EHE/NHAS Workgroup Report

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

November 13-14, 2019

Workgroup History/ Charge

- Established in April 2019
- Co-chairs: Greg Millett/ Jennifer Kates
- WG purpose:
  - provide input, advice, and recommendations to the CHAC on considerations for updating the National HIV/AIDS Strategy (NHAS)
  - Address implications of EHE vis-à-vis the NHAS
- Additional members outside of CHAC (from EHE sites) added to the WG

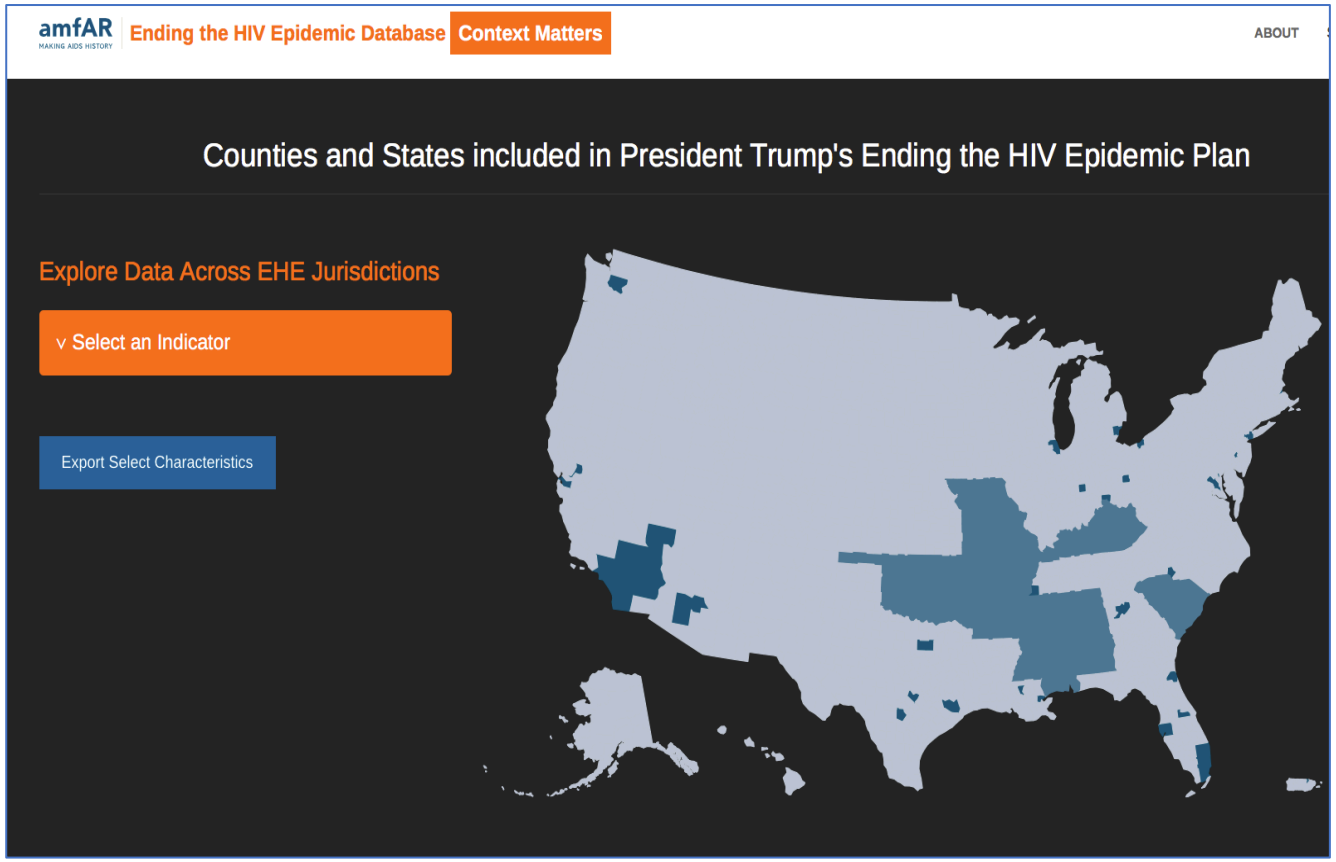
- **CHAC Members**
- Devin Hursey
- Jen Kates
- Greg Millett
- Susan Philip
- Michael Saag
- Lynn Taylor

Workgroup Members:

- Rose Conner
- Marlene McNeese
- Laura Reeves
- Nathaniel Smith
- Kathleen Toomey

Workgroup Activities

- Drafted and approved Terms of Reference for WG
- Shared information on EHE planning and meetings with agency principals responsible for EHE
- Discussed and provided input on amfAR database of EHE sites
- Discussed and provided recommendations on a proposed CDC project associated with EHE



http://ehe.amfAR.org

HIV Recency Project Background

- The goals of EHE are to reduce HIV transmission by 75% by 2025 and 90% by 2030
- To assess these goal, it is imperative to distinguish between new and chronic HIV infections
- CDC currently uses CD4 to ‘stage’ new diagnoses as recent or chronic infections
  - But CDC used to use recency assay in the past that were abandoned due to logistical issues, costs, and comparability to CD4 staging
- Technological improvements in recent assay testing have prompted CDC to re-evaluate recency assay incidence estimation
- CDC is considering a pilot project in a select number of health departments to assess whether RITAs (recent infection testing algorithm) are a better tool for HIV incidence estimation compared to CD4 staging

Workgroup information gathering

- In early September, the WG discussed the project
  - Issues raised:
    - Costs (monetary, lab work flows, necessary approvals)
    - Cost effectiveness and precision relative to existing CD4 testing
    - Community perceptions/ feedback
  - Decided to gather additional insight from 3 expert panels

- On September 27th and 30th a subgroup of the WG convened three separate calls with:
  - Health department officials
  - Laboratory/ surveillance officials
  - Community advocates versed in HIV surveillance

- Questions for panels:
  - How will the proposed pilot project serve to improve U.S. efforts to estimate incidence of HIV infection; reduce new HIV infections; and advance national and health department efforts to end the U.S. HIV epidemic?
  - Will findings of the proposed pilot project be adequately generalizable to allow for expansion of the technology nationally?
  - What vulnerabilities should CDC anticipate as a result of this pilot project, and how could these be addressed?

Comments from Subject Matter Experts

State & Local HD call

- Relative benefit of proposed project vs existing CD4 method
- This project will heighten existing community concerns around phylogenetic testing
- Recency testing has been helpful for HDs experiencing opioid-related outbreaks

Community call

- Expensive–relative value compared to current methods?
- Privacy concerns/ how will data be used? Individuals protected?

Lab/ Surveillance call

- Why going back to method that was discontinued?
- Instituting lab reporting changes are arduous
- Invalid data if ARV/ PrEP expanded across all groups

CHAC workgroup recommendations for CDC consideration:

- **Prior to implementing the pilot:**
  - Provide 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:
    - IRB amendments to documents;
    - extended timelines due to lab work flow changes;
    - issues with shipping of specimens; and others.
- **If the pilot moves forward:**
  - Establish an ongoing process for community involvement, such as a community advisory board.
  - Include 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.
  - Provide support for 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.

Considerations for CHAC

- Thoughts about proposed recommendations to CDC in distributed letter?
- Any additional considerations CHAC should provide to CDC?
  - Thoughts on the FOA process?
  - Thoughts on execution of the project?
  - Should this project be implemented? (If so, any additional guidance to CDC not captured in the letter; if not, why should the project not be implemented)?
- CHAC approval of letter
- Next steps
  - Remain apprised about status of the proposed pilot
    - CDC report back to CHAC