

Models for Implementing LAI ART with a Lens on Equity: Abstract ID# 25560

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Models for Implementing LAI ART with a Lens on Equity: Intro to Today's Session

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Project Support



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Learning Objectives

- At the conclusion of this activity, participants will be able to:
 - Identify approaches for implementing equitable roll-out of long-acting injectable antiretroviral therapy (LAI ART)
 - Describe different models for implementing LAI ART
 - Understand potential challenges and their associated solutions for implementing LAI ART

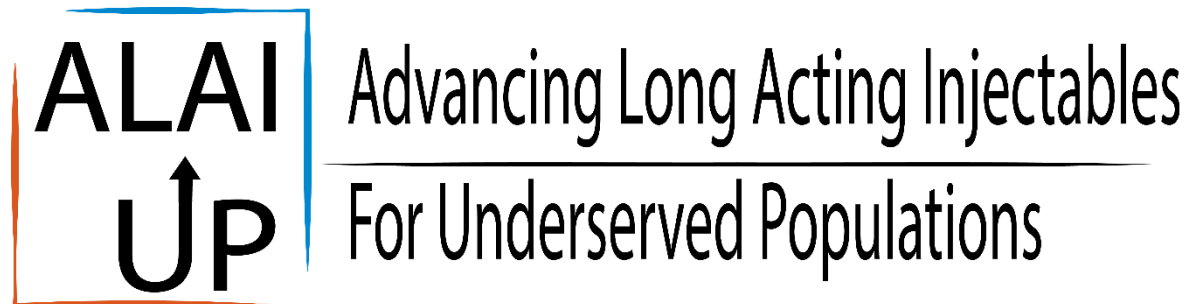
Overview



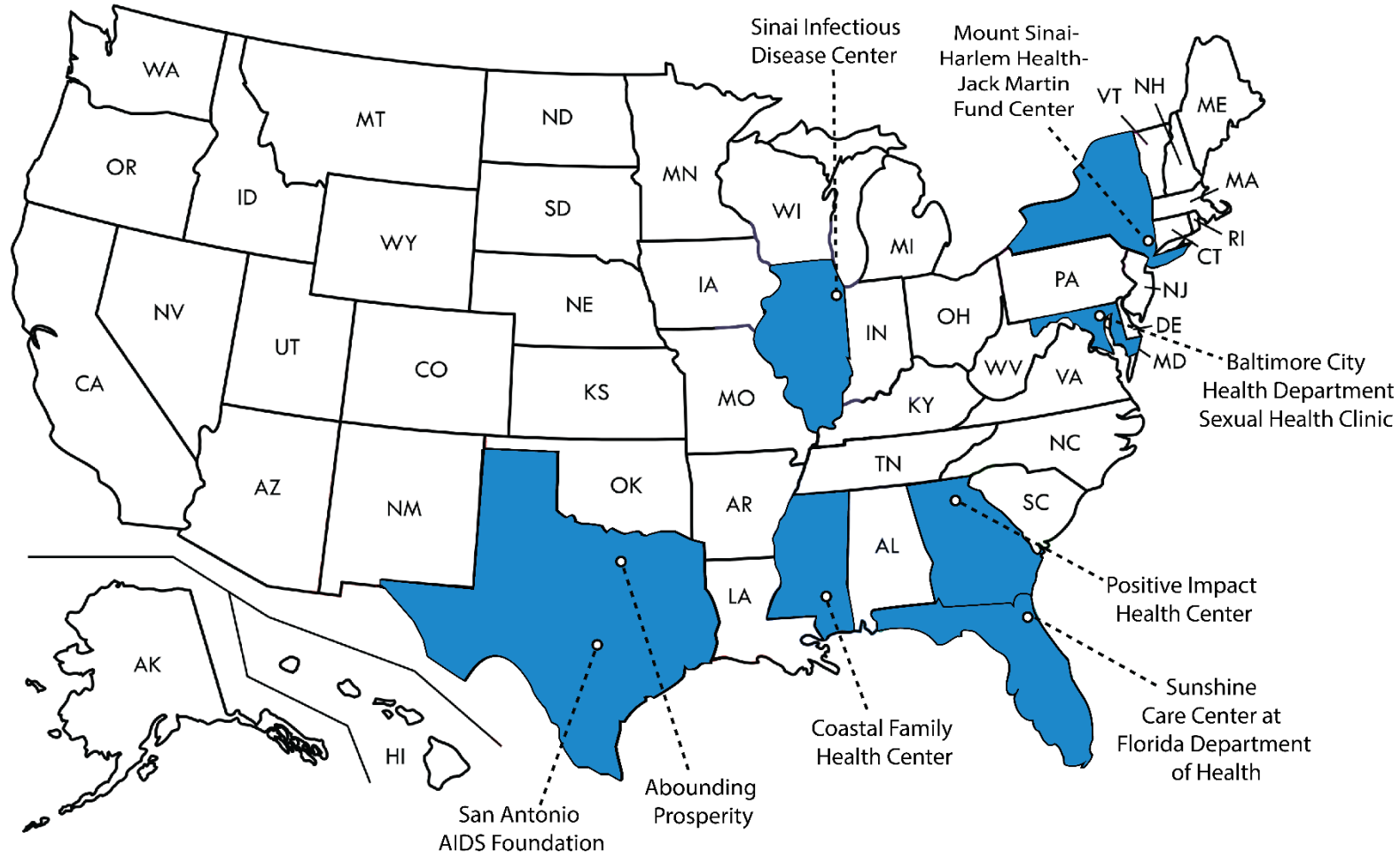
- Three clinics will present their models for implementing LAI ART with a lens on equity:
 - Sinai Chicago (Chicago, IL) will present a pharmacist-led model in a hospital-based outpatient infectious disease clinic.
 - Abounding Prosperity (Dallas, TX) will present a community-led model in a community-based organization.
 - Positive Impact Health Centers (Atlanta, GA) will present a provider-led model in a community-based Ryan White HIV/AIDS Program and STD clinic.

Background: ALAI UP

- These 3 sites are part of Advancing Long-Acting Injectables for Underserved Populations (The ALAI UP Project)
 - A Special Project of National Significance funded by HRSA and Minority HIV/AIDS Fund that seeks to reduce HIV-related health inequities in achieving and maintaining viral suppression among priority populations.



Background: ALAI UP demonstration sites



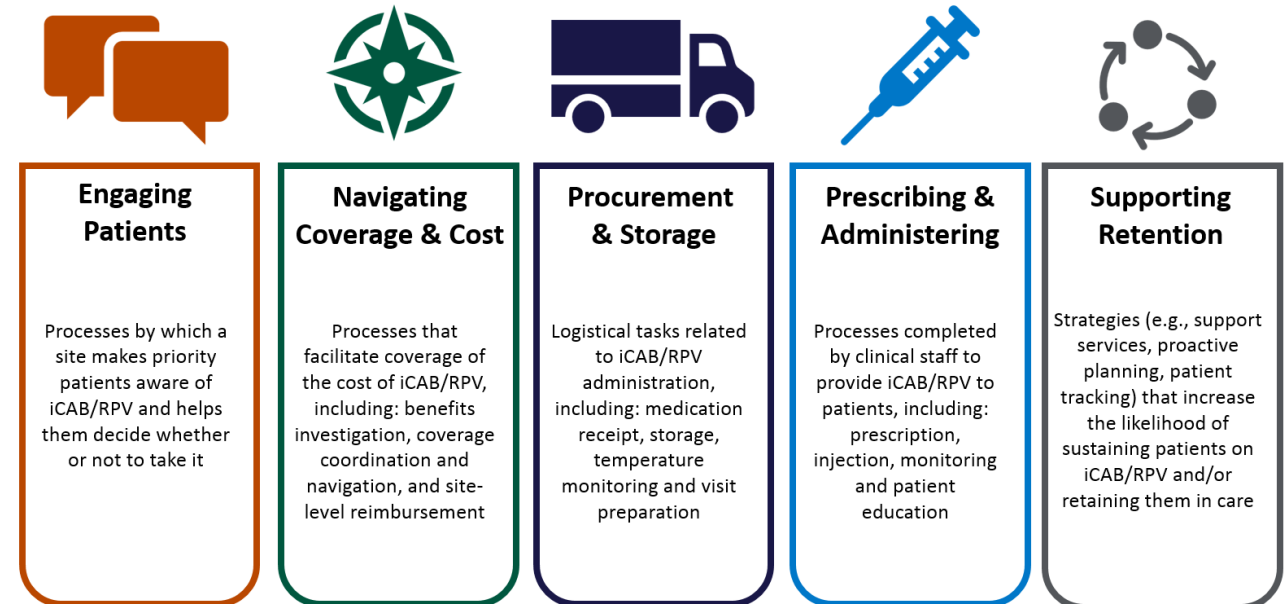
Orienting our audience



- To help orient our discussion we will each be discussing our models using the “Programmatic Building Blocks” identified by the ALAI UP resource incubator
- You will hear from each site about who is leading / contributing to each block and how the work is being done

Programmatic Building Blocks

1. Engaging Patients
2. Navigating Coverage & Cost
3. Procurement & Storage
4. Prescribing & Administering
5. Supporting Retention



1. Engaging Patients

- Engaging Patients refers to the processes by which a site brings awareness of injectable cabotegravir/rilpivirine (iCAB/RPV) to patients and helps them explore this novel HIV treatment option.
- This process includes:
 - a) educating patients about the availability of iCAB/RPV at the site
 - b) assessing iCAB/RPV as a treatment option for a given patient, based on medical eligibility, willingness to consider monthly or bimonthly injections, and insurance coverage
 - c) providing decision-making counseling to help patients decide whether iCAB/RPV is the right choice for them physically, emotionally, socially, and financially
 - d) providing wrap-around supports to increase iCAB/RPV access and sustainability

2. Navigating Coverage & Cost

- Navigating Coverage and Cost refers to processes that cover the cost of iCAB/RPV for patients.
- This process may include:
 - a) investigation of benefits coverage
 - b) coordination of medication coverage (e.g., prior authorization, advocacy, facilitating access to patient assistance programs)
 - c) ensuring site is appropriately reimbursed for medication (if applicable), administration visits, and labs

3. Procurement & Storage

- Procurement and Storage refers to the logistical tasks that are necessary for the acquisition and administration of iCAB/RPV at the site. These tasks ensure both that the medication can be safely provided to patients, but also impacts the coordination of visits and timing.
- This process includes:
 - a) protocols for obtaining the medication from either an authorized distributor or specialty pharmacy
 - b) protocols for medication acquisition, storage, temperature monitoring, injection preparation, (i.e., bringing the medication to room temperature before injection), and injection administration

4. Prescribing & Administering

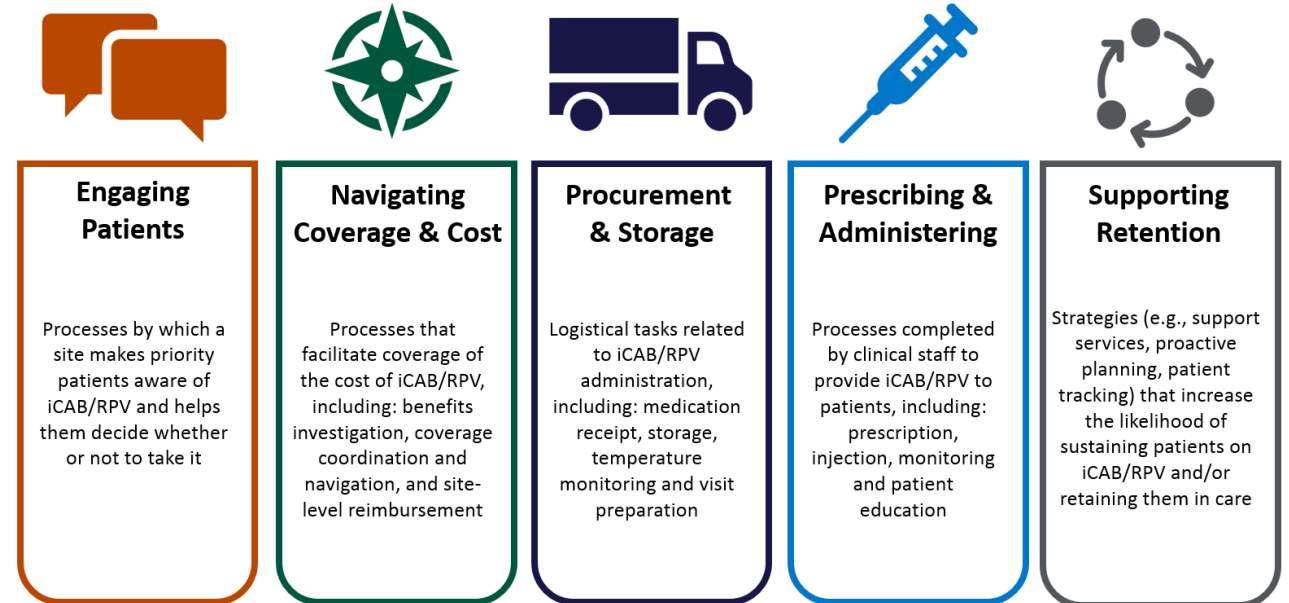
- Prescribing and Administering refers to processes done by clinical staff to provide injectable CAB/RPV to patients.
- This process includes:
 - a) prescribing injectable CAB/RPV for medically eligible and/or interested people with HIV
 - b) administering injectable CAB/RPV injections
 - c) educating patients about injectable CAB/RPV side effects and how to effectively manage them

5. Supporting Retention

- Supporting Retention refers to strategies that increase the likelihood of sustaining patients on iCAB/RPV and/or sustaining coverage with oral ART if they miss or discontinue injections.
- This process includes:
 - a) provision of supportive services to increase patients' ability to sustain engagement in iCAB/RPV and HIV care
 - b) regular check-ins with patients following injection visits
 - c) proactive contingency planning for missed visits, potential discontinuation, or patients moving to new city/state
 - d) logistical tasks related to patient tracking and follow-up

Programmatic Building Blocks and Centering Equity

1. Engaging Patients
2. Navigating Coverage & Cost
3. Procurement & Storage
4. Prescribing & Administering
5. Supporting Retention



Lens on Equity: Defining Equity

- Equity as defined in ALAI UP:
 - The prioritization of resources to address barriers that underserved populations face in accessing LAI ART so that all PWH can access the HIV treatment modality that most effectively allows them to thrive and reach the highest attainable standard of health.

Lens on Equity: Equity as an Outcome

- Equity as defined in ALAI UP:
 - The prioritization of resources to address barriers that underserved populations face in accessing LAI ART so that all PWH can access the HIV treatment modality that most effectively allows them to thrive and reach the highest attainable standard of health.
- Equity as an outcome is achieved when a person's social position or social identity does not predict their access to and successful use of LAI ARTs.*

*NYC Department of Health Race to Justice Initiative

Lens on Equity: Equity as a Process

- Equity as defined in ALAI UP:
 - The prioritization of resources to address barriers that underserved populations face in accessing LAI ART so that all PWH can access the HIV treatment modality that most effectively allows them to thrive and reach the highest attainable standard of health.
- Equity as an outcome is achieved when a person's social position or social identity does not predict their access to and successful use of LAI ARTs.*
- Equity as a process requires that all people are valued equally, with due recognition of historical injustices and provision of resources according to need (rather than equal support to everyone).*

*NYC Department of Health Race to Justice Initiative



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Models for Implementing LAI ART with a Lens on Equity: Provider-Led Model

Presented by: Shin Ly, PharmD

Director of Pharmacy

Positive Impact Health Centers (PIHC), Atlanta, GA

August 22, 2024

Shin Ly has no relevant financial relationships with ineligible companies to disclose.

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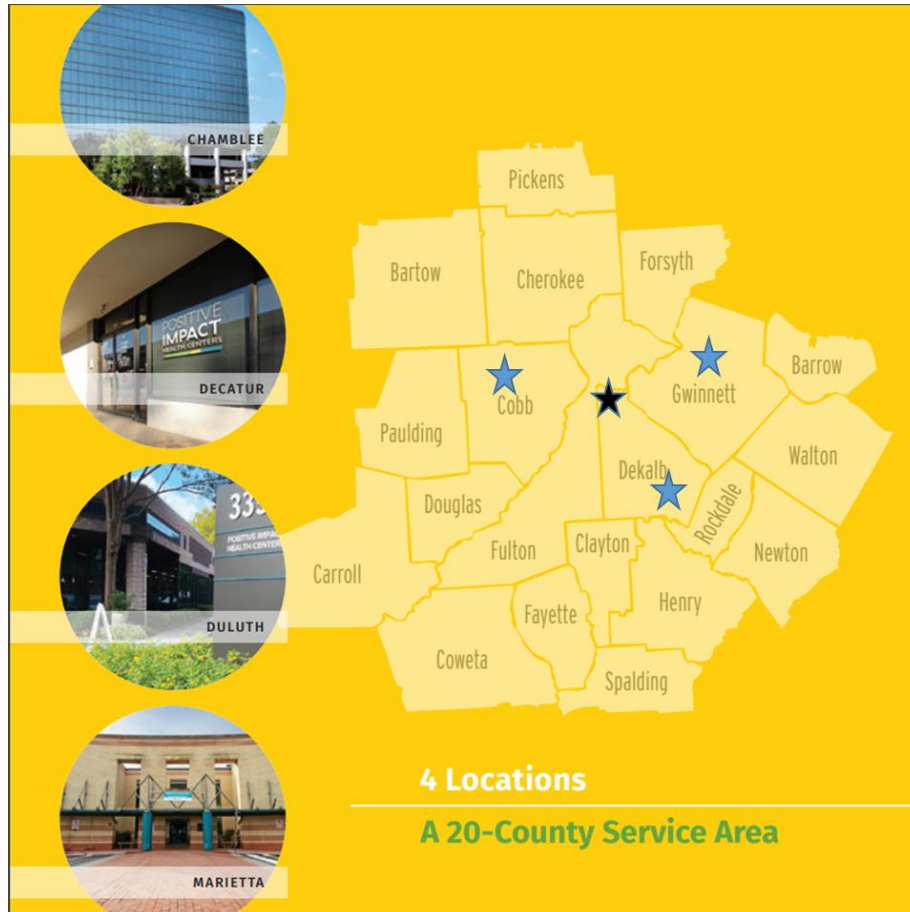
Introduction to PIHC



OUR MISSION:
Positive Impact Health Centers provides
client-centered care to the HIV community to
have a life worth loving.

POSITIVE**IMPACT**
HEALTH CENTERS

Positive Impact Health Centers



- 3 clinics serving metro Atlanta community (20 county service area)
 - Decatur Clinic – **3800 patients YTD**
 - Duluth Clinic – **2500 patients YTD**
 - Marietta Clinic – **1100 patients YTD**
 - embedded in Cobb County DPH
- Ryan White (Part A, B and C) and STI Grantee
- 2 on-site pharmacies in Decatur Clinic and Duluth Clinic
 - 1 contract pharmacy at Marietta Clinic

PIHC – Decatur Clinic

- **Community-Based Clinic**
 - Urban setting, under-resourced population
 - ~1600 PWH clients (June 2024)
 - ~ 65% African American, male and >50% are between 25-39 years old
 - Georgia - Medicaid non-expansion state
 - Georgia - ADAP with limited formulary
- **Medical Care**
 - 2 Medical Co-directors, 6 NPs, 6 RNs, 11 MAs
 - 3 outpatient PharmDs, 1 Clinical PharmD, 1 Patient Care Coordinator Pharmacy Technician
- **Wrap-Around**
 - Case management, insurance/eligibility navigation, mental health and recovery services, oral health, nutrition, transportation, housing

LAI ART Program at PIHC



- Established LAI ART Program **June 2021**
- Considerations for Implementing LAI ART Program
 - **Patient level** - clinical eligibility, pill burden against clinic appointment burden, route of administration, cost, time and transportation
 - **Clinic level** – increased staffing needs and capacity, clinical staff training on new therapy delivery and administration, scheduling training and availability of appointments, infrastructure (space/lab/personnel)
 - **System level** – cold chain coordination, medical billing experience, access navigation and cost

LAI ART Program: Considerations in 2021

Provider Champions

Uninsured vs.
Insured Population
2021 - ~60%
uninsured

Billing and Revenue
Cycle Inexperience

Payor and
Reimbursement
Landscape

Pharmacy Services
Expertise

LAI ART Program at PIHC

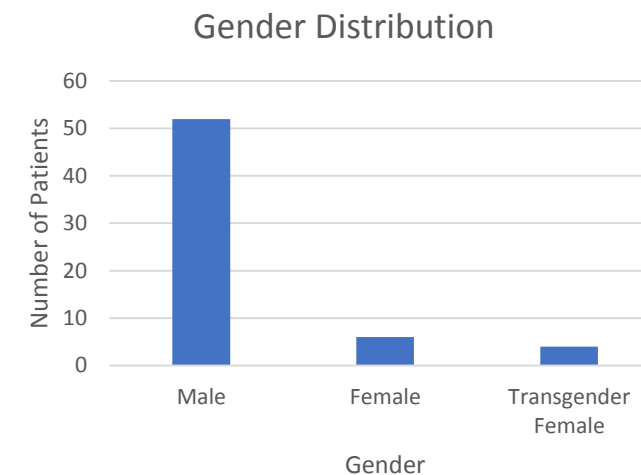
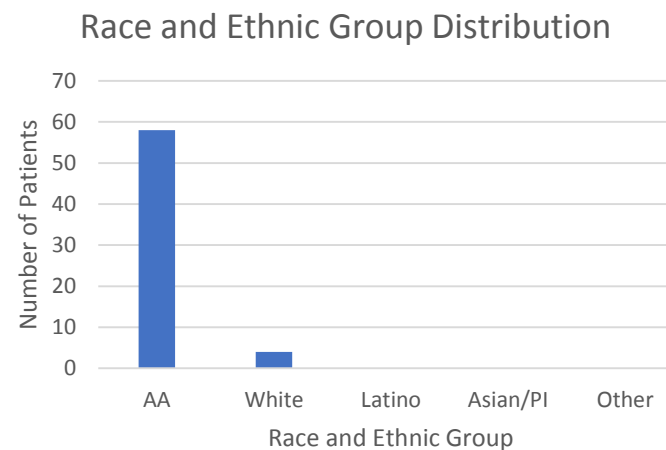
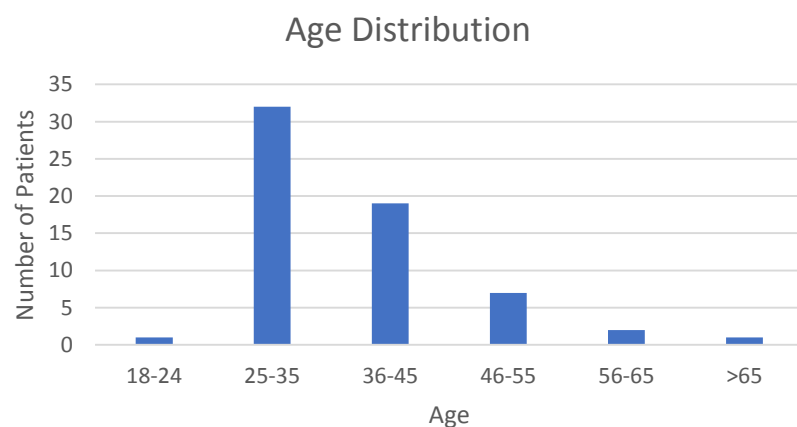
- Provider-led model for implementation of LAI ART: Rationale
 - Strong pharmacy services to support clinic
 - Lack of sufficient administration support in clinic to coordinate navigation and access in 2021
 - Cost vs. Benefit considerations
 - Risk
 - Equity
 - Scale
 - Insurance navigation
 - **60% uninsured** in 2021 to **70% insured** in 2024
 - On patient level, socioeconomic demographic do not differ between uninsured and insured population at PIHC across all sites
 - HICP – support initial payments to allow for enrollment

What does equitable access look like at PIHC ?
How can we work towards more equitable access?

LAI ART Program at PIHC

- iCAB/RPV Program at PIHC
- Insured, pharmacy benefit

As of June 2024	Patients Enrolled
Decatur	63
Duluth	19
Marietta	32



Engaging Patients in LAI ART

- **Current Strategy: Led by provider**
 - Education is delivered as 1:1 discussion between provider and patient primarily at medical appointment
 - Initiated by patient or provider
 - Decentralized model
- **Additional Strategy**
 - Marketing team support development of passive and targeted campaigns, internal and at community events
 - English and Spanish
- **Future Strategy to Reach Increased Equity**
 - Enable increased engagement by non-provider staff - develop more scalable educational training materials around LAI ART, track training
 - Incorporate LAI ART assessment into multidisciplinary team huddles within new PCMH model, coordinate effort and identify and address barriers to LAI ART

Navigating Cost & Coverage

- **Current Strategy: Led by pharmacy department**
 - Clinical and operational collaboration
 - Proactive intervention to ensure stable insurance access
 - Stewards of scarce dollars to support services in uninsured population
- **Additional Strategy**
 - Partner with insurance navigators to enroll patients in plans that would favorably cover LAI ART if patient expresses interest
 - Support first 2 months of insurance premiums to enable time to coordinate and complete insurance enrollment
- **Future Strategy to Reach Increased Equity**
 - Move toward centralized model in clinic – allocate administrative support for navigation in uninsured population with embedded pharmacy support in clinic
 - Medical billing infrastructure build-out

Procurement & Storage

- **Current Strategy: Led by pharmacy department**
 - Embedded on-site pharmacy with expertise in procurement, storing cold assets with tight inventory control and temperature tracking
- **Future Strategy to Reach Increased Equity:**
 - Support clinic infrastructure to enable offering LAI ART for uninsured patients
 - Pilot with MAT – Vivitrol MAT
 - Advocacy for ADAP access for local LAI ART dispense to reduce need to coordinate external procurement and management of separate inventories

Prescribing & Administration

- **Current Strategy: Led by provider**
 - All providers actively prescribe LAI ART
 - Reviews appropriateness – targeted approach
 - Offer LAI ART appointments during all operating hours to meet needs
- **Future Strategy to Reach Increased Equity:**
 - Move to centralized model led by clinical RN Lead
 - Develop SOP and didactic training materials to cover screening, prescribing, administration, documentation, scheduling, follow-up, retention efforts to enable expansion of capacity and scale program in predictable and consistent way

Supporting Retention

- **Current Strategy: Led by various departments**
 - Wrap-around services to meet non-medical needs
 - Same day care
 - Additional services – STI, Gender Affirming Care
- **Additional Strategy:**
 - Injection calendar for visibility by clinic and pharmacy to enable proactive population management and tracking
- **Future Strategy to Reach Increased Equity:**
 - Increase use of technology to promote patient communication with clinic for reminder calls/texts
 - Care team huddles to proactively outreach and better coordinate multi-disciplinary efforts that meets the needs of patients, identify when patients are at risk of falling out of care proactively for targeted intervention

Lessons: Strengths

- Provider-led strategy supported by strong embedded pharmacy department enabled very early adoption of new therapeutic options by using our respective expertise
- Used program revenue to support insurance navigation to scale clinic operations and enabled PIHC to shift our patient population from mostly uninsured to ~70% insured – full access to healthcare
- Able to adapt to changing healthcare landscape and treatment options quickly

Lessons: Challenges

- Recognize need to move towards more centralized model for program; more clearly define roles and responsibility
- Prioritize resources to support development of clinical and operational SOPs for LAI ART Program
- Proactively consider data and quality review needs to help direct decisions
- Emphasize need for multidisciplinary approach and encompass the continuum of the LAI ART program; continuously review how to achieve more equitable access

Next Steps



- On-boarding RN Lead for LAI ART Program
 - Administrative support to navigate access and cold-chain coordination with external parties in collaboration with pharmacy for uninsured population
 - Training program that is scalable
 - PCMH and multidisciplinary huddles
- Invest in medical billing infrastructure
- Continue advocacy efforts

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 - Christopher Pride MSN, AGPCNP-BC
 - Director of Clinical Care Department, Positive Impact Health Centers
 - Laura Evans, RN, MSN
 - Clinical Outcomes & Quality Manager, Positive Impact Health Centers



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Models for Implementing LAI ART with a Lens on Equity: Community-Led Model

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Director of Clinical Services

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Dallas, TX 75215

August 22, 2024

Melissa Curry has no relevant financial relationships with ineligible companies to disclose.

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Introduction to AP Inc.



Abounding Prosperity (AP, Inc.) has over 15 years of serving high risk populations with the Black and Latinx communities. This includes MSM, transgender and cisgender women, individuals with a history of substance misuse and mental health challenges, as well as those with unstable housing.

Our mission is to provide services that address health, social and economic disparities among Black Americans with a particular emphasis on gay & bisexual men, cisgender women, transgender men & women, and their families.

The organization provides HIV, STI, testing and screening, treatment, prevention and care services, mental health & harm reduction, substance use support, emergency rental and utility assistance, transgender ID program and health services, as well as education and support programs for high-risk populations within the southern sector of Dallas County.



AP Inc. – H.O.P.E. Clinic



Community Based Clinic

- Urban setting, under-served population
- 1188 patients served (2023)
- ~65% Black cisgender male and approx. 50% between 18-29 years old

Equitable Access

- Free medical & supportive services provided
- Location, location, location

Medical Care

- 1 Medical Director, 1 Clinic Director, 1 Health Services Director, 1 NP, 1 RN, 2 MA's, 2 Case Managers, 2 Peer Navigators

Wrap-Around Services

- Case management, insurance/eligibility navigation, mental health and substance use services, harm-reduction therapy, transportation, housing support

Site Background



84 PWH SERVED AT
THE CLINIC



84 PWH ON ANY ART



17 PEOPLE ON
ICAB/RPV



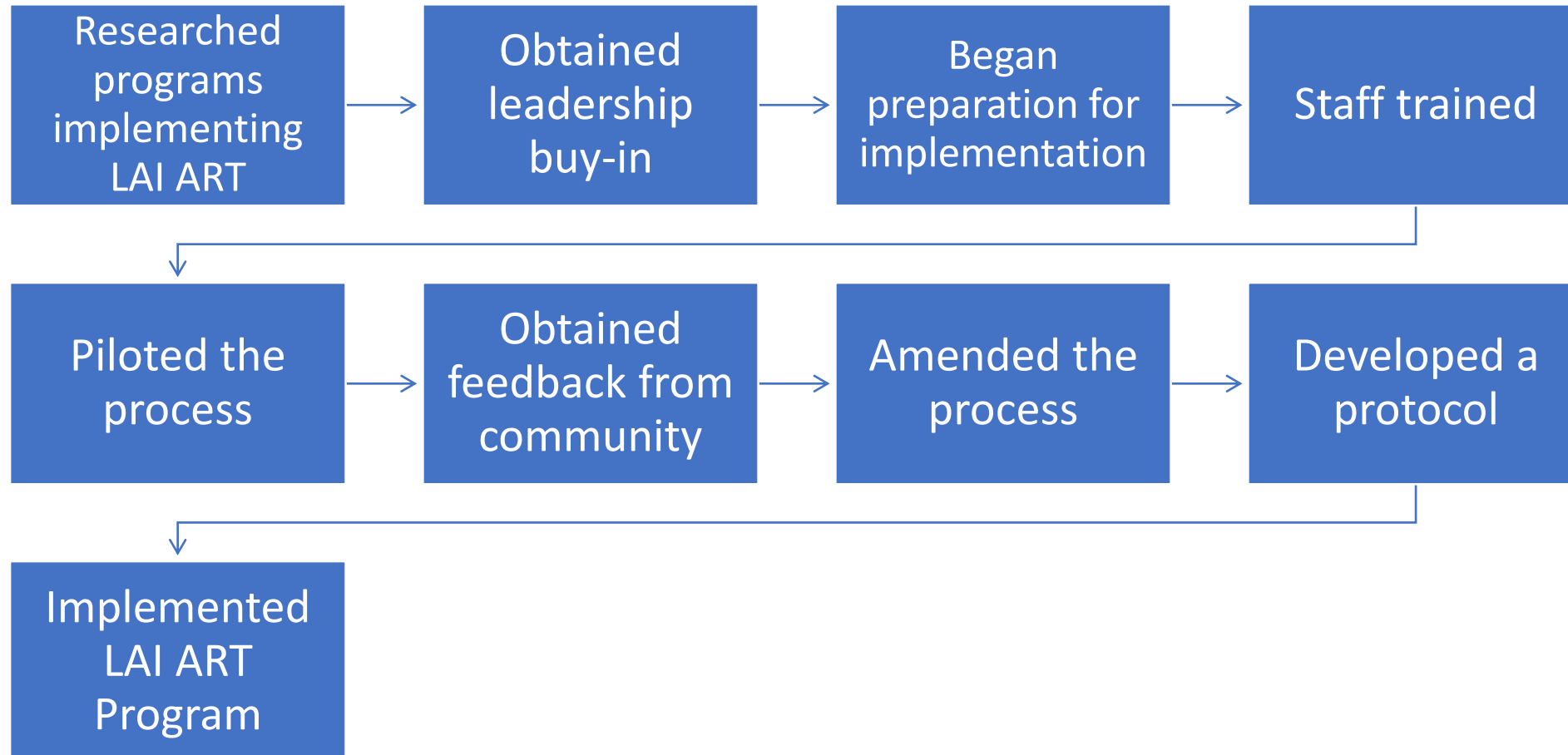
15 PEOPLE ON
ICAB/RPV ARE BLACK

LAI ART Program at AP Inc



- Established LAI ART Program in October 2022
- Considerations for Implementing LAI ART Program
 - **Patient level** - clinical eligibility, insurance eligibility, barriers to care, injection phobia.
 - **Clinic level** – staffing capacity, determine every 2 month vs. monthly injections or combination.
 - **System level** – policies and procedures in place, fiscal management, cold chain coordination, medical billing experience, access, navigation and cost.

LAI ART Program Timeline



Engaging Patients in LAI ART

Clinical Strategy

- Community outreach efficiency
- Incorporation of social media into outreach methodologies
- Diversification of resource provision
- Protocol driven by community voices
- Representation of community within the organization

Equitable Strategy

- Increase our social media presence to better engage youth
- Expand services to address stigma and additional barriers

Future Strategy

- Increase resource provision by:
 - Providing more robust medical services on the mobile van.
 - Research funding for ongoing support of social determinants of health.

Navigating Cost & Coverage

Clinical Strategy

- At present, AP Inc. can provide iCAB/RPV to patients with all coverage types except ADAP
- AP Inc. can provide patients with insurance navigation assistance and resources to access payment assistance programs.
- If the patient is insured, then a benefits investigation is performed, which then sends the site an explanation of benefits (EOB) which lists the specialty pharmacies that the insurance determines we use for iCAB/RPV.

Equitable Strategy

- Research resources and programs to assist with covering the cost of labs for uninsured patients
- Case Manager provides education on understanding explanation of benefits (EOB) and uses an insurance brokerage firm to provide options for patient to choose insurance coverage rather than being assigned.

Future Strategy

- Hiring a staff person who specializes in prior authorizations, benefits counseling, and medical billing.

Procurement & Storage



Clinical Strategy

Case Manager contacts the pharmacy to arrange delivery of medication 7 days before the patient's scheduled injection visit.

Communication with the pharmacy and the status of the prescription is documented in the clinic iCAB/RVP log.

Client is reminded of their appointment in a day 3-2-1 algorithm prior to their appointment.



Future Strategy

Once AP Inc. becomes credentialed and is able to perform medical billing for iCAB/RPV, the buy-and bill process will be implemented to expand capacity to provide more clients with the opportunity to receive iCAB/RPV

Prescribing & Administration



Clinical Strategy

Clinic staff prepares the patient for the injection, by:

Answering any questions/concerns about the injection or side effects.

Giving the patient the clinic's injection starter kit and review its components.



Equitable Strategy

Client meets with case management at each visit prior to their medical visit to address social barriers and additional needs beyond their medical care.



Future Strategy

To scale up capacity, this process requires additional staff to manage the care for additional patients.

Supporting Retention

- Clinical Strategy
 - Developed a plan of action upon determining eligibility, ie. Retention plan and LAI ART tracking log.
 - Retention plan includes methods of contact, methods of adherence, and strategies of accountability.
- Equitable Strategy
 - To support adherence barriers AP Inc. has incorporated an intensive case management program to work with patients that may have challenges with making their follow up appointments.
 - Consent for communication via email and social media to expand methods of communication in relation to limiting factors of phone/text with the community served.
 - Refer to partnering organizations that can assist with providing cell phones and other means of communication.
- Future Strategy
 - Utilize technology-based retention software and data analytics to support client retention and engagement.

Lessons: Strengths



Partnerships/Wrap around Services

Consistent referrals from partnering agencies, and our bridge care model help with program sustainment.

The partnering agencies all have a role to play within the implementation of the community led model.



Meaningful Involvement of PWH

Utilization of community listening sessions, advisory boards, employment of PWH, and townhalls led by PWH to advance equity and better understand the needs of the community served.



Client centered care

Utilization of strength-based interventions for care and case management.

Social determinants of health remain priority in care provision.

Lessons: Challenges



- Finding funding resources to sustain the LAI ART program particularly for those who are uninsured.
- Assistance with the expansion of the current software reporting system to build a seamless process of quality management and data reporting.
- Staff turnover
- Time spent navigating coverage.

Next Steps



Continue to advocate for policy changes and funding to support the community.



Increase electronic health record access for medical billing.



Develop a more efficient method of data reporting for LAI ART.



Increase staffing capacity to increase patient volume for LAI ART.

Final Thoughts



“Equality is leaving the door open for anyone who has the means to approach it; equity is ensuring there is a pathway to that door for those who need it.”

-Caroline Belden (Writer, 'The Inclusion Solution')-

Contact Us



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- **Acknowledgement:**
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 - Nurse Practitioner, Abounding Prosperity Inc.
 - Korey Willis
 - Director of Health Services, Abounding Prosperity Inc.



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Models for Implementing LAI ART with a Lens on Equity: Pharmacist-Led Model

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Sinai Infectious Disease Center



- Sinai Infectious Disease Center (SIDC) at Sinai Chicago
 - Part of Sinai Chicago, a safety-net health system
 - Located on Chicago's west and southwest sides
 - Serving primarily AA & Latinx patients in under-resourced communities
 - Our hospital-based outpatient ID clinic serves ~400 PWH
 - Medical care (3 ID physicians, 2 NPs, 1 PharmD, 1 MA)
 - Wrap-around support services (case management, patient navigation, mental health & psychosocial, etc.)

Site Background

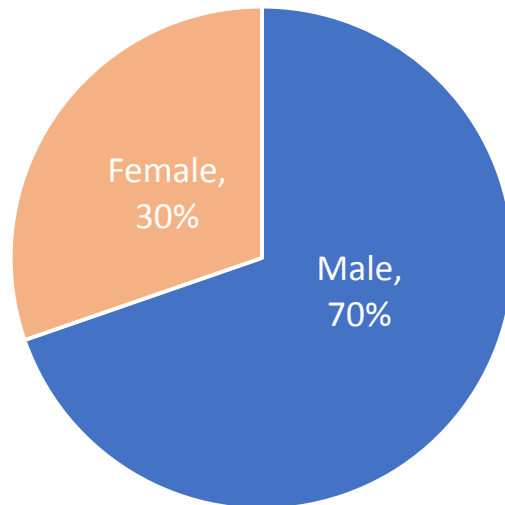


- LAI ART at SIDC
 - Established LAI ART program in April 2022
 - Currently serving 30 PWH on LAI ART
 - LAI ART patient population:

Site Background: PWH on LAI ART by Gender

- LAI ART at SIDC
 - Established LAI ART program in April 2022
 - Currently serving 30 PWH on LAI ART
 - LAI ART patient population:

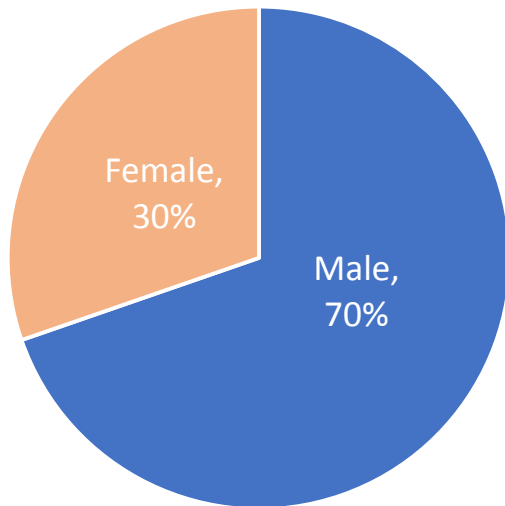
Gender of LAI ART patients



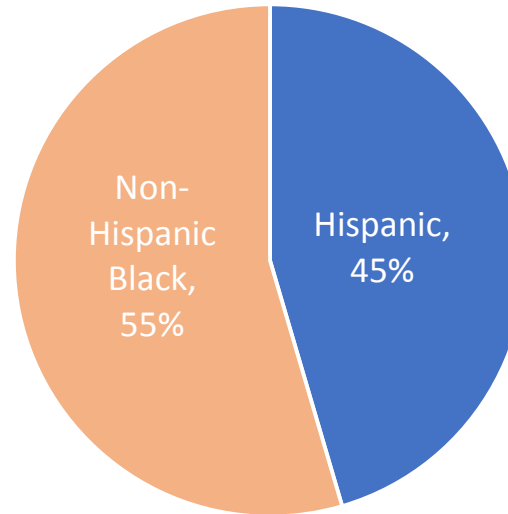
Site Background: PWH on LAI ART by Race & Ethnicity

- LAI ART at SIDC
 - Established LAI ART program in April 2022
 - Currently serving 30 PWH on LAI ART
 - LAI ART patient population:

Gender of LAI ART patients



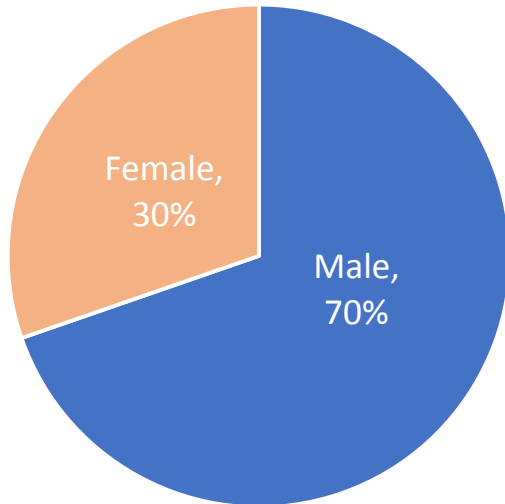
Race & Ethnicity of LAI ART patients



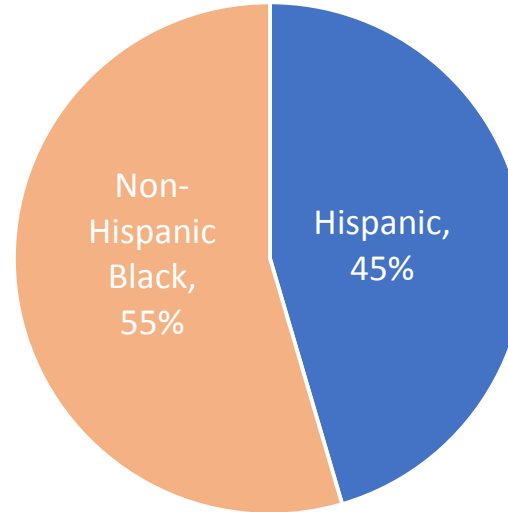
Site Background: PWH on LAI ART by Payor Source

- LAI ART at SIDC
 - Established LAI ART program in April 2022
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 - LAI ART patient population:

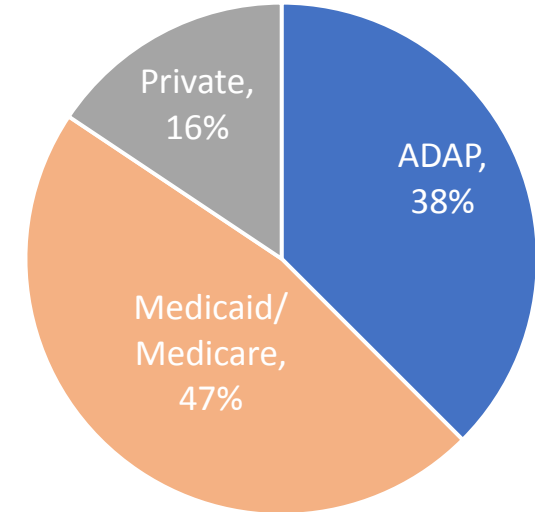
Gender of LAI ART patients



Race & Ethnicity of LAI ART patients

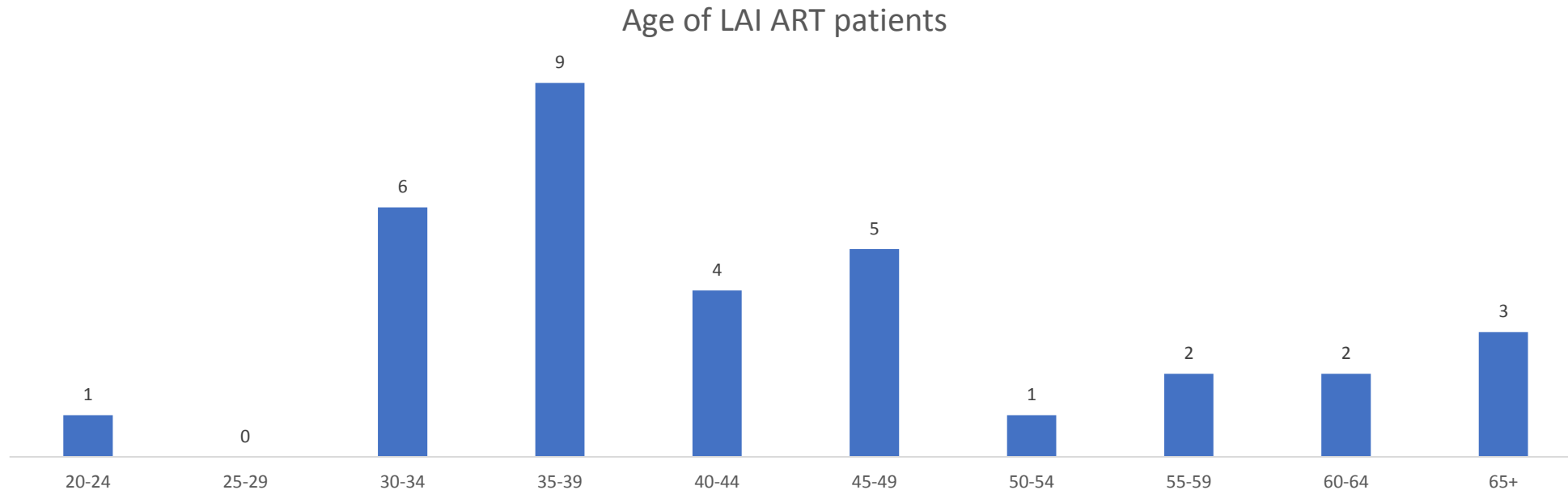


Payor source of LAI ART patients



Site Background: PWH on LAI ART by Age Group

- LAI ART at SIDC
 - Established LAI ART program in April 2022
 - Currently serving 30 PWH on LAI ART
 - LAI ART patient population:



Engaging Patients

Led by non-clinical staff



- The process for engaging patients is led by non-clinical staff (case managers, patient navigators, etc.)
- Education is typically provided by phone using a script/checklist
- Patients are identified by running the upcoming appointment list for the upcoming month and ALL patients are provided with education about LAI ART
 - Exceptions: patients with RPV, multiple NNRTI, or INSTI resistance, HBV coinfecting patients, and new clinic patients who are coming for their first initial appointment
- In order to ensure equitable roll-out of LAI ART:
 - ALL patients are provided with education before being assessed for eligibility (with the exception of the criteria noted above)
 - Education is provided in both English & Spanish based on language preference

Navigating Costs & Coverage

Led by pharmacist



- Pharmacist
 - Investigates insurance benefits coverage
 - Completes, submits and tracks all prior authorizations
 - Completes and submits appeals if prior authorization is denied
 - Coordinates with case management to ensure ADAP is set up as secondary coverage in case insurance coverage is unexpectedly terminated
 - Establish a workaround for medical billing as our site is not set up for buy and bill
- In order to ensure equitable roll-out of LAI ART:
 - Patients are presented with LAI ART option regardless of their insurance status

Procurement & Storage

Led by pharmacist



- Pharmacist
 - Establish relationships with internal and external pharmacies to ensure timely medication refills
 - Manage a monthly report to coordinate iCAB/RPV refills with upcoming LAI injection appointments
 - Coordinate monthly deliveries of iCAB/RPV refills between the internal/external pharmacies and ID clinic
 - Ensuring prompt and safe storage of iCAB/RPV in clinic fridge after medication delivery
- In order to ensure equitable roll-out of LAI ART:
 - Patients are presented with LAI ART option regardless of their pharmacy

Prescribing and Administering

Led by clinical care team



- All three ID Physicians in our group are actively prescribing LAI ART to their patients as applicable
- Our ID Medical Assistant administers injections on Mondays and Tuesdays with oversight from our Nurse Practitioner
- Post injection after-care instructions and assessing patients 10 minutes after first initiation iCAB/RPV injection have improved quality of care and patient satisfaction
- In order to ensure equitable roll-out of LAI ART:
 - Our trained MA provides competent and compassionate care and is able to help ease anxiety of patients who may have fear of needles/injections

Supporting Retention

Led by various team members



- Transportation and other SDOH wrap-around support is provided by non-clinical staff
- Appointment reminder texts/calls
 - One week in advance by pharmacist and one day in advance by receptionist
- Non-clinical staff holds case conference every 2 weeks
- One week post-initiation call is made by NP
- Appointments are tracked by pharmacist (attended, rescheduled, and upcoming appointments)
- In order to ensure equitable roll-out of LAI ART:
 - Those who may need more support for LAI ART to work for them (eg transportation, grocery cards) will receive the support they need to be able to engage

Lessons learned

- Developing a protocol and testing feasibility with a small number of patients first before expanding widely
- Carefully consider capacity before expanding too much
- Be clear on who (staff/roles) will be responsible for each task in the workflow
- Consider approaches that can be taken at each stage to ensure equitable roll-out of LAI among your patient population

Contact Us



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