How EHE Jurisdictions Can Increase Uptake of Long-Acting Injectables for HIV Treatment

THURSDAY, August 18, 2022

12:00 PM – 1:00 PM EST
11:00 AM – 12:00 PM CST
10:00 AM – 11:00 PM MST
9:00 AM – 10:00 AM PST

Ending The HIV Epidemic

TAPin Technical Assistance Provider innovation network

A Project of CAI

Cooperative Agreement Award # U69HA33964

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of the Year 3 award totaling $6,000,000 with 0% financed with non-governmental sources. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, HRSA, HHS or the U.S. Government.

Ending The HIV Epidemic

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Strengthen & support implementation of jurisdiction Ending the HIV Epidemic (EHE) Plans to contribute to achievement of reduction in new reported HIV cases by 75% by 2025

Tip: Get TAP-in TA and Training by Contacting TAP-in@caiglobal.org

Moderators

Dr. Christina Madison, PharmD, FCCP, AAHIVP

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Faculty, Pacific AETC-NV
HIVLN Steering Committee Member

THE PUBLIC HEALTH PHARMACIST®

Tom Donohoe, MBA

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Agenda

I. Why Long Acting Injectables (LAIs)?

II. Evidence for LAIs

III. Steps to Successful Implementation

IV. Implementation Barriers and Facilitators

V. Panel Discussion

VI. Readiness Assessment

VII. TAP-in Training and TA

Objectives

- **Discuss** the current science of LAIs for HIV treatment
- **Review** patient and provider challenges and success stories with LAIs
- **Consider** how EHE jurisdictions can increase uptake of LAIs without increasing health disparities
- **Identify** training and TA needs and resources

Polling Question 1

What best describes your primary HIV role?

A. Health Department (county administrator, leadership, staff, etc)

B. Clinician

C. Case Manager/Navigator

D. Mental Health Services Provider

E. Substance Use Treatment Provider

F. Clinic Administrator

G. Other (please write in chat)

Polling Question 2

What do you <u>feel</u> is the number one challenge in increasing uptake of LAIs for treatment in your jurisdiction?

- **A** — **Payment/Cost Issues** (including insurance authorization)
- **B** — **Not Enough Clinics/Clinicians Offering LAIs for Treatment**
- **C** — **Administrative Issues at Clinics** (establishing clinic protocol/flow, policies, roles)
- **D** — **Staffing Issues**
- **E** — **Low Patient Demand for LAIs**
- **F** — **Other** (please write in chat)

Case Presentation: DeWayne

Case Presentation: DeWayne

DeWayne is a 41-year-old person with HIV in your EHE jurisdiction. He has been living with HIV for 15 years and has an undetectable viral load. He currently goes to a Ryan White clinic where he has bonded with his HIV treatment team, who he says,

"saved my life, and helped me get through many, many challenges."

Case Presentation: DeWayne

DeWayne is considering switching from his oral HIV medication to long-acting injectables (LAIs) as he interviewed for a job that requires travel. He feels it will

“feel better to not have to worry about taking medications on the road, as I may be required to share a hotel room at times.”

Case Presentation: DeWayne

He also likes the idea of not taking a pill everyday. However, he worries that his new job's insurance may not cover the injectable medication. The last time DeWayne met with his primary care provider he told her he was somewhat interested in LAIs.

At his next visit he plans on telling her about his new thinking, and possible new job.

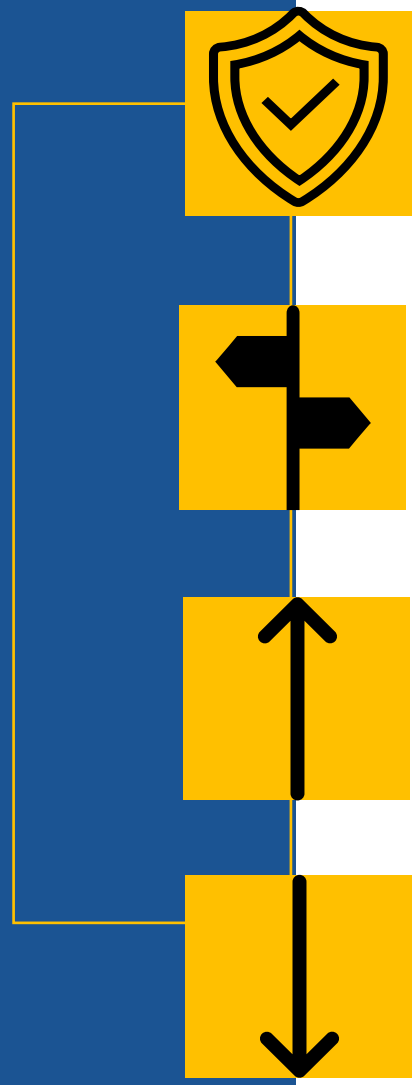
Case Presentation: DeWayne

1. What else would you like to know about DeWayne?

2. What is your #1 concern for DeWayne being able to access LAIs?

I. Why Long-Acting Injectables (LAIs)?

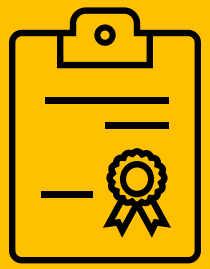
Potential Advantages



- Safety
- Patient Choice
- Improved Adherence
- Reduce Stigma

Potential Advantages

Source: Kerrigan et al 2018, Murray et al, 2020.



Common Strategies for Successful Clinic Implementation are Known

Does not Require GI Absorption

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II. Evidence for LAIs

FDA Approved Long-Acting Injectable Therapy

- Cabenuva® FDA approved January 2021
  - First FDA approved injectable complete HIV regimen
- Patient must be undetectable for 3-6 months per DHHS guidelines
- *(optional)* One-month oral lead-in prior to initiation every month or two-month dosing
- Regular follow up needed due to risk of resistance

FDA Approved Long-Acting Injectable Therapy (continued)

- Initiation Injections
  - CABENUVA 600-mg/900-mg Kit
- Continuation Injections
  - CABENUVA 400-mg/600-mg Kit
- Injection site reactions were common
- Minimal drug-drug interactions

Where Are We Now?

Approval of Long-Acting Injectable Maintenance Therapy for HIV

Highlighting Landmark Trials

FLAIR

- Open label, non-inferiority trial
- Long-Acting Cabotegravir + rilpivirine after oral induction
- Daily oral induction therapy with DTG/ABC/3TC
- 1:1 continuation of oral therapy or switch to oral CAB + RPV x 1 month followed by long-acting injectable CAB + RPV

Where Are We Now?

Approval of Long-Acting Injectable Maintenance Therapy for HIV

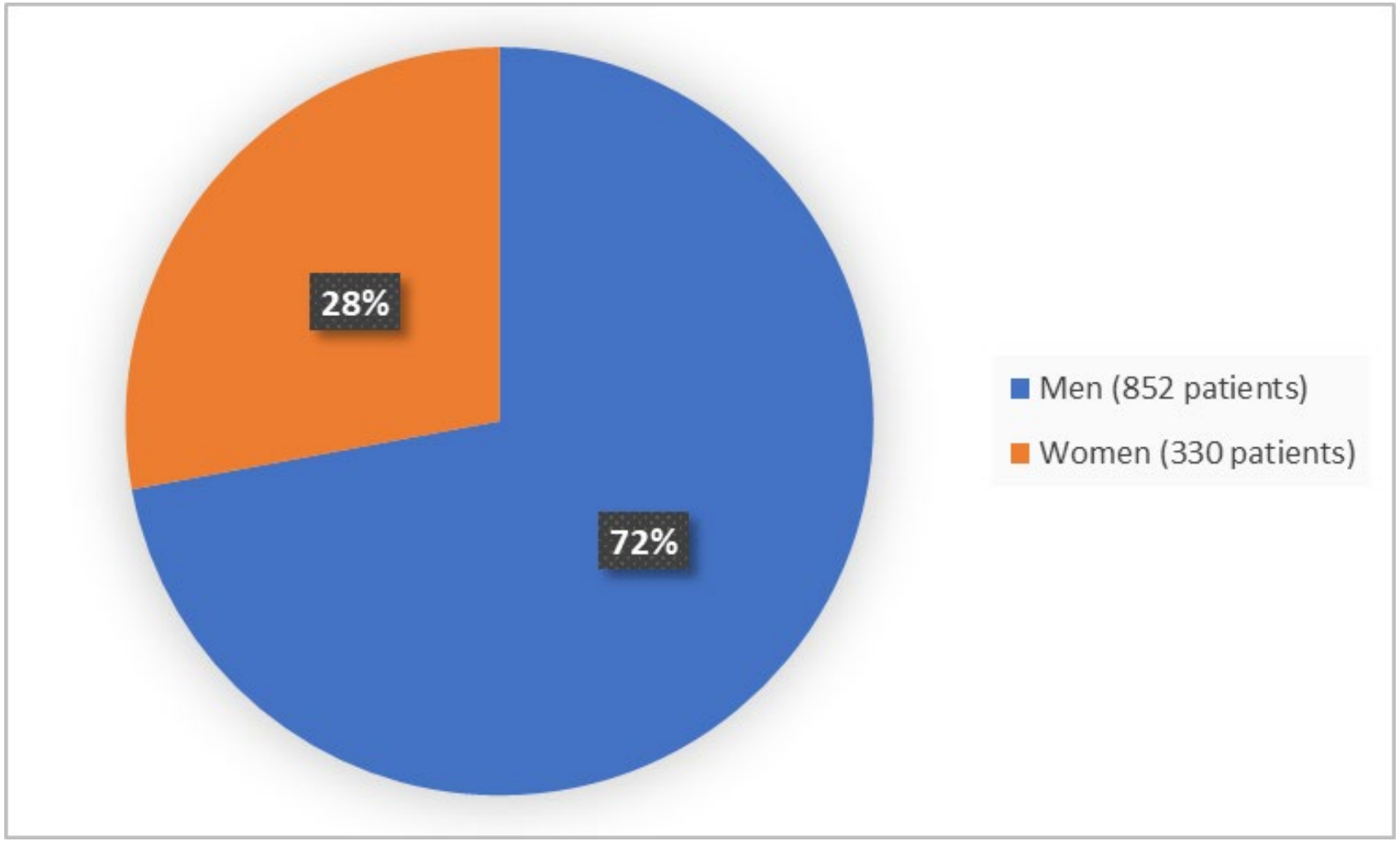
Highlighting Landmark Trials

ATLAS

- Open label, non-inferiority trial
- Undetectable VL x 6 months on standard ART regimen
- 1:1 random selection of oral therapy or switch to IM injection of long-acting CAB + rilpivirine

Figure 1: Demographics By Sex

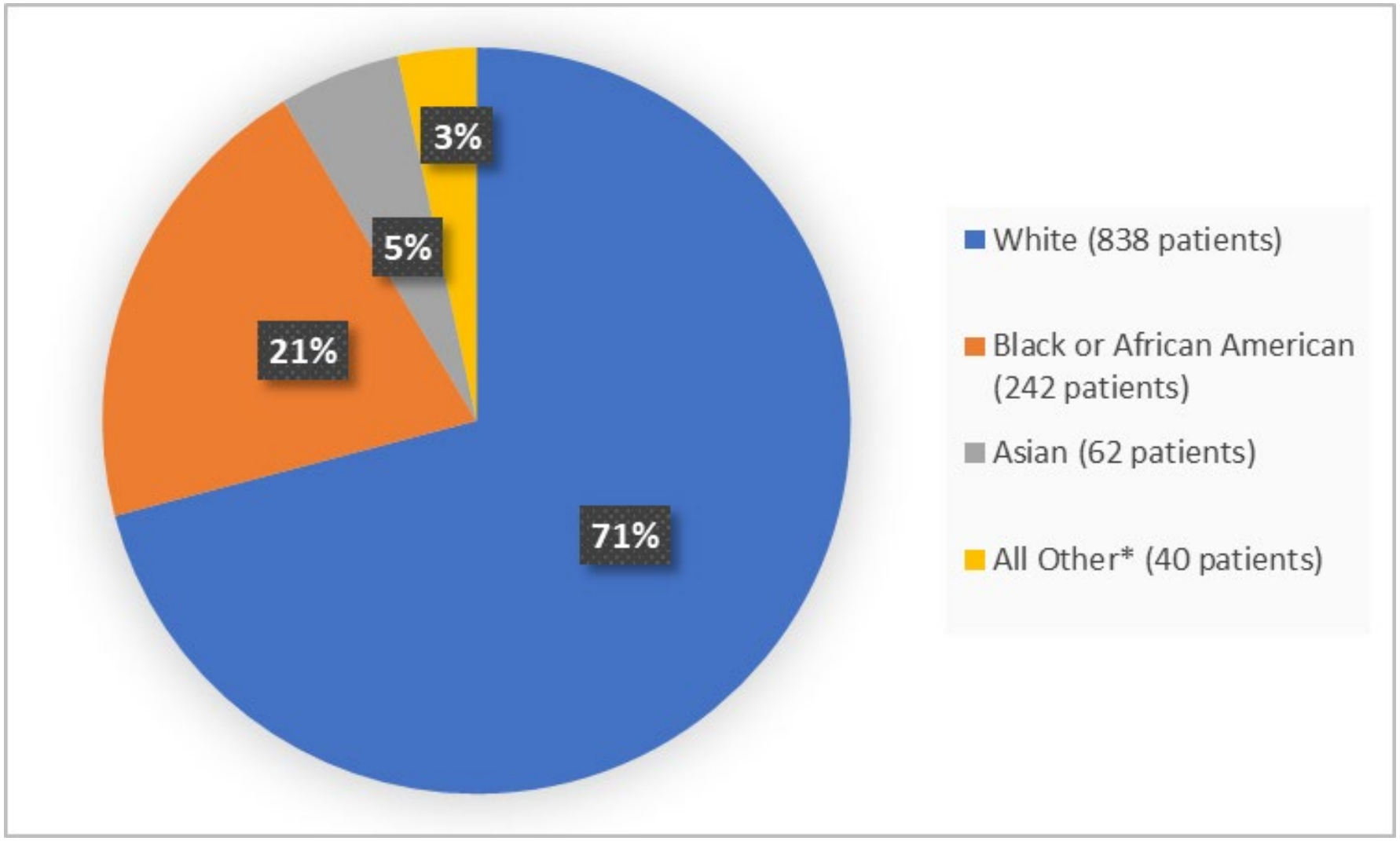
Trial 1/ NCT02938520 and Trial 2/ NCT02951052



Adapted from FDA Review

Figure 2: Demographics By Race

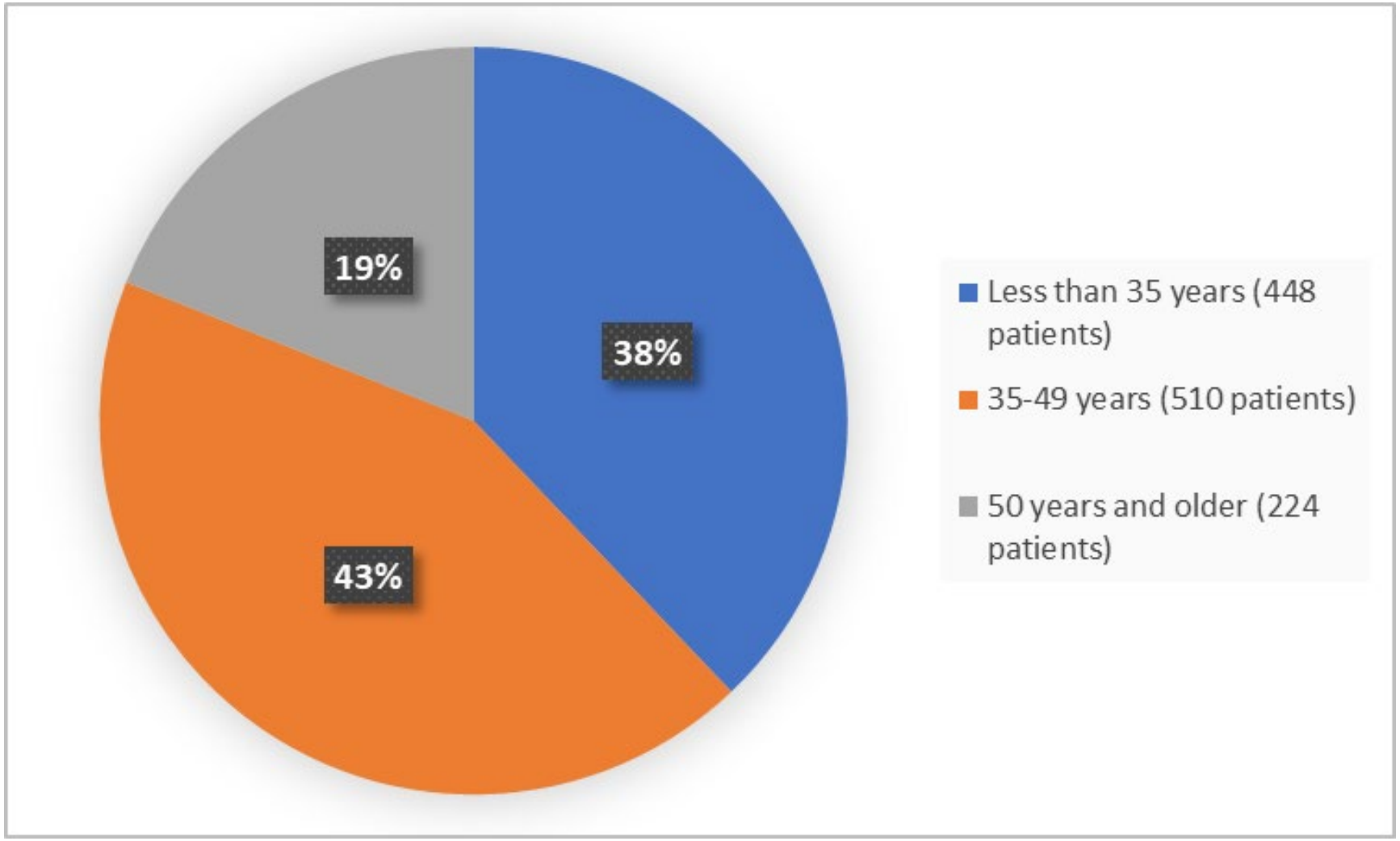
Trial 1/ NCT02938520 and Trial 2/ NCT02951052



Adapted from FDA Review

Figure 3: Demographics By Age

Trial 1/ NCT02938520 and Trial 2/ NCT02951052



Adapted from FDA Review

Where Are We Going?

"Simplified ART"

- *Prevention*
- *Treatment*

Lenacapavir SQ injection

- Capsid inhibitor
- Indications
- Highly treatment experienced patients (CAPELLA Study)
  - Treatment naïve (CALIBRATE study)
  - Prevention
- Long-acting injectable therapy every 6 months dosing
- Possibly self-administered

Submitted for FDA approval

- July 2021 (study held)
- June 2022 (highly treatment experienced patients)

Where Are We Going?

"Simplified ART"

- *Prevention*
- *Treatment*
  - *Long-term remission*

Islatravir

- Dosed daily, weekly and perhaps monthly
- Implant (annual)
- Monthly and annual formulations are for PrEP
- Switch to islatravir/doravirine for dual maintenance
- **MK-8507**
  - New NNRTI studied with weekly dosing of islatravir

GSK3739937 (VH3739937) - Maturation Inhibitor

- In development as a long-acting injectable formulation
  - Subcutaneous and intramuscular

Where Are We Going?

"Simplified ART"

- *Prevention*
- *Treatment*
  - *Long-term remission*
  - CURE

Albuvirtide (Phase 3)

- Long-acting weekly Fusion Inhibitor formulation
- Already approved in China
- With 3BNC117 Antibody (Phase 2)

bNAbs

- Many bNAbs are in development for prevention, treatment and cure research – often in long-acting LS formulations and in dual or triple combinations

Avoid Increasing Health Disparities

PLOS ONE

RESEARCH ARTICLE

Perspectives on preparing for long-acting injectable treatment for HIV among consumer, clinical and nonclinical stakeholders: A qualitative study exploring the anticipated challenges and opportunities for implementation in Los Angeles County

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Citation: Jolayemi O, Bogart LM, Storholm ED, Goodman-Meza D, Rosenberg-Carlson E, Cohen R, et al. (2022) Perspectives on preparing for long-acting injectable treatment for HIV among consumer. clinical and nonclinical stakeholders: A

Implementing Best Practice Need Not Increase Health Disparities

Reframing implementation science to address inequities in healthcare delivery

Ana A. Baumann[†] and Leopoldo J. Cabassa[*†]

Abstract

Background: Research has generated valuable knowledge in identifying, understanding, and intervening to address inequities in the delivery of healthcare, yet these inequities persist. The best available interventions, programs and policies designed to address inequities in healthcare are not being adopted in routine practice settings. Implementation science can help address this gap by studying the factors, processes, and strategies at multiple levels of a system of care that influence the uptake, use, and the sustainability of these programs for vulnerable populations. We propose that an equity lens can help integrate the fields of implementation science and research that focuses on inequities in healthcare delivery.

Main text: Using Proctor et al.' (12) framework as a case study, we reframed five elements of implementation science to study inequities in healthcare. These elements include: 1) focus on reach from the very beginning; 2) design and select interventions for vulnerable populations and low-resource communities with implementation in mind; 3) implement what works and develop implementation strategies that can help reduce inequities in care; 4) develop the science of adaptations; and 5) use an equity lens for implementation outcomes.

Conclusions: The goal of this paper is to continue the dialogue on how to critically infuse an equity approach in implementation studies to proactively address healthcare inequities in historically underserved populations. Our examples provide ways to operationalize how we can blend implementation science and healthcare inequities research.

Keywords: Implementation science, Healthcare inequities, Adaptation, Equity

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Workplan Goals, Objectives, Action Steps, and Outcomes Should Be

SMARTIE

Specific
Measurable
Achievable
Realistic
Timely
Inclusive
Equitable

III. Steps to Successful Implementation

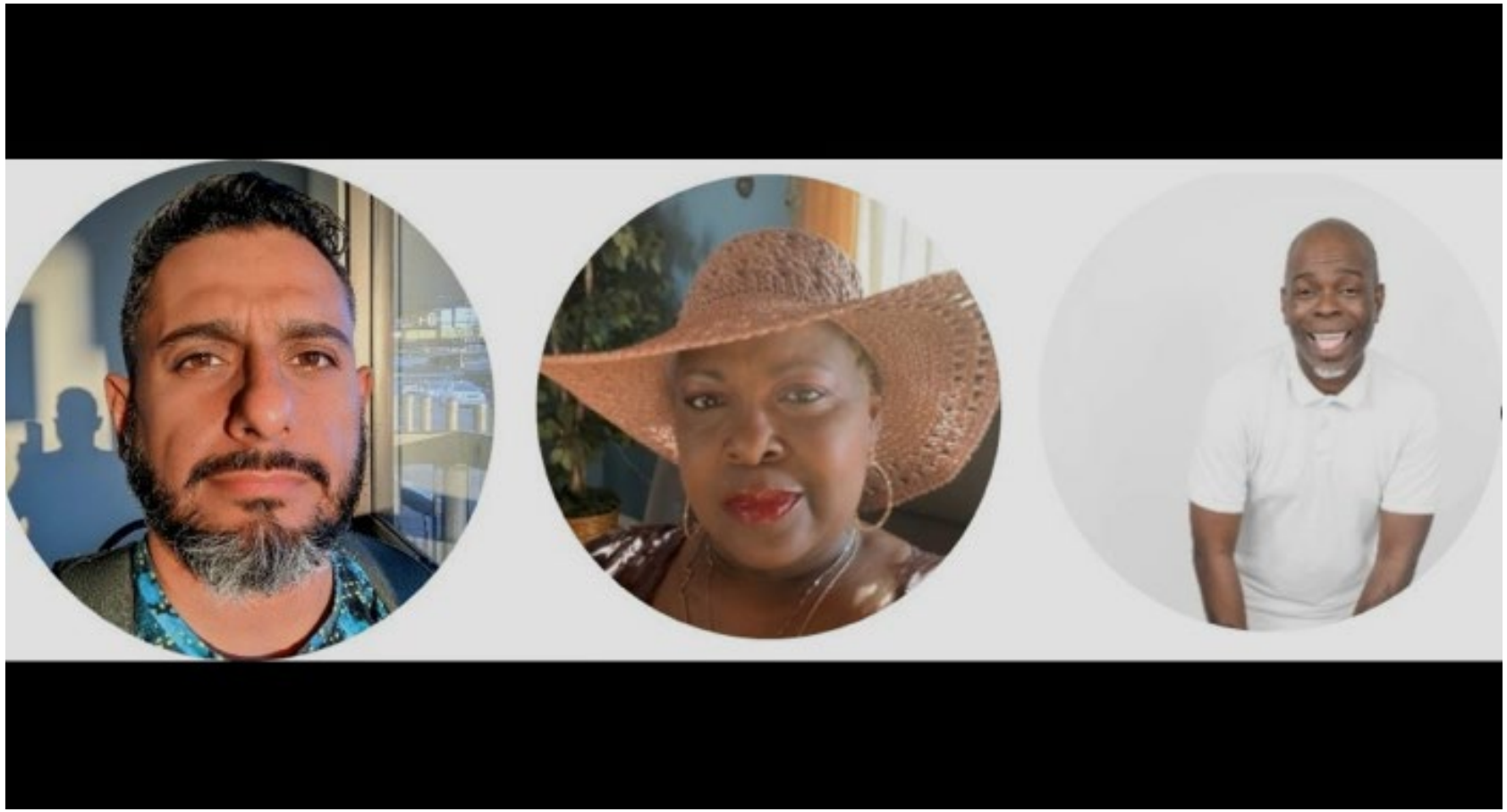
Patient Perspectives

Carlos Cuauhtemoc

Jay Reed

Morris A. Singletary

Patient Perspectives



To view this video visit: https://www.youtube.com/watch?v=4tA2uLD1eug&feature=emb_imp_woyt

IV. Implementation Barriers and Facilitators

Bumps in the Road to Long-Acting Injectable Antiretroviral Therapy

By Elizabeth M. Sherman, PharmD, AAHIVP; Sheila Montalvo, PharmD, BCPS; Paula A. Eckardt, MD, FACP, FIDSA, AAHIVS

WE WERE ELATED when the first long-acting (LA) injectable antiretroviral therapy (ART), cabotegravir/rilpivirine, was approved in January 2021. This was the first of many new and emerging LA ART regimens for the treatment of HIV. These monthly, and now bi-monthly, injections were a dream come true because they removed the requirement of taking daily oral medication for treating HIV, representing a significant advancement in HIV medicine. Many of our patients established an early interest in switching their ART regimen potential to improve their adherence. With two clinical pharmacists in our Ryan White-funded HIV clinic serving over 1,500 people with HIV in South Florida, we soon began building a list of potential patients who were clinically eligible and interested in switching their current ART to these new agents.

However, our enthusiasm and the patients' optimism were soon tempered when faced with the reality of accessing these medications in our clinical setting. The rollout of LA ART leaves room for improvement as access to LA ART has proven impractical for many who would benefit from it. Our experience within our health system has been challenged by difficulties navigating insurance benefits and acquiring these medications. The company is quick, efficient, and able to accommodate these requests seamlessly. The oral lead-in is often received within two days of making the request. However, we warn prescribers that while the oral lead-in is easy to obtain, the ensuing process to obtain the intramuscular injections can be problematically tedious and time-consuming. Providers should be forewarned to avoid ordering the oral lead-in therapy before the injection is fully approved by a patient's insurance.

In one instance, a provider ordered the oral lead-in before ordering the injection, and the patient finished the oral lead-in without having the injection available to administer. In this case, the issue resolved when the patient received the initiation injection seven days later. Ideally, this patient should have received their initiation injection on

consider LA ART as non-formulary and will exclude it entirely—an obstacle we are unable to overcome. In cases where the medication is covered, various insurance plans cover it differently. Florida Medicaid and Medicare cover it under pharmacy benefits and allow for quick processing of the medication. However, we have found that most commercial insurances cover it under medical benefits, an obstacle for pharmacies to process efficiently. If an insurance will only cover the medication under medical benefits and the pharmacy processes the prescription under pharmacy benefits, the claim will be rejected and oftentimes does not move forward in the process at the pharmacy.

This distinction between medical and pharmacy benefits is important and presents an additional recurring problem. Pharmacies need to process prescriptions differently depending on how they are covered. For example, although our clinic provides medical care to our patients, pharmacies cannot process these prescriptions unless our clinic is known to the insurance companies as a medical benefits provider. Up until now, this has not been a common challenge in our practice and the remedy has proven time- and labor-intensive.

And then there are seemingly arcane issues that we face resulting in delays, such as inconsistencies between the online and paper enrollment forms and challenges with obtaining a copay card online. These smaller issues are not insurmountable, but they further indicate that the process must be improved.

Lessons Learned

Throughout this process we have learned some important lessons. Specifically, it is necessary to have a highly organized system or dedicated person, to oversee the medication acquisition process. It is necessary to meticulously plan and track each patient to ensure the medication is ordered and available on time. As always, efficiency improves with experience as the key features of typical situations and insurance companies are learned. Accordingly, we have streamlined a process for obtaining medication through buy-and-bill. Our healthcare system's specialty and home infusion pharmacies were able to navigate this process flawlessly for us and we are grateful for their collaboration in

with each other, we believe sub-optimal circumstances such as the one described could have been better prevented.

Improving Access for Injectables

We continue to struggle with the acquisition of the injectable agents themselves. We have found that benefits investigations may be inaccurate, particularly if the patient has more than one form of insurance or coverage. In the case of more than one payor source, benefits investigations are performed independently and fail to consider how the two payors work simultaneously for coverage. Often the investigation reveals that a medical or pharmacy prior authorization is necessary, which results in additional delays in obtaining the medication.

We have found it necessary to take additional steps in acquiring this medication, particularly for underserved communities. With the goal of ending the HIV epidemic, we need to make modern advances in HIV medicine easily accessible to all patients, not just those with exceptional insurance or those who can afford to pay out of pocket. While we cannot speak for the rest of the country, we can attest to our experience in South Florida which carries the highest HIV burden of any metropolitan area in the country. Our ability to easily acquire LA ART for our patients is significantly limited. The willingness of providers and patients to adapt to new medication delivery systems depends on their implementation and the global perceptions of their advantages.

LA ART is a huge part of the future of HIV medicine, and we know several additional LA ART agents are likely to receive approval in the near future. The challenges we describe can be overcome by competent providers, especially those with abundant resources, but they represent an undue challenge to those serving vulnerable patient populations. It is imperative that we work together now to streamline acquisition and ensure equitable patient access to these medications. **HIV**

ELIZABETH SHERMAN, PharmD, is an associate professor of Pharmacy Practice at the Nova Southeastern University College of Pharmacy in Fort Lauderdale, Fla. She holds a clinical appointment with the Memorial Healthcare System Division of Infectious Disease in Hollywood, Fla. as a clinical pharmacist with expertise in HIV/AIDS.

SHEILA MONTALVO, PharmD, is HIV/Infectious Disease clinical pharmacist for the Memorial Healthcare System. She currently practices at both Memorial Physician Group's Division of Infectious Disease in Hollywood, Fla. and Memorial Specialty Pharmacy in Miramar, Fla. providing comprehensive pharmaceutical support to patients within their Ryan White HIV/AIDS Program-funded clinic and pharmacy.

DR. PAULA ECKARDT is the chief of Memorial Division of Infectious Disease, medical director of Antimicrobial Stewardship and Infection Control, and medical director of Memorial Health Care System's Ryan White Clinic in Hollywood, Fla. She is also a clinical assistant professor of medicine at FIU Herbert Wertheim College of Medicine in Miami, Fla.

Source:https://aahivm.ygsclicbook.com/pubs/hiv-specialist/2022/march-2022/live/index.html (page 22-23)

Experiences from South Florida

“Bumps in the road, how can we overcome the possible barriers”

- Providers and patients excited for LAIs
- Limited number of clinics offering LAIs
- Built list of patients who qualified
- Patient's perceptions of LAIs
- Ancillary staff, scheduling, and clinic space challenges
- All Clinic providers and staff should be aware of the process to obtain the Injectable medication to avoid confusion.

Experiences from South Florida

“Bumps in the road”

- Oral lead-in medications easy to obtain
  - Provided free and processed quickly
- Injectable medications could be difficult to obtain or timed out of sync
  - Medical versus pharmacy benefit challenges versus Buy & Bill
  - Patient with multiple insurances (RW/AP)
  - Use of in-house specialty pharmacy to navigate benefits
- Patient education and managing expectations of the LAIs process
  - Side effects, drug interactions, missed doses

Experiences from South Florida

“Bumps in the road”

- Necessary to have an organized system—or dedicated person—to oversee the medication acquisition process
- Efficiency improves with experience
- Transparency and education prior to initiating LAI ensures adherence and positive outcomes

- **LAIs need to be available to all patients and it could be a way to end the HIV epidemic**

V. Panel Discussion

Panelists

Amy Killelea, JD

Ardis Moe, MD

Jeff Cheek

Paula Eckardt, MD

Sheila Montalvo, PharmD

VI. Readiness Assessment

Clinics and Jurisdictions Can

- Complete Clinical Data
- Assess Insurance Coverage
- Assess RWAP Coverage
- Obtain Patient and Community Input
- Assess Clinic Readiness
- Put Change in Perspective
- Establish Partnerships
- Convene and Share Insights
- Determine Coverage and Costs
- Summarize Feedback

Develop an Action Plan: Where would you like to be one year from now?

Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients

Find answers to these questions:

- **How can RWHAP clients access LAI ART?**
- **How is injectable LAI ART covered by insurance and billed by providers?**
- **Can RWHAP help cover the costs of LAI ART?**

The first LAI ART product was approved by the U.S. Food and Drug Administration in January 2021 and others are in the treatment (and prevention) pipeline. LAI ART could be an important treatment option for people with HIV, particularly people for whom daily pill regimens pose adherence barriers. However, there are specific public and private insurance coverage and cost-sharing considerations for an injectable product that are different from oral antiretroviral medication. For instance, LAI ART is given intramuscularly, requiring a medical visit for administration of the medication, which has a separate cost from the medication itself. It can also be difficult to tell if an injectable product is covered by public and private insurance because it may be categorized as a medical benefit instead of a pharmacy benefit.

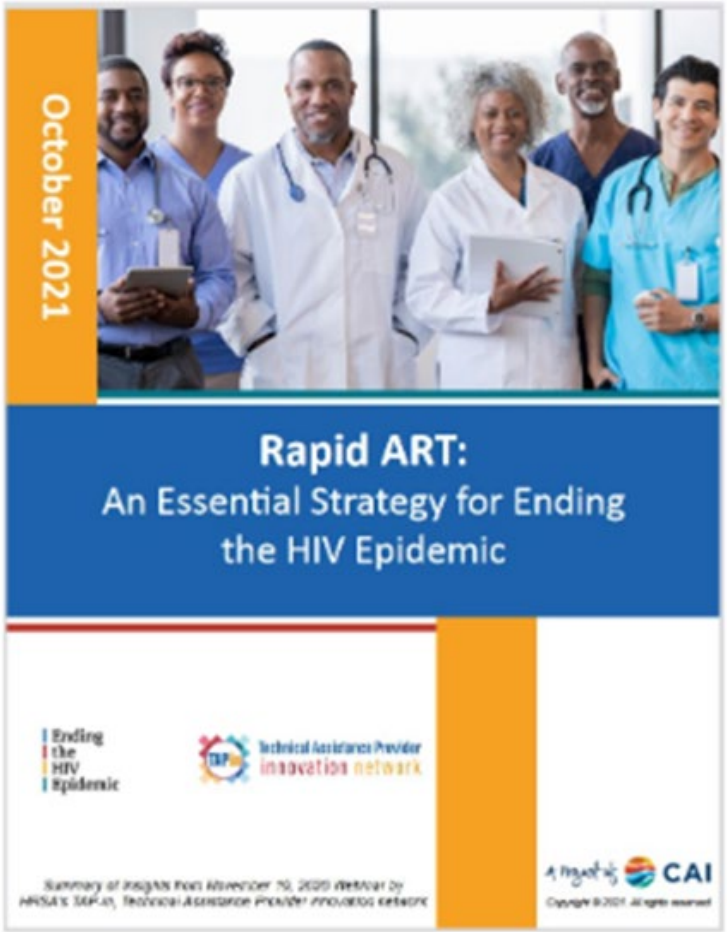
How do RWHAP clients get LAI ART?

LAI ART uses a different administration route than once-daily oral pill regimens. It is important to understand the different components of administration involved with LAI ART in order to understand how to determine if LAI ART is covered by public and private insurance and what cost-sharing may be associated with it. **Figure 1** below walks through each component of LAI ART. RWHAP clients should check with their medical provider about whether LAI ART is the right medication for them and where they can access LAI ART.

How do I know if LAI ART is covered by an insurance plan or RWHAP AIDS Drug Assistance Program (ADAP)?

A public or private insurance plan typically lists all medications that are covered on its formulary, along with any cost-sharing or utilization management requirements. Injectable products that are not self-administered, however, are sometimes covered as a medical benefit instead of a pharmacy benefit. Especially in the case of private insurance plans, this means that LAI ART may not show up on a plan's regular drug formulary, and consumers may have to look at other plan documents to determine if the product is covered and how much it will cost them. In addition, the process for adding a new drug to a formulary takes time; public and private insurance plans and ADAPs periodically review their formularies and make decisions about adding newly approved medications, and payers will update formularies periodically throughout the plan year.

Figure 1: LAI ART: Breaking Down the Intervention

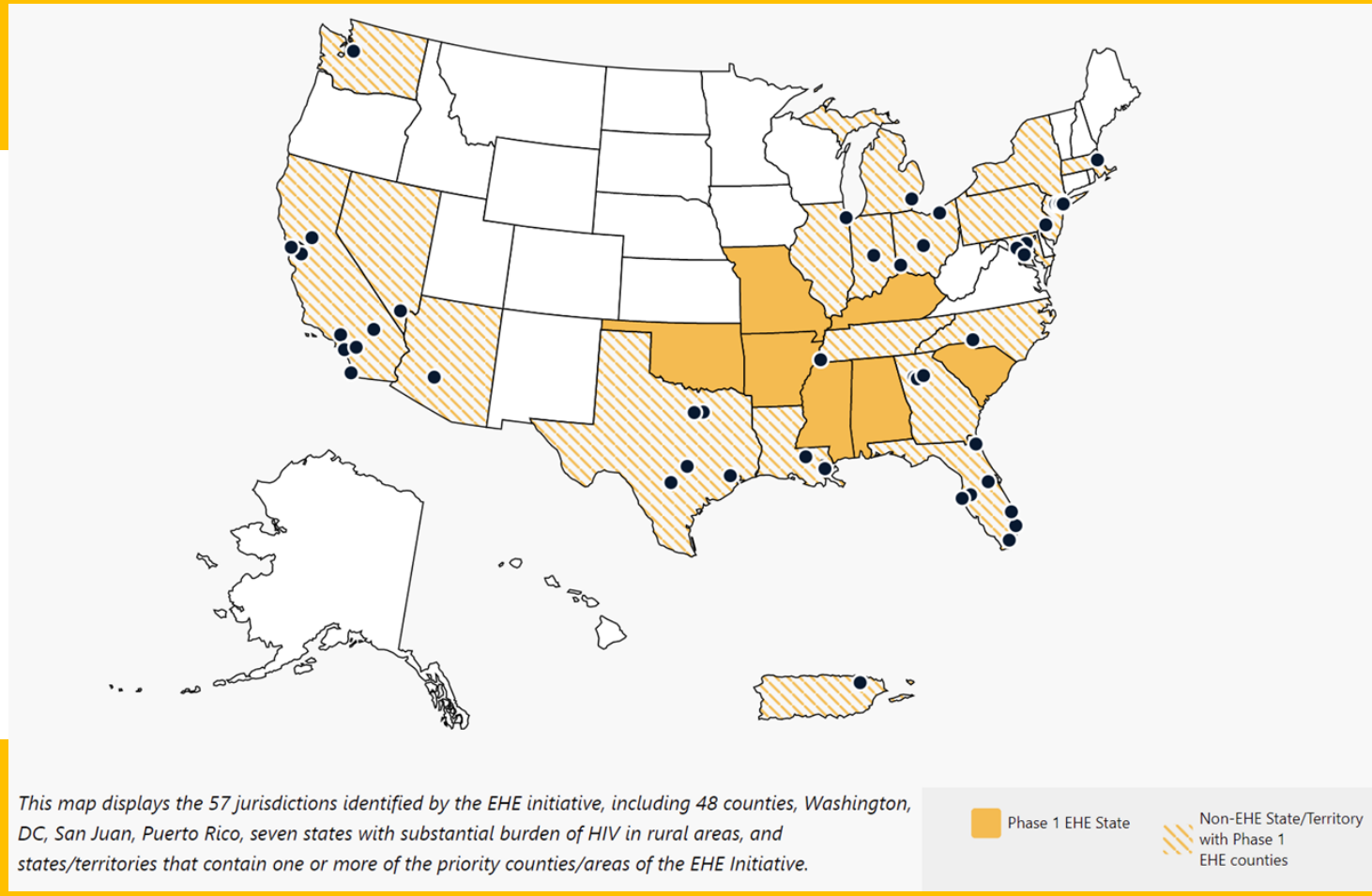


Polling Question 3

What do you feel is the #1 area your jurisdiction could MOST use TA in the coming months to increase local uptake of LAIs for treatment?

- **A** — **Obtaining Community Input** (holding town halls, surveys, etc)
- **B** — **Bring in National Experts to Present** to Jurisdiction, Clinics, Planning Council, etc.
- **C** — **Help Local Clinics Access Training, Coaching, TA, Tools, etc.**
- **D** — **Help With Local Media/Social Media Campaigns to Increase Uptake of LAIs**
- **E** — **Help Jurisdiction Identify 'Gaps' Where EHE Funding Could Increase Uptake**
- **F** — **Help address "hardly reached" to avoid increasing disparities**
- **G** — **Other** (please write in chat)

VII. TAP-in Technical Assistance



This map displays the 57 jurisdictions identified by the EHE initiative, including 48 counties, Washington, DC, San Juan, Puerto Rico, seven states with substantial burden of HIV in rural areas, and states/territories that contain one or more of the priority counties/areas of the EHE Initiative.

What We Can Do For You

- Provide on demand technical assistance
- Develop a tailored jurisdictional TA plan
- Provide access to a pool TA providers
- Facilitate peer to peer consultation
- Link to regional and national resources

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How to Request TA

Email: tap-in@caiglobal.org

Question and Answer

Closing | Next Steps

Thank You

WE WANT TO HEAR FROM YOU!

To complete our evaluation, you must be registered for this webinar.

If you have not registered, please register using the link in the chat.

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