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Dear Drs. Redfield and Sigounas:

Earlier this year, the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) organized a new working group (The NHAS/ EHE Working Group). We serve as co-chairs for the working group-- the purpose of which is to provide input, advice, and recommendations to the CHAC on considerations relevant to the National HIV AIDS Strategy update (NHAS) and the Ending the HIV Epidemic Initiative (EHE). Recently, the working group discussed the proposed CDC recency testing pilot program. One of the main outcomes of the discussion was the need to solicit additional information from a range of stakeholders, including health department personnel, laboratory and surveillance officials, and informed community representatives. On September 27 and September 30th, the working group held three consultation calls with identified experts in each category. Recommendations for CDC, based on these consultations, are described below.

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. 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. 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 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. The working group asked each panel of experts about:

- The advantages and disadvantages of the proposed new project vs existing CD4 testing technology to determine HIV infection recency
- The costs (monetary, time, technical expertise and unanticipated issues) of transitioning from the current recency testing methodology to the Modified Bio-rad recency assay
- Their suggestions for next steps should CDC move forward with the pilot.

Recommendations

Based on stakeholder input, the CHAC working group recommends that CDC consider:

Prior to implementing a pilot:

- Providing clear background on the existing evidence on recency testing (as well as other methodologies for estimating incidence), remaining questions, and the specific information the pilot is expected to produce.
- A thorough evaluation of the costs associated with transitioning to a new testing technology. Concerns were expressed about the need for amendments to IRB documents and, in some cases, state and local regulations; extended timelines due to lab work flow changes; issues with shipping of specimens; and others. 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.

Engaging in meaningful consultations with the community. Given existing community concerns with molecular surveillance, the proposed project raises issues regarding the clinical benefit to patients (in an era where ART is offered to all who test positive irrespective of disease stage); 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 or cannot be inferred by the testing technology; how consent will be obtained from people testing for HIV, and other issues.

If the pilot does move forward:

- Establishing an ongoing process for community involvement, such as a community advisory board.
- 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.
- Providing support for health departments and labs if there is a transition to the new testing methodology. Past efforts 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 standardization in reporting/ surveillance would ease implementation of the pilot project if it is moved forward.

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

Respectfully,

EHE/ NHAS Working Group Co-chair,
Greg Millett, MPH

EHE/ NHAS Working Group Co-chair,
Jennifer Kates, PhD

cc:
Dr. Laura Cheever
Dr. Jonathan Mermin
CHAC Members