

Assessing Perceptions and Preferences around Long-acting Injectables (APPLI)

— an Academic-Government-Provider Partnership
Supporting Equitable Treatment Access

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Disclosures

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Learning Objectives

1. Recognize how implementation science can be used to avoid missed opportunities for health equity in relation to biomedical advances
2. Identify points of commonality and of difference in client and provider perceptions of long-acting injectable (LAI) antiretroviral therapy (ART), based on the focus group findings presented
3. Discuss how discrete choice experiments (DCEs) can be used to gain insight into preferences between treatment options and stronger versus weaker influences on decision-making about those options, and ultimately to optimize engagement in treatment interventions

- Presentation is structured to highlight key areas of work (Aims) under the APPLI grant collaboration, framed with an opening and a closing section

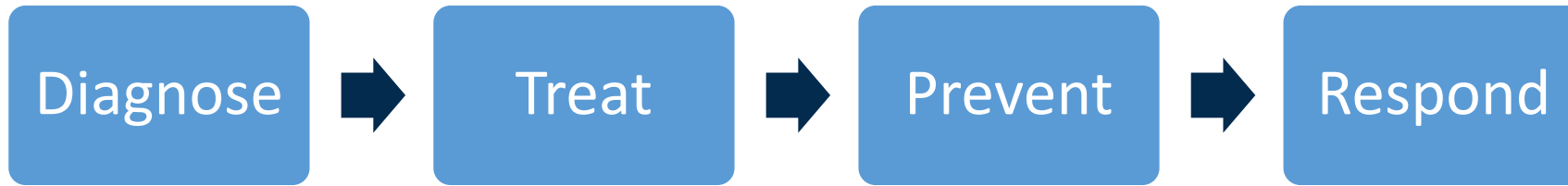
Sections:

- Introduction
- Aim 1 - Focus Groups
- Aim 2 - Discrete Choice Experiment Surveys
- Aim 3 - Preliminary Work on Strategies to Support LAI ART
- Next Steps & Discussion

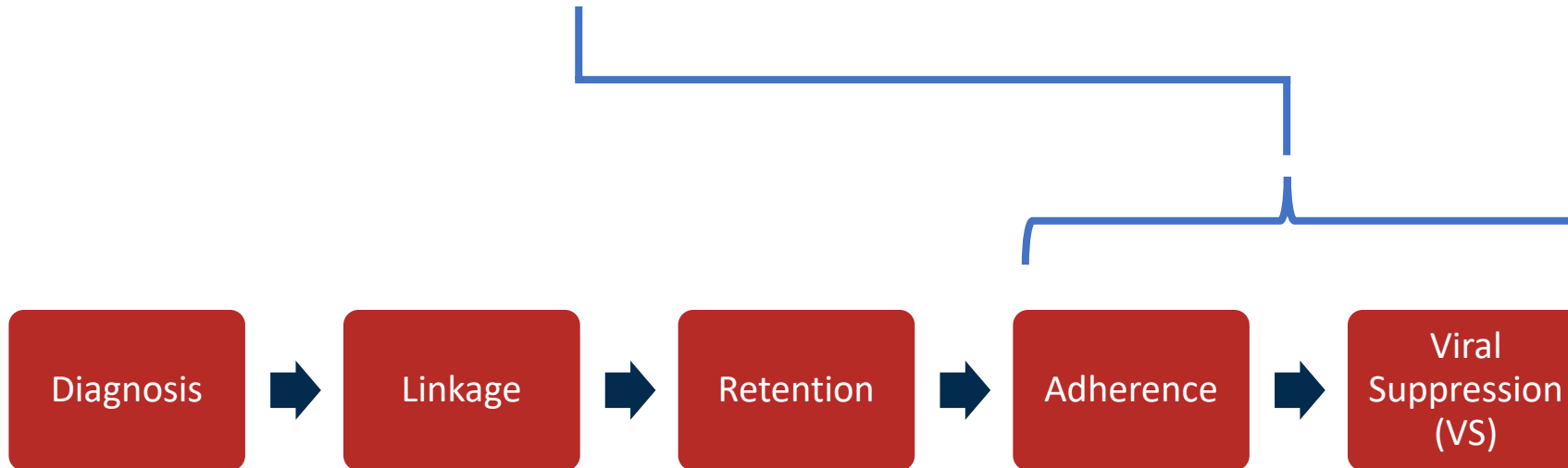
Introduction

Project Context, Intent and Aims

Background



Pillars of the Ending the HIV Epidemic Plan



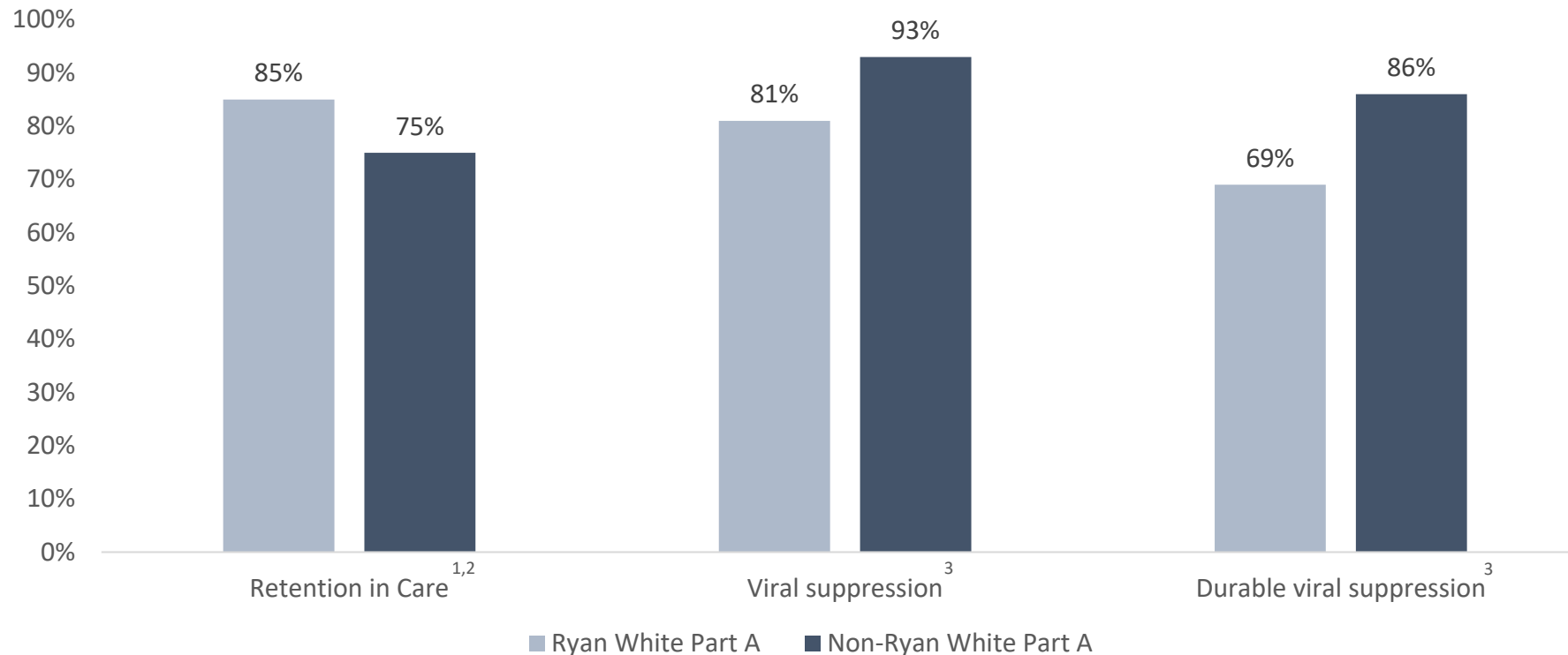
The HIV Care Continuum

Background (Cont'd)

- Long-acting injectable (LAI) ART shifts adherence from a *daily* task for people with HIV (PWH) to a task to be completed *every 1-2 months*.
- Phase 3 trials of long-acting injectable (LAI) ART showed comparable safety and efficacy to daily oral ART and higher patient satisfaction.
- FDA approved the 1st (monthly) LAI ART regimen in January 2021, and approved a bimonthly LAI ART regimen by February 2022

HIV Care & VS Among PWH in NYC, by Ryan White Part A Client Status

Ryan White Part A (RWPA) vs non-RWPA retention in care and viral load outcomes, 2020



¹Among PWH who are in care in NYC (defined as having any laboratory evidence of NYC HIV care between January 1, 2015 and December 31, 2019)

²Retention in care: having at least one viral load test reported in calendar year 2020

³Among those retained in care in calendar year 2020

Implementation Science

- Addresses gap between evidence on interventions’ efficacy and their adoption and use among those who may benefit in the ‘real world’¹
 - e.g., COVID-19 vaccines, PrEP
- Focuses on the ‘how and why’ of evidence-based interventions’ adoption, implementation and sustainment in practice.
 - e.g., factors at the level of the system, organization, provider, intervention...
- Informs “the use of strategies to introduce or change evidence-based health interventions within specific settings”²
 - with input from the people participating in those service settings

¹CUNY ISPH Implementation Science Toolkit (<https://cunyisph.org/isph-toolkit/>)

²Proctor et al., Administration and Policy in Mental Health. 2009 36(1). doi: 1007/s10488-008-0197-4

APPLI (Assessing Perceptions & Preferences around Long-acting Injectables)

Purpose

- Inform strategies for delivery and support of LAI ART in Ryan White HIV/AIDS Program Part A (RWPA) settings

Premise

- LAI ART may be a game-changer, but only if it reaches those who most need alternatives to daily oral ART

Partnership

- APPLI is an **academic-government-provider** collaboration, using an implementation science framework

APPLI Aims

- 1. Elicit perceptions, barriers/facilitators and expectations** of LAI versus daily oral ART delivery options, in six focus groups
- 2. Quantify preferences** and drivers of engagement in ART delivery and support strategies, including options for LAI and daily oral ART, via discrete choice experiments (DCEs) with patients & providers
- 3. Select and pilot strategies** to promote LAI uptake, adherence and impact in real-world HIV care settings.

Aim 1

Focus Groups

Focus Group Objectives

- Gather initial feedback to identify issues to be addressed through the rest of the project, including:
 - general awareness and current perceptions about LAI ART
 - acceptability of LAI ART
 - barriers/facilitators for implementation
- Inform the design of the Discrete Choice Experiments (DCEs)

Focus Group Recruitment

- **Process:** 6 partnering medical case management (MCM) sites referred clients
- **Eligibility**
 - MCM clients (aged 18+, virally *unsuppressed*, able to converse in English or Spanish)
 - MCM direct service providers, administrators, and prescribing providers
- **Sample:** 16 providers, 5 clients
 - Clients identified as Black women, and ranged in age from their 20s to 60+ years of age
 - Providers identified as Latino/a (44%), White (25%), Black (12.5%), Asian (12.5%), or Mixed-race (6%), and represented three gender groups (75% women)
 - Providers ranged in age from their 20s to 60+ years of age; 44% were in their 30s

RESULTS - Acceptability & Readiness: Advantages

*Advantages
compared to
oral regimen*

CLIENTS

- Not having the daily risk of forgetting to take ART
- Makes HIV seem less scary and more manageable

- Not having to take pills daily
- Less stigma

PROVIDERS

- Accessibility, if they can get the shot with their existing provider
- More discreet and private than pills
- Treatment method isn't vulnerable to theft or temptation/coercion to be sold
- *Unlikely to have interactions with other drugs*
- *Level of adherence would be more straightforward*

Key: Capsule-shaped area of overlap in center represents responses shared by clients and providers.
Italicized text indicates a response solely from the prescribing provider.

RESULTS - Acceptability & Readiness: Disadvantages

CLIENTS

- Potential side effects

- Dislike or fear of needles
- Pain at injection site
- Apprehension about intramuscular shots in buttocks

PROVIDERS

- Can't just refill medication if client misses appointment
- Client can't "stop taking" the drug in the course of the month if they're having negative side effects
- *Can't give Rilpivirine to people with high viral load*
- *Can't give Rilpivirine to people with Hep B infection*
- *LAI appointments can't be done via telemedicine*

Disadvantages compared to oral regimen

RESULTS - Acceptability & Readiness: Barriers

*Potential
barriers to
starting and
staying on
LAI regimen*

CLIENTS

- Doubt and fear about the product itself and tolerability
- Feelings about the COVID vaccine reducing willingness to get an injection

- Fear of the unknown
- COVID vaccine hesitancy
- Trouble getting insurance to approve

PROVIDERS

- Hesitancy because it's such a new treatment
- Perception of being treated as guinea pigs
- Misinformation about LAIs, including the idea that it's a vaccine
- Concerns about adherence
- Difficulty of tracking down people who are lost to care (esp. in the pandemic)

RESULTS - Acceptability & Readiness: Facilitators

*Potential
facilitators
for starting
and staying
on LAI
regimen*

CLIENTS

- Low copays

- Certainty that insurance will cover/continue to cover it
- Reminder texts and calls
- Less frequent injections (e.g., every 2 months)

PROVIDERS

- Linking clients to sources they trust
- Peer support from someone on LAI ART
- Convenient and fast appointments
- Post-appointment communication
 - Rapid follow-up with client
 - Frequent check-ins to see how they're feeling post-injection

RESULTS - Acceptability & Readiness: Levels of Acceptability

What could facilitate greater acceptability?

CLIENTS

- Learning more!

- Getting questions answered
- Clarity on frequency of injections

PROVIDERS

- Seeing a study on individuals who were virally unsuppressed at baseline
- Studies that test on a range of ages, ethnicities, genders
 - People going through/post-menopause
 - Pregnant people and babies exposed in pregnancy
- *More clarity about drug resistance and timing of labs*
- *Unified messaging for providers*

RESULTS - Implementation Considerations & Agency Readiness: Facilitators & Barriers

FACILITATORS

- Experience in treating clients with different regimens
- Experience with trauma-informed care
- Rapport with clients, facilitating open conversations about LAI ART
- Requirement for clients who are unsuppressed to come in monthly (current practice for at least one agency)
- Appointment scheduling/rescheduling mechanisms
 - MCM programs tend to have direct lines of communication with medical providers
- Transportation assistance and accompaniment services already in place

BARRIERS

- Current nursing shortage, due to COVID
- *Existing case management is good but understaffed*

RESULTS - Implementation Considerations & Agency Readiness: MCM Components

Home Visits

- Option of at-home injection would be helpful for some
- Potential involvement of home health attendants

- Some clients wouldn't be comfortable with home visits
- Wouldn't be feasible for some agencies, who would need to hire a new staff person to carry it out

Drop-In Hours

- At least one clinic already allows informal drop-ins

- At least one organization is operating under stricter scheduling protocols because of COVID
- Not feasible for one FQHC due to quantity and types of clients
- Not compatible with hospital security protocols

Incentives

- Incentives could be a helpful tool for appointment adherence

- Not feasible right now for all agencies
- Some providers are opposed to incentives, but acknowledge that helping with transportation and childcare is very helpful

RESULTS - Providers' Closing Thoughts

MCM PROVIDERS

- Will be life-changing for some
- Will be empowering for clients to have another treatment option
- Needs to be offered to those who can benefit most
- Would be more meaningful for this population if/when changes are made

PRESCRIBING PROVIDER

- Will be more enthusiastic to prescribe once approved for administration every 2 months*
- Looks forward to future innovations that can be administered even less frequently

* Focus groups occurred in fall 2021, prior to FDA approval of bi-monthly LAI ART regimen

Aim 2









Discrete Choice Experiment Surveys

Discrete Choice Experiments (DCEs)

- Discrete Choice Experiments (DCEs) measure preferences.
- Participants are presented with combinations of pre-defined features of a product or service and choose which combination they like best as a whole. This is called a *choice task*.
- The combinations are made up of attributes, each with multiple levels.
- By looking at patterns of choices that participants make, we can identify specific program features (aka levels) participants prefer.

Imagine that you had to choose between two treatment options with the features below. Select the one you would prefer.

(3 of 10)









	Option A	Option B
ART delivery mode	 An ART medication injection in each buttock once a month	 Daily oral ART pill(s)
Service location and mode	 Walk-in for injections at clinic	 Pick up pills at program site
Rewards	 \$20 gift card for every injection visit in the right window	 \$35 gift card for viral suppression every 6 months
Support	 Peer support group for clients on or considering long-acting injectable ART	 Calls and texts to remind about taking pills
	<input type="button" value="Select"/>	<input type="button" value="Select"/>

Example from APPLI DCE pilot
 Black and white icons from The Noun Project

Ice Cream Example

Choice task 1

Which option do you prefer?









Option A	Option B
<p>Ice cream flavor</p>  Vanilla	<p>Ice cream flavor</p>  Chocolate
<p>Cone or cup</p>  Cone	<p>Cone or cup</p>  Cup
<p>Toppings</p>  Sprinkles	<p>Toppings</p>  Nuts
<p>Size</p>  Large	<p>Size</p>  Small
<input type="button" value="Select"/>	<input type="button" value="Select"/>

Attributes	Levels
Flavor	Vanilla Chocolate
Container	Cone Cup
Toppings	Sprinkles Nuts
Size	Small Large

Ice Cream Example (Cont'd)









Choice task 2

Which option do you prefer?

Option A	Option B
Ice cream flavor  Vanilla	Ice cream flavor  Chocolate
Cone or cup  Cup	Cone or cup  Cone
Toppings  Sprinkles	Toppings  Sprinkles
Size  Large	Size  Large
<input type="button" value="Select"/>	<input type="button" value="Select"/>

Choice task 3

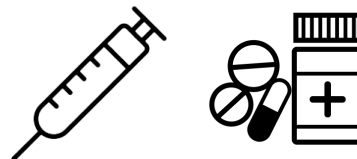
Which option do you prefer?

Option A	Option B
Ice cream flavor  Vanilla	Ice cream flavor  Vanilla
Cone or cup  Cone	Cone or cup  Cup
Toppings  Sprinkles	Toppings  Nuts
Size  Small	Size  Large
<input type="button" value="Select"/>	<input type="button" value="Select"/>

DCE Attributes and Levels

Attribute	Levels
Type of ART Medication	An ART injection in each buttock once a month
Type of ART Medication	An ART injection in each buttock once every <u>two</u> months
Type of ART Medication	Daily oral ART pill(s)

Helper Images



DCE Attributes and Levels 2

Attribute	Levels
Service location and mode	[Injection] Injections by appointment at clinic
Service location and mode	[Injection] Walk-in for injections at clinic with no appointment required
Service location and mode	[Injection] Injections by appointment at home
Service location and mode	[Pills] ART pills delivered to home
Service location and mode	[Pills] ART pills pickup from a pharmacy or other non-program location
Service location and mode	[Pills] ART pills pickup from program location

Helper Images



DCE Attributes and Levels 3

Attribute	Levels
Support	[Injection] Calls and texts to remind about injection appointments
Support	[Injection] Free transportation provided to get injections
Support	[Injection] Post-injection follow-up calls from program staff
Support	[Injection] Peer support group for clients on or considering long-acting injectable ART
Support	[Pills] Calls and texts to remind about taking ART pills
Support	[Pills] Free transportation provided to primary care appointments
Support	[Pills] Peer support group to help with ART pill adherence

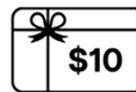
Helper Images



DCE Attributes and Levels 4

Attribute	Levels
Rewards	[Injection] \$10 gift card for every injection visit in the right time frame
Rewards	[Injection] \$20 gift card for every injection visit in the right time frame
Rewards	[Pills] \$35 gift card every 6 months for having undetectable or suppressed viral load
Rewards	[Pills] \$70 gift card every 6 months for having undetectable or suppressed viral load
Rewards	[All] Rewards ceremony with program staff to celebrate meeting treatment goals

Helper Images



Acceptability of Intervention Measure (AIM)[†]

1. LAI ART meets my approval.
2. LAI ART is appealing to me.
3. I like LAI ART.
4. I welcome LAI ART.

Intervention Appropriateness Measure (IAM)

1. LAI ART seems fitting.
2. LAI ART seems suitable.
3. LAI ART seems applicable.
4. LAI ART seems like a good match.

Feasibility of Intervention Measure (FIM)

1. LAI ART seems implementable.
2. LAI ART seems possible.
3. LAI ART seems doable.
4. LAI ART seems easy to use.

[†]The AIM is included in both the Client and the Provider survey.

*All items are assessed on a 5-point rating scale from “completely disagree” to “completely agree”

- Six vignettes, like case studies, of medical case management clients varying across several dimensions:
 - Age
 - Gender
 - History of infection, viral suppression, and adherence to oral ART
 - Distance to primary care and/or medical case management
 - Other lifestyle dimensions
- Designed to understand how providers weigh specific client factors in deciding for whom LAI ART would be appropriate or beneficial

Sample Vignette

Desirée, a **53-year-old married cisgender woman**, has been **virally suppressed for most of the past 20 years**, but recently **started missing doses of her ART**. When her stepson moved out a few years ago, she and her husband moved into a smaller apartment about a **30-minute drive** from her community-based MCM program and affiliated clinic.

Her husband, who drives her to her appointments, has told her case manager and her primary care provider that Desirée has been **increasingly forgetful** and “scattered,” and he thinks it might be time to consider LAI ART for her.

Client DCE Data Collection

- Online survey designed to be self-administered in English and Spanish with demo videos and the sample ice cream task
- Pilot testing April – May 2022 (N=10)
- LIVE survey deployment June – September 2022 (N=200)
- Eligibility: 18+, enrolled in RWPA MCM at any of the six partner sites
- \$25 incentive

Provider DCE Data Collection

- Online survey designed to be self-administered in English, with demo videos and the sample ice cream task
- Pilot testing June 2022
- LIVE survey deployment July – September 2022 (N=200)
- Eligibility: MCM staff and prescribing providers at any of the 29 RWPA MCM provider agencies in the New York eligible metropolitan area
- \$25 incentive

Aim 3 (Preliminary Work)

APPLI Patient-Provider Decision Making Tool and Planning for Future Implementation

Background: MCM Current Adherence Support

- Self-management assessments
 - Client and provider tools to evaluate client's HIV self-management skills
- Care plans
 - Semi-annual plans used to set goals for client and ensure collaboration between care team and client
- Modified Directly Observed Therapy (mDOT)
 - Directly observing client administer treatment
- Health education
 - One-on-one or group sessions covering one or more health topics in response to client needs

APPLI Patient-Provider Decision-making Tool

- Drawing upon the results of the focus groups and DCEs, this tool will assist clients and providers with discussions of ART-related options
- This client-centered tool is meant to assess individual needs, resources, interests and challenges with regard to ART use/adherence
- The tool will guide and document ART regimen and service selections

Preliminary Development of Decision-making Tool

- Performed a literature review on patient-provider tools used in healthcare settings
- Adapted Ottawa Hospital Research Institute template

[Should I Take [Option 1] For My [Health Condition]??]
 A decision aid to discuss options with your [insert health care professional (HCP) such as doctor, nurse, clinician, etc]

- This decision aid is for you if:**
- [Your HCP says you have health condition]
 - [Your HCP has offered option 1 to help your condition]
 - [additional inclusion criteria]

What is [health condition]?
 [2-3 sentences describing the health condition]

What is [option 1]?
 [2-3 sentences describing option 1, rationale for taking it, possible drawbacks]

- What are your options?**
- [icon for option 1] **[option 1]**. [brief description of option]
- [icon for decline option 1] Decline **[option 1]** and discuss other options with your HCP

What other health factors may affect your choice?
 Check any that apply and discuss your concerns with your HCP.

<input type="checkbox"/> [health condition]	<input type="checkbox"/> [health condition]
<input type="checkbox"/> [allergy]	<input type="checkbox"/> [health condition]
<input type="checkbox"/> [health condition]	<input type="checkbox"/> Other
<input type="checkbox"/> None of these apply to me	

Preliminary Development of Decision-making Tool (Cont'd)

- Motivational interviewing model:
 - Open-ended questions
 - Affirming statements
 - Reflection
 - Summary

Should I start long-acting injectable (LAI) ART?

A decision aid to discuss options with your health care provider

This decision aid is for you if:

- You are seeking to decide which ART regimen is right for you
- You would like to learn more about LAI ART
- You would like to learn more about the pros and cons of daily oral ART regimen and LAI ART regimens

What is long-acting injectable (LAI) ART?

[2-3 sentences describing option 1, rationale for taking it, possible drawbacks]

Points to highlight:

- Monthly or bimonthly treatment administered by a healthcare professional through two intramuscular injections
- Just as effective as daily oral regimen
- Approved by FDA
-

+ What are your options?



LAI ART: Monthly or bimonthly treatment administered by a healthcare professional through two intramuscular injections



Daily oral regimen: Daily pill-based treatment administered by patient

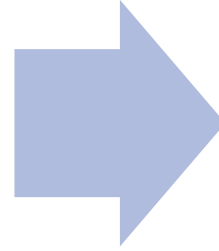
Potential Future Use in MCM Program Model

- Integrate into comprehensive baseline assessment & initial care plan
- Use in semi-annual updates to care plans & ongoing decision-making
- Support the new tool with health education (already in MCM model), integrating the latest LAI ART information available

Next Steps

Fall 2022

- Community feedback session with HIV Planning Council
- DCE data collection completion
- DCE data analyses
- Advisory Board meeting/selection of strategies to pilot
- Refinements to decision-making tool



January 2023-
September 2023

- Pilot test at six partner agencies
- Refinements to LAI ART support strategies based on pilot experience

- Role of RWPA MCM
 - Foundation for building access to and success with new treatment advances
 - Can expand treatment options by stabilizing life circumstances and health
- Role of IS
 - Avoid the pattern: **hot** new biomedical intervention → **lukewarm** reception (or greatest uptake among populations with lowest need/most resources)
 - Maximize adoption, reach and impact
- What would you want in a patient-provider decision-making tool?
- How can we ensure our work is relevant to other jurisdictions?

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 - SUNY Downstate/Brookdale STAR program
 - Council on Adoptable Children
 - La Casa de Salud
 - Open Door Family Medical Centers
 - TOUCH
 - Sun River Health



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