



## **Giving Women a Shot:**

# Implementation and Scale-Up of Long-Acting Antiretroviral Therapy (LA-ART) among Cis and Transgender Women

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# Project Support



This project and product was supported by Grants P0649850, H97HA27430, H12HA24850 from the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of HRSA.

## Disclosures



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# Learning Objectives



At the conclusion of this activity, participants will be able to:

- 1. Discuss strategies for implementation of long-acting antiretroviral therapy among cis and transgender women
- 2. Describe multidisciplinary approaches to successful scale-up of LA-ART, particularly among women
- **3.** Identify challenges and lessons learned with rollout of LA-ART

### Case 1



- 31 year-old Black cisgender woman with perinatally acquired HIV/AIDS (VL 600,000 copies/mL; CD4 1/0%)
- Years-long struggle with medication adherence and pill intolerance

- Lack of social support
  - Both parents died of AIDS-related complications
  - Trying to support remaining relatives
- Multiple psychosocial and structural factors including:
  - Depression
  - Housing instability
  - o IPV
  - Stigma
  - Pill aversion and PTSD
  - Financial instability

# Case 1 (2)



- On exam, cachectic and severely underweight (BMI of 12)
- +thrush, often hypotensive in clinic
- No recent menstruation, concern re: childbearing potential

- Multiple hospitalizations for opportunistic infections
- Concern for IPV
- Many missed clinic visits, persistent viremia

# Case 1 (3)



 After recent hospitalization, expresses to her doctor that she is tired of taking pills and wants to be on the shot

# The Epidemic and LAI-ART



- January 2021 → FDA approved CAB/RPV for therapy in HIV-1
- Cabotegravir (CAB) extended release injectable + Rilpivirine (RPV) (Cabenuva) extended release injectable
- Intramuscular (gluteal) administration
- Every 4 or 8 weeks
- FDA approved for virologically suppressed

- Lenacapavir (Sunelnca): Capsid inhibitor FDA approved for treatment of multidrug resistant HIV
- Subcutaneous administration
- Cannot be used alone for treatment

### **IAS-USA Guidelines Revision**



Can consider Cabenuva in certain viremic patients with the below provisions:

- Unable to take oral ART consistently despite extensive efforts and clinical support
- High risk of HIV disease progression (CD4 cell count <200/µL or history of AIDS-defining complications)</li>
- Virus susceptible to both CAB and RPV

If applicable, patients should also be referred for treatment of substance use disorder and/or mental illness.

Note: As of now, Cabenuva in viremic patients is still considered off-label

# NewYork-Presbyterian Hospital's Comprehensive Health Program (CHP)

# RYANWHI CONFEREN

#### **HIV Care & Treatment**

- •Serving Pediatric (including exposed infants and children), Adolescent, Young People, and Adults
- Primary Care, Behavioral Health & Supportive Services
- Hepatitis C Treatment for Co-infected Individuals

In 2022, CHP actively served **2,451 clients** living with HIV in NYC.

#### Sexual Health

- Serving individuals of all ages at risk of HIV infection
- •STI Testing (including HIV & Hepatitis C)
- PrEP, PEP, Primary Care, Mental Health & Supportive Services

#### Linking to Hepatitis C Treatment

- Targeting individuals with Hepatitis C mono-infection
- Mental Health & Supportive Services while in Treatment
- •Transition to Primary Care





Figure 1. New York City Map.

# The CHP: The Population



- Status-neutral comprehensive
   HIV and sexual health clinic
- NYC metropolitan area
- Serves ~3,000 patients
- Majority Black and/or Latinx
- Growing immigrant population

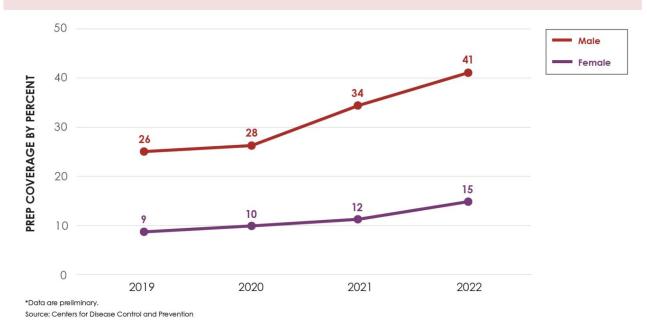




# Cisgender women with HIV



#### TRENDS IN PREP PRESCRIPTIONS AMONG PEOPLE WHO COULD BENEFIT, BY SEX AT BIRTH, 2019-2022\*

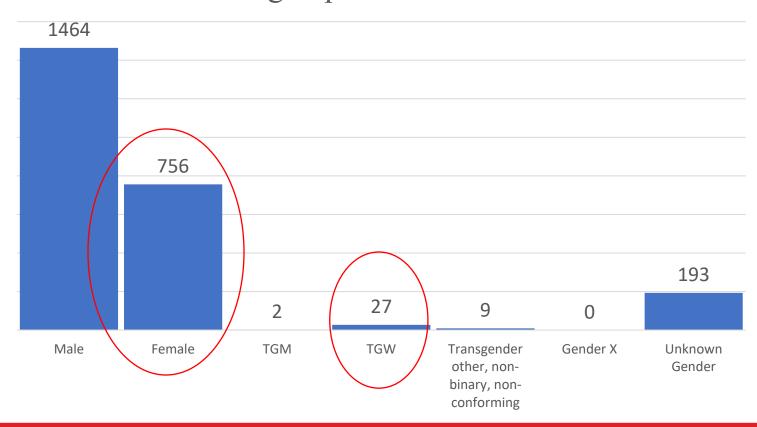


- 34,800 new HIV diagnoses in 2019
- 18% (6,400) were women
- 54% of women with HIV are Black
- Health issues among women
  - Increased cervical cancer risk
  - **OCVD**
  - Perinatal transmission
  - STDs including syphilis
  - HIV and aging

## Women at CHP



#### Gender Subgroups of Active CHP Patients



# Why LA-ART?



aids selling-medications
viremic dysphagia
stigma financial-insecurity
unstable-housing trauma
adherence-struggles busy
absorption-issues

## Women and LA-ART



# A multi-site study of women living with HIV's perceived barriers to, and interest in, long-acting injectable anti-retroviral therapy

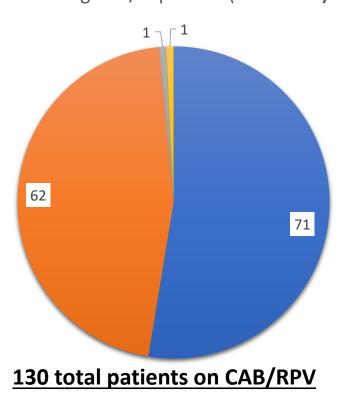
- 2020 study from Philbin et al
- Interviewed 59 women in multiple metropolitan area clinics
- Most endorsed preference for monthly LAI-ART over pills

- Reasons cited
  - Confidentiality
  - Perceived effectiveness
  - Avoiding being reminded of HIV diagnosis
  - Convenient
  - o Pill burden

# Women on LA-ART at CHP: Gender Subgroups



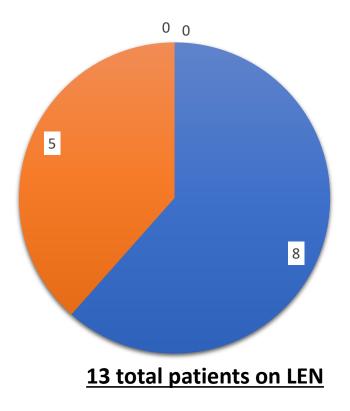
Cabotegravir/Rilpivirine (Cabenuva)



Cabotegravir (Apretude) (Treatment)



Lenacapavir (Sunlenca)



# CHP: Implementation of LA-ART



Patient-provider discussion and shared decisionmaking

Provider review of eligibility

Pharmacy benefits investigation & prior authorization

Schedule first dose visit and delivery of to clinic

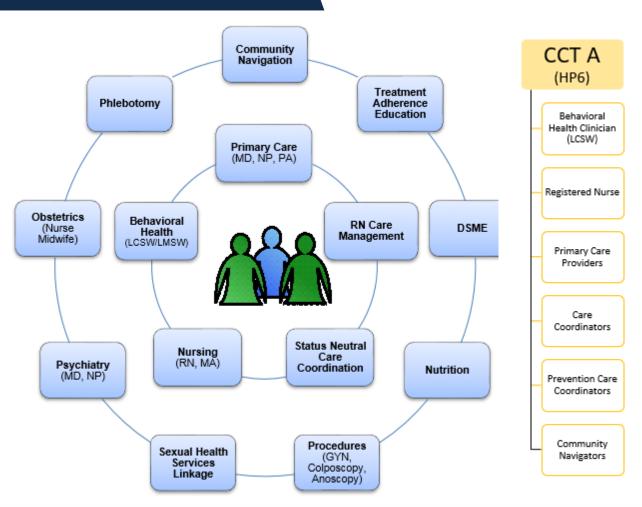
Care coordination of appointment attendance

LA-ART administration by clinical RN RNCM support of future dose scheduling and follow-up

## The CHP: Team Care Model



- PFA
- Medical Assistant
- RN
- Care coordinator
- Social worker
- Pharmacist
- Pharmacy liaisons
- MD and NPs (including psychiatry)
- Community health worker



### **Care Coordination**



- Conduct psychosocial assessments to identify barriers to care
- Create care plans to address patient needs and improve health outcomes
- Enroll patients into suitable programs to support their health navigation
- Assistance for uninsured and under-served patients



## Health Home





- Care Management
- Monthly outreaches for follow up
- Appointment reminders + rescheduling appointments
- Transportation to medical visits
- Follow up with pending referrals or ongoing treatment
- Case conferences between Rx, Medical Team & patient
- Referrals to community resources
- Reduce ED and Inpatient visits

## BHCs + CHWs



#### Behavioral Health Clinician

- BHC (Social Workers) are tasked with supporting patients with their mental health
- By using Problem Solving Therapy, patients are supported with the use of motivational interviewing (MI) to create their own goals
- BHCs collaborate with psychiatry to help address mental health barriers

### Community Health Worker

- CHWs are tasked with supporting patients with health navigation
- CHWs conduct escorts to appointments, home visits and connect patients to community resources
- CHWs complement our Care Teams by being our community footprint

# RN Care Manager



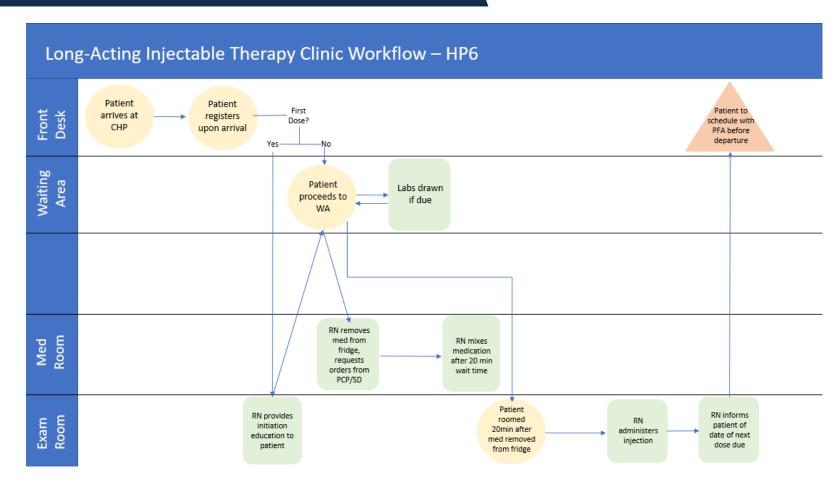
- Interdisciplinary care coordination across multiple settings
- Clinical care team facilitation
  - Monthly review of LA-ART appointments
  - Weekly outreach for missed visits
  - Care coordination and health home support
- Team-based panel management
- Adherence counseling and patient education for LA-ART and chronic comorbidities
- Quality initiatives and grant support
- Transitions of Care



# Nursing



- Day-of workflow
- Obtaining LAI orders
- Medication prep and administration
- First dose education
- Special training in LA-ART administration
- Triaging side effects



### Medical Provider

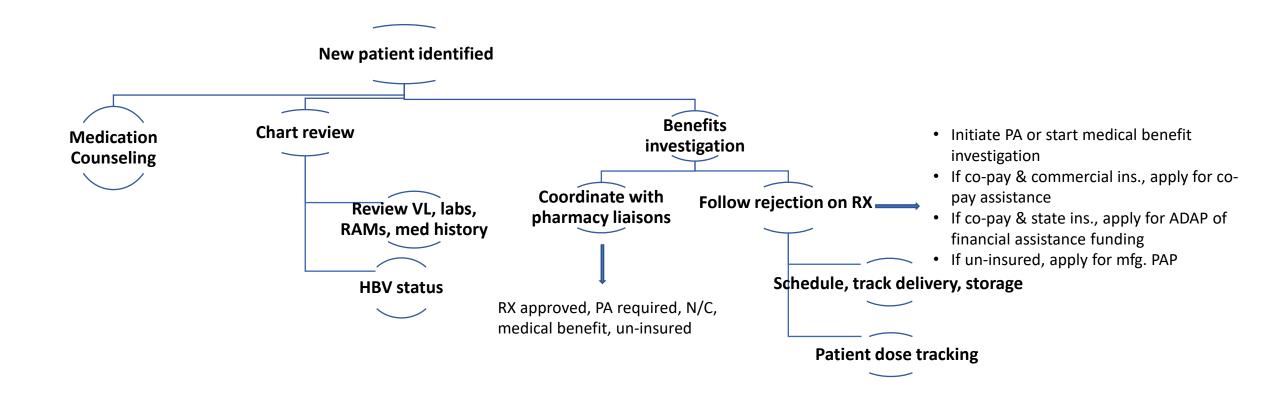


- APP or Physician
- Ideally, has built therapeutic alliance with patient
- Provision of medications, education, counseling

- Evaluate candidacy for LA-ART (review of genotypes, sending genosure archive, hep B status, ensure no contraindications)
- Shared decision making
- Hormonal contraception
- CAB/RPV NOT approved for use in pregnancy

## Pharmacist Role





# Pharmacy vs. Medical Authorizations



#### **Pharmacy Billing Information for Cab/Rpv**

#### **Patient supplied**

Pharmacy Benefit Prior Authorization info:

- ICD-10 Code: Z 21 or B20
- Verify provider information
  - NPI number
  - Ensure provider is registered
- Patient specific clinical information
  - PA might be needed for loading & maintenance
- Comes from pharmacy with a patient-specific label

#### **Medical Billing Information for Cab/Rpv**

**Buy & Bill or Floor-Stock** 

Medical Benefit Prior Authorization info:

CPT Code: 96372

ICD-10 Code: Z 21 or B20

HCPCS Code: J0741

- Verify site information with Tax ID & address
- Verify provider information
  - NPI number
  - Ensure both are in-network
- Patient specific clinical information
  - PA might be needed for loading & maintenance

# Applying the model: Care team roles



РСР	<ul> <li>Shared decision-making</li> <li>Evaluating genotype, eligibility, previous injectable regimen at outside facility</li> </ul>		
Pharmacist	<ul> <li>Facilitated benefits investigation and PA process, medication delivery, set-up dose scheduling for Len/Cab, 1 week post administration follow-up calls</li> </ul>		
Care Coordinator	Intensive support with outreach, transportation, reminders, mobilizing CHWs		
Community Health Worker	Escort to appointments		
RN Care Manager	<ul> <li>Adherence support</li> <li>Care team coordination, weekly case conferencing, monthly appointment audits</li> </ul>		
SW/BHC	<ul> <li>Psychotherapy and pharmacologic treatment for depression</li> <li>Trauma-informed approach</li> </ul>		
Clinical RN	• First dose education, medication prep/administration, evaluate needle size, triage any side effects & defer to provider &/or pharmacist if needed		
Medical Assistant	Support with rooming, lab work, emotional support		
PFA	•Verify accurate insurance information, register patient for RN or provider visits, relay messages from patient calls, scheduling appointments		

# Back to our case: how things are going



- Started on CAB/RPV monthly → given resistance issues and persistent viremia added on LEN q6m as well
- VL <20 (6/3/24)
- CD4 1 $\rightarrow$  559 (6/3/24)
- Normalized BMI
- Regular mental health engagement
- No overdue or missed injections
- Rarely misses MD visits
- Preconception counseling

# Informational Pamphlet



## Is Cabenuva right for me?

I am undetectable or could become undetectable.

I am comfortable coming to the clinic once a month for the first 6 months of treatment.

I do not have resistance to cabotegravir, rilpivirine or a related HIV medication.

I do not have plans to travel away from NYC for more than 2 months at a time.

I am comfortable with needles and will not mind 2 injections at each visit.

I have no plans to breastfeed while on treatment.

I do not have liver problems, including a history of hepatitis B treatment or infection. Ask your provider about any history of hepatitis B or need for hepatitis B vaccination.



Your doctor will also need to do blood tests and look at your medical history to make sure Cabenuva is a good treatment option for you.

#### What are the side effects?

Most side effects are mild, and very few people stop taking Cabenuva because of them.

#### Common side effects:

Pain, swelling, redness and bump at injection site

#### Less common side effects:

Fever, headache, nausea, sleep problems, tiredness, muscle pain, dizziness, rash

#### Ready to start?



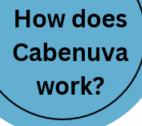
We are committed to helping you become or stay undetectable.

We will work with you to find out if Cabenuva is covered by your insurance or could be covered through a patient assistance program.

Call the CHP clinic at (212) 305-3174 to set up an appointment with your healthcare provider to see if Cabenuva will be a good fit.

Supported by the Health Resources and Services Administration (HR84) and the Minority HIWAIDS Fund of the U.S. Department of Health and Human Services (HHB) as part of an award totaling \$7,000,000.

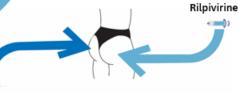




Cabenuva works by stopping HIV from making copies of itself.

It contains 2 HIV medicines, **cabotegravir** and **rilpivirine**.

These 2 medicines are given as 2 shots, one in each butt cheek



Cabotegravir

Injections are given every 4 weeks. It is important to attend every injection visit on time so that your drug levels are high enough to keep HIV from making copies of itself in your body.

Some patients may be able to switch to an <u>8 week</u> injection schedule. Talk to your provider about what injection schedule will work best for you.

Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	Received 4 Injection	s	6	7
			H27770			
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	21
29	30	31	Target 1 Injection Date	2	3	
S	6	7	8	9	10	11

#### Sample injection schedule

If you get an injection on the 4th of the month, your next injection will be scheduled for 4 weeks later (target injection date).

You can schedule the next injection up to 7 days before or after the target injection date (any of the days shaded in blue).

## How is Cabenuva different?

#### Cabenuva



- Come to the clinic in person for injections 4 weeks or 8 weeks apart.
- Receive an injection in each butt cheek at every visit.

#### Other HIV Treatment



 Take one or more pills by mouth every day.

# Focus Groups



- 1) Focus Group #1
  - Initial feedback during pamphlet development
- 2) Focus Group # 2
  - Ongoing engagement interdisciplinary discussion with
     50+ program participants

# Addressing Interpersonal Violence (IPV)



- Women experiencing IPV have higher rates of suboptimal ART adherence, unstable housing, missed appointments, unsuppressed VLs
- RW Part C Grant for IPV screening
- RWHAP Part D WICY Community of Practice Trauma-Informed Care and Behavioral Health
- Stigma reduction, increased independence, empowerment through shared decision-making
- Apretude and Lenacapavir\* as PrEP options

<sup>\*</sup>under review

## Case 2



- 35 year-old Black transgender woman (VL >500,000copies/mL; CD4 270/16%)
- Non-adherent to oral meds
  - o ~3 months
- Psychosocial factors
  - Cycles in & out of care
  - History of trauma
  - History of depression
  - Reports mood instability
  - Multiple partners (WSM & WSW)

- Seeks appointment to re-engage into HIV care
- Inquires about treatment options
  - Unstable on current regimen but eager to start alternative option

# Transgender women with HIV



- Per CDC- 2019, transgender individuals made up 2% of new diagnoses
- 14% of TGW are HIV positive
- New diagnoses increased by 9% from 2015-2019
- Face unique systemic issues surrounding stigma, isolation, mental health struggles, systemic racism, access difficulties, unstable housing
- Lower rates of HIV suppression compared to cisgender individuals

# LAI among TGW



Transgender Women's Barriers, Facilitators, and Preferences on Tailored Injection Delivery Strategies to Administer Long-Acting Injectable Cabotegravir (CAB-LA) for HIV Pre-exposure Prophylaxis (PrEP)

- Interviews among 15 transgender women in NYC
- Theme of need for multiple delivery systems including injection drop in sites or self-injection

Tagliaferri Rael et al. AIDS Behavior. 2021

# Note about LA-ART in individuals with implants



- As of now, CAB-RPV is approved for gluteal intramuscular administration
- Gluteal implants X contraindication
- Small implementation study from Viiv→ lateral thigh injections

#### Case 2



- A few months after established care, she inquires about LAi option
- VL 200,000 copies/mL; CD4 370/16%
- No history of resistance
- No history of Ols
- HBV Immune
- BMI 30

# Applying the model: Care team roles



РСР	<ul> <li>Education on LA-ART as possible option, shared decision-making, evaluation</li> <li>Gender affirming care and referral for gender affirming surgeries/procedures</li> </ul>
Pharmacist	Facilitated benefits investigation and PA process, medication delivery coordination and next-dose tracking
Care Coordinator	• Intensive support with outreach, transportation, reminders, mobilizing CHWs
Community Health Worker	Escort to appointments
RN Care Manager	<ul> <li>Adherence counseling</li> <li>Care team coordination, weekly case conferencing, monthly appointment audits</li> </ul>
SW/BHC	<ul> <li>Psychotherapy and pharmacologic treatment for depression/anxiety</li> <li>Resuming psych appointments</li> </ul>
Clinical RN	• First dose education, medication prep/administration, evaluate needle size, triage any side effects
Medical Assistant	Support with rooming, lab work, emotional support
PFA	•Verify accurate insurance information, register patient for RN or provider visits, relay messages from patient calls, scheduling appointments

### How's it going?



- Initiated on LAi while viremic
  - OQ4 weeks
  - Tolerating well
- Maintains timely injectable appointments
- 3 months post VL <50copies/mL</li>

\*\*Moving out of state & unclear if will continue injectable therapy

### Issues Identified: Follow-up



- Spring 2023 QA evaluation showed 24% of LA-ART treatment patients had no follow-up visit scheduled
- RNCM monthly appointment audit for 100% appt scheduling
- Monthly team conferences
- Ongoing CM/CC and pharmacist support for missed visits

## Implementation Lessons <a href="Learned and Barriers Identified">Learned and Barriers Identified</a>



#### Pitfalls

- Follow-up issues (scheduling, no-shows, communication issues)
- Insurance and coverage/funding
- Different EMRs and systems
- Gaps in knowledge
- Transportation
- Travel and moving (eg out of state), housing instability
  - Not necessarily transferrable outside of NY state
- Factors such as substance use, mental health, difficulty contacting patients
- Drug Resistance

#### Possible Solutions

- RN care management and care team meetings
- Pharmacy liaisons
- Compass Rose
- Cell phone provision
- Off-label use of CAB +LEN

# Next Steps and Ongoing Questions



- MMU utilization for LA-ART administration in community
- EMR developments > "therapy plans" in Epic for better clinical management of injection schedules
- Additional research
  - Off-label uses- need for RCTs (eg LATITUDE)
  - Qualitative research focus groups, in-depth interviews
- Peer education opportunities, especially with youth

### Acknowledgements



- HRSA and Ryan White Foundation
- Ryan White Parts C and D
- SPNS Grant
- Comprehensive Health Program Team

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#### Post-Presentation Questions



- What are some successful strategies for implementing LA-ART among cis/transgender women?
- Name three ways cis/transgender women can benefit from engagement in LA-ART options.
- What are three lessons learned from the rollout of LA-ART in this setting?
- How does a multidisciplinary team benefit the implementation of an LA-ART program such as this one?





# The Design, Implementation, and Expansion of a Long Acting Injectable (LAI) Program at a Large, University Based HIV Clinic

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### Learning Objectives



At the conclusion of this activity, participants will be able to:

- 1. Define the components used to design and implement a sustainable long acting injectable (LAI) program
- 2. Outline and define the roles of the key staff necessary to implement an LAI program
- Compare and contrast differences in design and implementation of an LAI program based on organizational barriers, staff matrix, and program goals





Largest Ryan White-funded HIV clinic in the state Annually, provides HIV primary care to over 2,300 people with HIV (PWH)

Patients served reside in 67 of 82 Mississippi counties

Patient cohort is predominantly Black/African American (85.7%) Nearly all (91.7%) fall at or below 200% of the federal poverty level (FPL)

#### Timeline



#### PHASE 1

2019

CUSTOMIZE trial initiated; UMMC designated a research site with approximately 15 patients

5 enrollees were ASCC patients

Q

#### March 2021

All patients in CUSTOMIZE trial transitioned to oral or commercially available CABENUVA



March 2022

ADAP added CABENUVA to formulary

ASCC maintained 10 of CUSTOMIZE partcipants and added 3 additional

FDA approves CABENUVA

January 2021

ASCC met with ADAP to provide training and discuss future plans

October 2021

ASCC added 30 additional patients for total of 43

March 2022- June 2022

#### Timeline continued





All aspects of CABENUVA therapy transitioned to medical case management (MCM) program



December 2022

Created CABENUVA MCM role

PHASE 4

#### PHASE 3

Additional 39 patients added (total 82)

June 2022- December 2022

Added additional CABENUVA MCM
11 total SUNLENCA patients

173 total CABENUVA patients

October 2023

# Phase 1: Ensuring access for research study participants



- 2019- March 2021
  - UMMC was a research site for CUSTOMIZE
  - CUSTOMIZE trial ended with a target date of transition of trial participants back to either oral therapy or commercially available CABENUVA by March 2021
  - CUSTOMIZE trial consisted of 5 ASCC patients & 10 from RWHAP from around the state
- October 2021
  - ASCC leadership and JMM Specialty pharmacist met with ADAP pharmacy leadership to provide education and training as well as discuss future plans once ADAP obtained access to CABENUVA and CABENUVA was added to the formulary
- October 2021- March 2022
  - ASCC maintained 10 of the CUSTOMIZE trial participants on CABENUVA and added 3 additional

## Barriers During Phase 1 October 2021- March 2022



ADAP did not have CABENUVA on formulary ADAP pharmacists were unsure how to gain access to CABENUVA through various mechanisms

Commercial pharmacy prescription benefit managers (PBMs) were not approving CABENUVA

Preauthorization approval process was unclear

No other clinics had the infrastructure to administer CABENUVA

JMM pharmacy had one specialty pharmacist and one pharmacy tech

# Phase 2: New enrollments, managed by JMM pharmacy staff



- March 21, 2022
  - ADAP approved CABENUVA on formular
- March 2022- June 2022
  - ASCC added 30 additional CABENUVA patients (total of 43)

#### Phase 3: Transitioned to MCM



- June 2022
  - Transition of responsibility of all management aspects of CABENUVA for majority of patients was transitioned to medical case management program
- June 2022- December 2022
  - Added an additional 39 patients (total 82)
  - MCM no longer able to manage growing program

### MCMs had 350-400 active patient load Expectations for monitoring included:

- Ordering lead in for all new starts
- Completing benefits investigations with ViiV and prior authorizations for non-specialty pharmacy patients (ADAP/out of network coverage)
- Proactive monitoring: scheduling, follow up, tracing, etc.

### Phase 4: Introduction of CABENUVA MCM



- December 2022
  - Added initial CABENUVA MCM (RN)

- October 2023
  - Added additional CABENUVA MCM (LPN)

#### Current program



Provider makes referral to Cabenuva MCM after careful consideration and patient approval

MCM reviews labs history, previous medications taken, compliance history, and identifies barriers to further assess if Cabenuva is appropriate therapy.

Complete benefits investigations with ViiV and prior authorizations for non-specialty pharmacy patients.

Initiate relationship with patient, discuss
LAI medication and Ses, expectations,
transportation barriers, lab monitoring,
preferred communication

### Current program continued



Proactive monitoring: followup appt scheduling, tracking of appt/labs, phone call follow-up after initial injections Maintain inventory list for LAI, maintain reminder list in Epic, monitor for cancellations or changes in appts, monitor Cabenuva cellphone for patient communications

Administration of all long acting injectables (LAI)

Schedule injections to coincide with provider visits if possible

#### Current cohort



- Total (active)174
- Total (previous) 34
- Total: 208
  - Includes 9 on salvage regimen of Cabenuva + Sunlenca

#### The ASCC Difference



Position preference for patient

Distraction with 2 dumdum lollipops with a smile and thanking them for coming

Time allowed for questions or concerns

Open communication encouraged

Flexibility to meet patient needs

Inpatient and at home injections



#### Lessons Learned



- Organization is key!
- Promote patient involvement
- Open communication
- Continued education
- Side effects
- Post injection instructions

- BMI alters the use of needle size
- Encourage patient input on preferences on position and injection location

### Q & A



#### References



• Czarnogorski M, Garris CP, Dalessandro M, D'Amico R, Nwafor T, Williams W, Merrill D, Wang Y, Stassek L, Wohlfeiler MB, Sinclair GI, Mena LA, Thedinger B, Flamm JA, Benson P, Spreen WR. Perspectives of healthcare providers on implementation of long-acting cabotegravir plus rilpivirine in US healthcare settings from a Hybrid III Implementation-effectiveness study (CUSTOMIZE). J Int AIDS Soc. 2022 Sep;25(9):e26003. doi: 10.1002/jia2.26003. PMID: 36094142; PMCID: PMC9465974.

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