kay Hayes, MPA; and Neeraj Gandotra, MD. Carl Schmid, Presidential Advisory Committee on HIV/AIDS Liaison, was also in attendance.

Dr. Cheever confirmed that 16 voting members and ex-officio members (or their alternates) were in attendance and constituted a quorum for CHAC to conduct its business on March 5, 2020.

CHAC Action

Dr. Kates made a motion to approve the November 2019 meeting minutes, seconded by Mr. Millet. Dr. Taylor noted that a correction is necessary to the conflict of interests, adding that she is a recipient of CDC funds. The minutes were accepted unanimously with the proposed correction.

National HIV Strategy/Ending the Epidemic Review of Recommendation Letter on Recency Assay-based Incidence Estimation Pilot Project

Greg Millet, MPH and Jen Kates, PhD

Workgroup Co-chairs

During the fall 2019 meeting, the CHAC discussed the CDC's proposed recency testing pilot program, which would be undertaken in the support of the Ending the HIV Epidemic Initiative (EHE). Information about the pilot and recency testing technology was presented to the CHAC by CDC. In addition, the CHAC was provided with a report from a CHAC working group on the National HIV/AIDS Strategy and the EHE (NHAS/EHE), which reviewed plans for the pilot and consulted with key stakeholders in September 2019. Based on this information and concerns raised during the November meeting, the CHAC moved to recommend that CDC consider these concerns and present responses to the CHAC prior to proceeding with the pilot.

The workgroup co-chairs drafted a letter to CDC and HRSA (*Attachment 2*). The letter recommends that CDC provide the CHAC:

- A clear overview of the new information the pilot is expected to produce;
- A plan for including a process evaluation during the pilot that could delineate the advantages and disadvantages of switching to a new technology versus existing methods for determining HIV recency Background on the existing evidence on recency testing relative to current methods;
- Information on the reliability and validity of new HIV infection estimates over time when switching from an old methodology to a new methodology. Will there be issues in data consistency between the two methodologies?
- An assessment of the costs associated with the proposed new testing approach, including costs related to the need for authorization, laboratory workflow changes, and shipping requirements;
- A plan for robust and ongoing community engagement in the development and implementation of the pilot;
- How concerns about the potential harmful use of data will be addressed and mitigated—particularly in states with HIV criminalization laws that do not reflect the current scientific facts about HIV transmission; and
- Information on how support would be provided to health departments and laboratories for transitioning to the new testing method.

Discussion

Minutes of Meeting

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment

March 5, 2020

Page 5

Mr. Hursey asked how long the specimens will be retained. CDC responded that this is still under consideration and it is also looking at the issue of informed consent.

Mr. Hursey asked how the community will be involved in this process. CDC responded that it is working to have extensive community involvement in implementing the pilot. Dr. Stoner added that CDC should respond to concerns before the pilot is conducted.

Mr. Hursey expressed concern about how state laws (e.g., criminalization of HIV transmission) will impact these actions. CDC responded that it is working with state health departments.

Ms. Hauser stated that she had concerns about whether the pilot is necessary and the resources required to conduct the pilot. She stated that she does not think the letter captures these concerns.

CHAC Action

Ms. Hauser made a motion to approve the letter, seconded by Dr. Taylor. The motion passed with one abstention (Mr. Hursey).

.

Recommendation for HIV and Youth

Debra Hauser, MPH

Workgroup Chair

Workgroup members have been concerned that EHE does not prioritize the needs of young people, who are disproportionately impacted by HIV. Given that there are effective interventions for this population, the workgroup has drafted a letter to Secretary Azar with recommendations related to young people (*Attachment 3*).

Discussion

Dr. Saag stated that this population is at very high risk and need to be prioritized.

Dr. Kates stated that this issue goes beyond CDC and HRSA. Dr. Stoner added that the letter is addressed to the Secretary of DHHS and should cover other HHS agencies.

Mr. Schmid suggested that the letter highlight effective activities carried out by CDC and HRSA. Dr. Stoner added that the letter should also discuss EHE. Ms. Hauser stated that the workgroup will revise the introduction to include these suggestions.

Adjournment

Dr. Cheever adjourned the meeting at 3:57 p.m. ET.

CHAC Co-CHAIRS' CERTIFICATION

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

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

(Date)

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

(Date)

Attachment 1: Participant List

CHAC Members Present

Dr. Jean Anderson, Co-Chair
Dr. Bradley Stoner, Co-Chair
Dr. Marvin Belzer
Dr. Jodie Dionne-Odom
Ms. Debra Hauser
Mr. Venton Hill-Jones
Mr. Devin Hursey
Dr. Jennifer Kates
Mr. Greg Millett
Dr. Michael Saag
Dr. Lynn Taylor

CHAC Members Absent

Dr. Wendy Armstrong
Dr. Demetre Daskalakis
Dr. Travis Gayles
Dr. Shruti Mehta
Dr. Johanne Morne
Ms. Kneeshe Parkinson
Ms. Gloria Searson

CHAC Ex-Officio Members Present

Dr. Pradip Akolkar
Dr. Paul Gaist
Mr. Richard Haverkate
Ms. Kaye Hayes
Dr. Neeraj Gandontra

CHAC Liaison Representative

Mr. Carl Schmid

CHAC Designated Federal Officers

Dr. Laura Cheever
HRSA/HAB Associate Administrator

Dr. Jonathan Mermin
CDC/NCHHSTP Director

Federal Agency Attendees

Dr. Theresa Jumento, HRSA
Ms. Sara Bingham, CDC
Ms. Margie Scott-Cseh, CDC

Dr. Paul Weidle, CDC
Ms. Sara Zeigler, CDC
Samantha Zenlea, HRSA

Attachment 2: Recommendation Letter on Recency Assay-Based Incidence Estimation

March 6, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention 1600 Clifton
Road, N.E. MS H21-10

Atlanta, GA 30333

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane, Rm 14-71
Rockville, MD 20857

Dear Dr. Redfield and Mr. Engels:

The CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met on November 14, 2019. During that meeting, the CHAC discussed the CDC's proposed recency testing pilot program, which would be undertaken in the support of the Ending the HIV Epidemic Initiative (EHE). Information about the pilot and recency testing technology was presented to the CHAC by CDC. In addition, the CHAC was provided with a report from a CHAC working group on the National HIV/AIDS Strategy Update and the EHE (NHAS/EHE), which had reviewed plans for the pilot and consulted with key stakeholders in September 2019. Based on this information and concerns raised during the November meeting, the CHAC moved to recommend that CDC first consider these concerns and present responses to the CHAC prior to proceeding with the pilot.

Background

In February 2019, during his State of the Union speech, President Donald Trump introduced a new initiative to end HIV transmission by 75% by 2025 and by 90% by 2030. The Ending the HIV Epidemic Initiative (EHE) is intended to reduce HIV transmission by scaling up effective HIV prevention and treatment interventions, including HIV testing. One of the metrics that will be used to ascertain the effectiveness of the initiative is HIV incidence, but measuring HIV incidence has proven challenging and HIV diagnoses are often used a proxy instead. However, it is possible that if the EHE is successful in increasing testing rates, it could result in an increase in HIV diagnoses, which may not reflect an increase in underlying incidence. Based on technological improvements in HIV recency assays and on more robust means for interpretation of recent assay results (i.e., recent infection testing algorithms, RITAs), CDC is therefore considering a pilot project to reassess recency assay-based HIV incidence estimation within a select number of health departments to determine if this method provides a

good metric to distinguish between new diagnoses and new infections.

While the CHAC recognizes the importance of tracking implementation of the EHE, including the need to understand if it is driving down HIV incidence, several concerns about the pilot were raised by stakeholders consulted by the working group and by CHAC members during the November meeting. These include concerns about:

- The lack of clarity about the purpose of the pilot and the specific information it is expected to produce;
- The lack of information on the relative benefits of recency assay testing compared to existing methods;
- The costs (monetary, time, technical expertise, and unanticipated issues) of the new method to assess new HIV infections relative to existing methods;
- The potential harmful use of the data, such as to prosecute individuals with recent incident HIV for transmitting HIV to others, particularly in states with HIV criminalization laws, and the risk of undermining community trust;
- The lack of clinical benefit to individuals under the pilot because treatment guidelines remain the same for individuals with new or chronic HIV infection; and
- The lack of a plan to engage community members in the pilot's conception or implementation.

These concerns echo the issues raised in consultations with subject matter experts representing health departments, surveillance and laboratory personnel and community representatives knowledgeable of HIV testing policies and practices. Summary comments from three separate calls on September 27th and 30th are described below:

1. Provide clear information on the benefits of the Modified Bio-Rad assay for HIV recency testing (as well as other methodologies for estimating incidence), remaining questions, and the specific information the pilot is expected to produce.
2. Conduct a thorough evaluation of the costs associated with transitioning to the latest HIV testing technology relative to the current methodology. Because CDC has used assay-based testing in the past, troubleshooting for any issues that were previously encountered should be sufficiently addressed before implementing the pilot project. Aside from monetary costs, these issues include:
 - a. the time and effort required to amend IRB documents and OMB approval to implement the new technology;
 - b. challenges in changing existing lab work flows to accommodate the new technology
 - c. resolving varying state and local regulations in the shipment of specimens and lab reporting

Conduct meaningful consultations with the community about the pilot project. Given existing community concerns with molecular surveillance, the proposed project raises issues in the HIV community regarding the clinical benefit to patients; privacy of test results and the possibility of data to be subpoenaed and used by courts to prosecute people living with HIV; the degree to which directionality of infection can be inferred by the testing technology; and how consent will be obtained from people testing for HIV. An ongoing process for community involvement, such as a community advisory board,

- should be an integral component of the pilot.
4. Support health departments and labs if there is a transition to the new testing methodology. Past efforts to obtain and ship specimens and to change lab reporting for commercial or public health labs have encountered issues with local laws, capacity or other issues. These issues must be worked out a priori such that specimen availability and shipping and standardization in reporting/ surveillance would ease implementation of the pilot project if it is moved forward.
 5. Because other assays in development may give equivalent or better estimates of recency without requiring another blood sample, new technologies should be considered if they offer advantages in terms of cost, feasibility or accuracy of recency estimates.

Recommendations

Based on stakeholder input, the working group report, and discussion at the CHAC meeting, the CHAC recommends that CDC first consider and respond to the various concerns raised before proceeding with the pilot. Specifically, we recommend that CDC provide to the CHAC:

- A clear overview of the new information the pilot is expected to produce;
- A plan for including a process evaluation during the pilot that could delineate the advantages and disadvantages of switching to a new technology versus existing methods for determining HIV recency Background on the existing evidence on recency testing relative to current methods;
- Information on the reliability and validity of new HIV infection estimates over time when switching from an old methodology to a new methodology. Will there be issues in data consistency between the two methodologies?
- An assessment of the costs associated with the proposed new testing approach, including costs related to the need for authorization, laboratory workflow changes, and shipping requirements.
- A plan for robust and ongoing community engagement in the development and implementation of the pilot;
- How concerns about the potential harmful use of data will be addressed and mitigated—particularly in states with HIV criminalization laws that do not reflect the current scientific facts about HIV transmission;
- Information on how support would be provided to health departments and laboratories for transitioning to the new testing method;

Thank you for your efforts on behalf of the populations served by our committee, and of our committee members.

Respectfully,

Jean R. Anderson, MD
CHAC co-chair

Bradley Stoner, MD, PhD
CHAC co-chair

cc:

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

Attachment 3: Recommendation Letter on HIV and Youth

DRAFT

January 15, 2020

The Honorable Alex M. Azar II, Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, D.C. 20201

Dear Secretary Azar:

The Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met on XXXX. During this meeting, the CHAC passed a resolution and is sending a recommendation, described below, for your consideration.

Background and Rationale

Currently *Ending the HIV Epidemic: A Plan for America* does little to prioritize the needs of young people disproportionately impacted by HIV and AIDS. In addition, the Administration's actions to fund abstinence-only programming, limit young people's access to confidential care for sensitive sexual health services, and expand religious exemptions that discriminate against LGBTQ individuals, undermine public health best -practices to meet the comprehensive HIV prevention and care needs of these youth.

Some facts:

- Young people, ages 13 to 24, accounted for 21percent of new HIV diagnoses in 2017. 7,125 youth, ages 13 to 24 were newly diagnosed with HIV in 2017. Twenty-one percent of these young people were 15-19 years of age.
- In 2017, 90percent of new HIV diagnoses among young people were experienced by gay and bisexual young men.
- In 2016, 50,000 youth were living with HIV. More than half (56percent) were unaware of their HIV status.
- Young people, ages 13-24 who are living with HIV, are the least likely of any age group to be linked to care in a timely manner. They also are the least likely of any age group to have a suppressed viral load.

The national HIV plan should prioritize the needs of young people, particularly gay and bisexual young men and trans youth, and take into account all of the strategies and tools available to educate, empower and affirm these young people. Currently the plan focuses on four strategies:

Diagnose, Treat, Prevent, and Respond. However, in many states, the barriers youth under age 18 face when seeking health care may stifle the plan's impact among this population. For example, in 2018, more than 30 states had laws requiring parental consent for minors to obtain PrEP. Condoms, which are more readily available to young people, are not prioritized within the current plan.

In addition, actions by agencies within the federal government are undermining public health efforts to end the epidemic.

Recent funding opportunities released by the Office of Adolescent Health propel implementation of ineffective and dangerous abstinence-only programs, rebranded as Sexual Risk Avoidance. These programs use fear and shame in an effort to control young people's behavior, stigmatize youth who are sexually active, and retraumatize survivors of sexual assault. However, fear, shame and stigma undermine young people's ability to disclose sexual health histories, obtain and use condoms and/or PrEP, seek STI/HIV testing, and obtain and remain engaged in health care services.

In addition, changes to Title X have limited minor's access to confidential services by removing federal requirements that Title X funded clinics provide young people with confidential access to sensitive health care services (contraception, drug and alcohol treatment, HIV and STI testing and treatment, and mental health care) regardless of state policy.

Significantly, in 2018, over 30 states had restrictions on minor's ability to obtain PrEP without parental consent or notification.

Finally, many of the administration's actions further stigmatize LGBTQ individuals and undermine public health efforts to end the epidemic. For example, over the past year, among other actions:

- The Department of Health and Human Services [announced](#) it would not enforce, and planned to repeal, regulations prohibiting discrimination based on gender identity, sexual orientation, and religion in all HHS grant programs. These include programs to address the HIV, opioid, and youth homelessness epidemics, as well as hundreds of billions of dollars in other health and human service programs.
- The Department of Education [published final regulations](#) permitting religious schools to ignore nondiscrimination standards set by accrediting agencies.
- The Department of Health and Human Services cancelled a plan to explicitly prohibit hospitals from discriminating against LGBTQ patients as a requirement of Medicare and Medicaid funds.
- Department of Housing and Urban Development [removed requirements](#) that applicants for homelessness funding maintain anti-discrimination policies and demonstrate efforts to serve LGBT people and their families, who are more likely to be homeless.

- Department of Housing and Urban Development (HUD) announced a plan to gut regulations prohibiting discrimination against transgender people in HUD-funded homeless shelters.
- Department of Defense put President Trump's ban on transgender service members into effect, putting service members at risk of discharge if they come out or are found out to be transgender.

Yet, there are programs within the federal government that have proven effective in helping young people reduce risk behaviors. From 2014-2018, for less than \$10 per student, CDC/DASH provided school districts with funding and technical assistance to: implement quality sex education, create formal referral networks to community health care services, and support GSAs. As a result of these efforts, funded school districts increased implementation of quality sex education to 88percent of middle schools and 93percent of high schools, increased access to key youth friendly health services, referring over 65,000 students, and increased safe and supportive environments by expanding student-led inclusive clubs to 76percent of schools. Together, these strategies led to statistically significant declines in the percentage of students who ever had sex, were currently sexually active, and/or had more than four partners.

And still, CDC/DASH's support only reaches eight percent of the 26 million middle and high school students nationwide.

Recommendations

CHAC calls on the Administration to prioritize young people, particularly gay, bisexual and trans youth within the National HIV Plan. CHAC further urges the Administration to return to public health principals that recognize the importance of confidentiality on the health care decisions of youth and rescind religious exemptions that discriminate against LGBTQ individuals. These religious exemptions stigmatize communities disproportionately impacted by HIV and AIDS and serve as barriers to care for these communities.

In addition, we urge HHS to expand CDC/DASH programs that have proven successful at building protective factors (school connectedness) and reducing sexual risk taking among youth (sexual health education and linkages to sexual health services, such as:

- Quality sex education. Quality sex education can build young people's ability to: communicate desires and boundaries and share sexual health histories, understand the difference between healthy and unhealthy relationships, obtain PrEP and condoms, normalize routine STI/HIV testing, and help young people to become informed consumers of health care services.
- GSAs in every school. Research shows the presence of a GSA provides a protective factor even for LGBTQ youth who do not participate in the GSA's programming.

- Access to confidential, youth-friendly and LGBTQ affirming sexual health services.
- Professional development for educators and other youth-serving professionals that helps them interrupt bullying, affirm LGBTQ youth, dismantle their unconscious bias and develop comfort and confidence to teach quality sex education.

In addition, young people need access to condom and PrEP availability programs without age restrictions or requirements for parental consent.

Thank you for your leadership and your continued commitment to ensure that prevention efforts are directed by the most current science and in advancing shared efforts to accomplish national goals.

Respectfully,

Jean Anderson, MD
CHAC Co-chair

Bradley Stoner, MD, PhD
CHAC Co-chair