

**Title Page**

**Full Title:** What Matters Most for Long-Acting Antiretroviral Therapy? A Best-Worst Scaling Discrete Choice Experiment

**Authors & Affiliations:**

Rebecca J Fisk-Hoffman, MPH, Department of Epidemiology, College of Public Health and Health Professions & College of Medicine, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-2421-2601 (Corresponding author, [rfisk@ufl.edu](mailto:rfisk@ufl.edu), 2004 Mowry Road Gainesville, FL 32610, phone: 352-273-5468, fax: 352-273-5365)

Yiyang Liu, PhD MPH, Department of Epidemiology, College of Public Health and Health Professions, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-5519-3853

Charurut Somboonwit, MD, Department of Internal Medicine, USF Health, University of South Florida, Tampa, Florida, USA

Maya Widmeyer, MD, Unconditional Love Incorporated, Melbourne, Florida, USA

Lori A Bilello, PhD, UF College of Medicine-Jacksonville, University of Florida, Jacksonville, Florida, USA

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Colby Cohen, MPH, HIV/AIDS Section, Bureau of Communicable Diseases, Florida Department of Health, Tallahassee, Florida, USA

Robert F Leeman, PhD MA, Department of Health Sciences, School of Community Health & Behavioral Sciences, Bouvé College of Health Sciences, Northeastern University, Boston, Massachusetts, USA, and Department of Health Education & Behavior, College of Health and Human Performance, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-7003-8907

Mattia Prosperi, PhD, Department of Epidemiology, College of Public Health and Health Professions, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-9021-5595

Ramzi G Salloum, PhD MA MBA, Department of Health Outcomes and Biomedical Informatics, College of Medicine, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-8139-2418

Robert L Cook, MD MPH, Department of Epidemiology, College of Public Health and Health Professions & College of Medicine, University of Florida, Gainesville, Florida, USA, ORCID: 0000-0002-7770-3754

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**Running head:** What Matters Most for Long-Acting ART?

## Abstract

**Introduction:** Florida remains a high-incidence, high-prevalence setting for HIV. Long-acting (LA) antiretroviral therapies (ART) could improve HIV-related outcomes and reduce transmission. This study identifies preferred LA ART characteristics and classes of preference among people with HIV (PWH) in Florida.

**Methods:** The Florida Cohort enrolls adult PWH from six counties. In February 2023, a best-worst scaling discrete choice experiment (BWDCE) was added which included 12 tasks with three alternatives and an opt-out (i.e., their current regimen). Six attributes were included: treatment type (e.g., shot), long-term effects, side effects, location (e.g., at home), effectiveness, and frequency. A Hierarchical Bayes model was used to estimate level utilities, attribute importance was calculated, and a latent class model was run in Sawtooth Software.

**Results:** Overall, 208 PWH participated (60% aged 50+, 49% non-Hispanic Black, 54%

male). Treatment type had the greatest impact on preference [27.2% (95%CI 25.1-29.3)], followed by frequency [23.4% (95%CI 21.6-25.2)], and long-term effects [19.0% (95%CI 17.8-20.3)]. Within treatment type, LA pills were preferred over other options, including their current regimen. Less frequent administration was preferred, but only yearly administration was preferred over their current regimen. Within long-term effects, participants preferred no increase in risk. Two classes were identified where one class (27% of participants) preferred their current regimen and the other (73% of participants) preferred an alternative, placing greater importance on frequency.

**Conclusion:** PWH preferred LA pills and less frequent administration, so future ART development could focus on options with these traits. Further exploration of user preference classes is needed.

**Keywords:** long-acting antiretroviral therapy, antiretroviral therapy, end-user preferences, HIV, choice modeling, patient preference

## Introduction

The Ending the HIV Epidemic Initiative (EHE) seeks to reduce HIV incidence in the United States (U.S.), a key pillar of which is increasing the rates of viral suppression to decrease HIV transmission.<sup>1,2</sup> Central to achieving viral suppression is adherence to antiretroviral therapy (ART) and, despite the advent of one-pill, once-daily regimens, many persons with HIV (PWH) still struggle with adherence.<sup>3-5</sup> The newly approved long-acting injectable (LAI) ART options offer an alternative to the daily pills.<sup>6,7</sup> Further, several other long-acting ART formulations are in development, further increasing options for PWH.<sup>8,9</sup> As new treatments are developed, it is

important to understand the preferences of end-users so that the end products are acceptable.<sup>10</sup>

Studies of ART preferences have found that preference was given to options that were more effective than their current regimen, delivered in pill form, and were needed less frequently.<sup>11–13</sup> Many of these studies were limited to injection-only options among PWH who had already achieved viral suppression. Therefore, work on the broader population of PWH and treatment options is needed. Additionally, some studies have found geographic variation in preferences.<sup>13,14</sup>

Florida is a high prevalence and incidence setting for HIV, and seven counties in Florida were EHE priority jurisdictions.<sup>15,16</sup> Further, only 70% of PWH were virally suppressed in 2022.<sup>17</sup> Previous studies on ART preferences have not included Florida, which is contextually different from other locations that have previously been studied. This study seeks to identify ART characteristics that are most desirable to PWH in Florida and explore how preferences differ among PWH using a best-worst scaling discrete choice experiment (BWDCE).

## Methods

### *Parent Study*

The Florida Cohort enrolls PWH from community-based clinics and case management agencies in Alachua, Brevard, Columbia, Duval, Hillsborough, Marion, Miami-Dade, and Palm Beach counties.<sup>18</sup> Participants were eligible for the Florida Cohort if they were receiving HIV-related care in Florida and were aged 18 or older. The main questionnaires captured demographics, and ART regimens and adherence. Between February and November 2023, English-speaking participants completing a baseline or 12-month follow-up visit were invited to complete the BWDCE independently online through Sawtooth Software or on paper.

## *Best-Worst Scaling Discrete Choice Experiment Design*

In a BWDCE participants are asked to select their preferred profile, similar to a traditional DCE, and their least preferred profile of the presented options. After reviewing the literature, conducting interviews with PWH and HIV care providers, and consulting with experts in HIV care and DCE design, the study team identified five attributes (treatment type, frequency, long- and short-term side effects, location, and effectiveness).<sup>12,19–24</sup> The BWDCE was designed using Sawtooth Software (Provo, UT, USA), which helps to create an orthogonal design, create sets of multi-profile comparison tasks, and randomize the tasks using a balanced overlap design. No prohibitions were imposed so any combination of levels was possible. Each BWDCE task included three alternatives, to increase the design's statistical efficiency without greatly increasing cognitive load.<sup>25</sup> The attribute presentation order was randomized so that the treatment type was always shown first, but the others were randomly ordered. Participants were also asked if they would switch from their current ART regimen to the option that had been selected as “best” above (i.e., opt-out). Each participant completed 12 tasks to create a balanced design (See Figure, Supplemental Digital Content 1, for an example). Sawtooth was used to estimate the necessary sample size based on the design. Assuming an opt-out frequency of 22%, based on our previous work, the estimated sample size was 208 participants.

### *BWDCE Data Analysis*

A Hierarchical Bayes (HB) estimation was conducted in Sawtooth to estimate the utility of each level within an attribute for each participant. Variables were effects coded and all attributes were coded using part-worth coding, where each attribute was categorical.<sup>26–28</sup> Both

raw and zero-centered difference utilities were calculated. From the utility data, we calculated the relative importance of each attribute as a percentage, indicating the level of impact of each attribute on stated ART preferences. Population average zero-centered utilities and importance scores were then estimated from these individual values. Sensitivity analyses are presented in the supplemental information (see document, Supplemental Digital Content 2).

An exploratory analysis sought to identify groups of PWH with similar preferences using Sawtooth's Latent Class Multinomial Logit model. The minimum number of segments was one and the maximum was five, with a maximum of 100 iterations.

### *Ethical Considerations*

The Institutional Review Board (IRB) at the University of Florida served as the IRB of record for the parent study and approved all study activities. Participants provided written informed consent.

### **Results**

Of the 245 Florida Cohort participants invited to complete the BWDCE, 208 participated (85%). Most (59%) participants were over the age of 50, 48% identified as non-Hispanic Black, 12% identified as Hispanic, and 55% were assigned male at birth. Most participants were on a pill-based regimen (91%), of whom 89% were adherent  $\geq 90\%$  of the time (see Table 1). [Table 1 near here]

### *Utilities & Importance*

The treatment type had the greatest impact on participant choice (27.6%, 95% CI 25.5-29.8%). Participants preferred pills over patches and shots, and implants were least preferred. In comparison to their current regimen, pills were more preferred, and implants were less preferred.

Administration frequency had the second greatest impact (23.4%, 95% CI 21.5-25.3%). Weekly administration was the least preferred and annual was the most preferred administration option, even over their current regimen. Options switched from being negatively viewed to positively viewed once administration frequency decreased to quarterly or less often.

Long-term effects were third in importance (18.8%, 95% CI 17.5-20.1%). Participants strongly preferred no increased risk over a small increase in any of the long-term effects, and a small increase in the risk of weight gain was slightly preferred over increases in the risk of organ damage. Options that included increases in the risk of organ damage were less preferred than their current regimen.

Side effects were fourth in importance (14.4%, 95% CI 13.7-15.2%). Preference for short-term side effects fell into three tiers: first, and most preferred, were mild fatigue and pain; second, moderate fatigue and mild diarrhea; and third, and least preferred, were moderate pain and diarrhea.

Location ranked second to last in importance (11.6%, 95% CI 10.6-12.6%). Participants preferred home administration over other options and were the least interested in having someone come to them to administer the medication.

Effectiveness was the least important attribute (4.2%, 95% CI 3.6-4.7%). Options that were more effective than pills were slightly preferred over those with the same effectiveness as pill-based regimens. See Figure 1. [Figure 1 near here]



## *Latent Class Analysis*

The best fitting model identified two classes. The “Frequency Driven” class (72.8% of participants) strongly preferred yearly administration and were against their current regimen. These participants gave the greatest importance to frequency (34.5%). The “Type Driven” class (27.2% of participants) strongly preferred their current regimen and gave the greatest importance to treatment type (42.7%). The Type Driven class also had a more negative view of injections. See figure and table, Supplemental Digital Content 3.

## **Discussion**

In a sample of adult PWH in Florida, the type of treatment and the frequency of administration were the two most important attributes under study. Within these categories, participants expressed strong preferences for pills and options that could be administered annually, and profiles with these characteristics were preferred over their current ART regimens. Additionally, two classes of PWH were identified and were largely defined by their preference for their current ART regimens.

Participants expressed strong preferences for less frequent or pill-based options.<sup>13</sup> Qualitative studies indicate that some PWH have a dislike of needles and are concerned about the pain from implantation and injections.<sup>23,29</sup> Although we assessed pain separately, participants may have made assumptions based on their previous experiences. Further, PWH with current or past injection drug use may see injections as triggering.<sup>24</sup> Patches were preferred over implants but they were not preferred over pills, which may be due to concerns about the visibility of a patch or concerns about patches adhering to the skin in the Florida humidity based on qualitative interviews with this population.<sup>30</sup> Less frequent administration may help to reduce the burden of

daily pills and the daily reminder of HIV.<sup>23,29</sup> Additionally, administration that aligns with routine HIV care would reduce travel for options that require an office visit.<sup>31</sup> Currently, lenacapavir is the only treatment approved for semi-annual administration, although it is not a complete regimen.<sup>7</sup>

There was a sharp divide based on the risk of long-term effects, preferring no increased risk, but short-term side effect preferences varied. These concerns about long-term and gastrointestinal side effects may reflect past experiences with ART and/or co-morbid conditions.<sup>32–34</sup> In a study on side effects, PWH were generally willing to accept small increases in risk of long-term effects over larger increases in risk and less frequent short-term effects.<sup>35</sup> Additionally, some small increases in long-term effects may be acceptable, but having long-acting options with similar risk profiles to current daily oral ART are likely to be better accepted.<sup>35</sup>

Factors related to location and effectiveness were generally less important than the other attributes. Despite this, qualitative work and the implementation of LAI cabotegravir/rilpivirine indicate that increased visits to a medical facility are a barrier to uptake, so future long-acting ART development could focus on self-administration.<sup>23,29,31,36</sup> We investigated whether locations that may be more accessible (i.e., pharmacies and mobile clinics were preferred over their HIV clinic, which have been proposed as alternative injection sites for LAI cabotegravir/rilpivirine and we found that neither were preferred and mobile clinics were not positively viewed.<sup>37</sup> This may be due to privacy concerns within these settings.<sup>38</sup> However, some PWH may be willing to exchange more travel for a longer-acting option. The lack of importance of treatment effectiveness is likely due to the levels selected (as effective as pills or more effective) and the high efficacy of daily oral ART.<sup>12</sup> Effectiveness is of paramount importance for individual health

outcomes and preventing transmission, as acknowledged in qualitative studies.<sup>23</sup> However, other studies have omitted effectiveness since any new ART option would have to be non-inferior to daily pills to be approved.<sup>22,39</sup>

The two classes identified in this study were defined by their preference for their current regimen or a long-acting alternative. This finding suggests that many PWH are content with their current ART as many modern regimens consist of single daily pills that are highly effective and forgiving.<sup>3</sup> Even within the class that preferred an alternative, a treatment in pill form was preferred, although frequency of administration was more important than treatment form. PWH within this class may be more interested in a weekly pill or semi-annual injections.<sup>8,40 8,41</sup>

This study has a few limitations. First, the Florida Cohort is a largely clinic-based sample, so these results may not be generalizable to out-of-care PWH. Second, the scenarios presented may have been difficult for participants to assess and may not reflect the actual choices participants would make. Third, the study was underpowered for the latent class analysis, so additional studies are needed. Similarly, the study was underpowered to assess interaction terms between the attribute levels. Finally, the module was only available in English, and Spanish- or Haitian Creole-speaking PWH may view ART options differently.

In conclusion, PWH preferred ART that is pill-based or can be administered less frequently, ideally annually, so ART development could focus on options with these traits. Preferences differed with most PWH favoring an alternative to daily oral ART. The wide confidence intervals in this study indicate preference heterogeneity, so future studies could focus on audience segmentation to build on the exploratory analyses conducted here.

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Supplemental Digital Content 2-<http://links.lww.com/QAI/C427>

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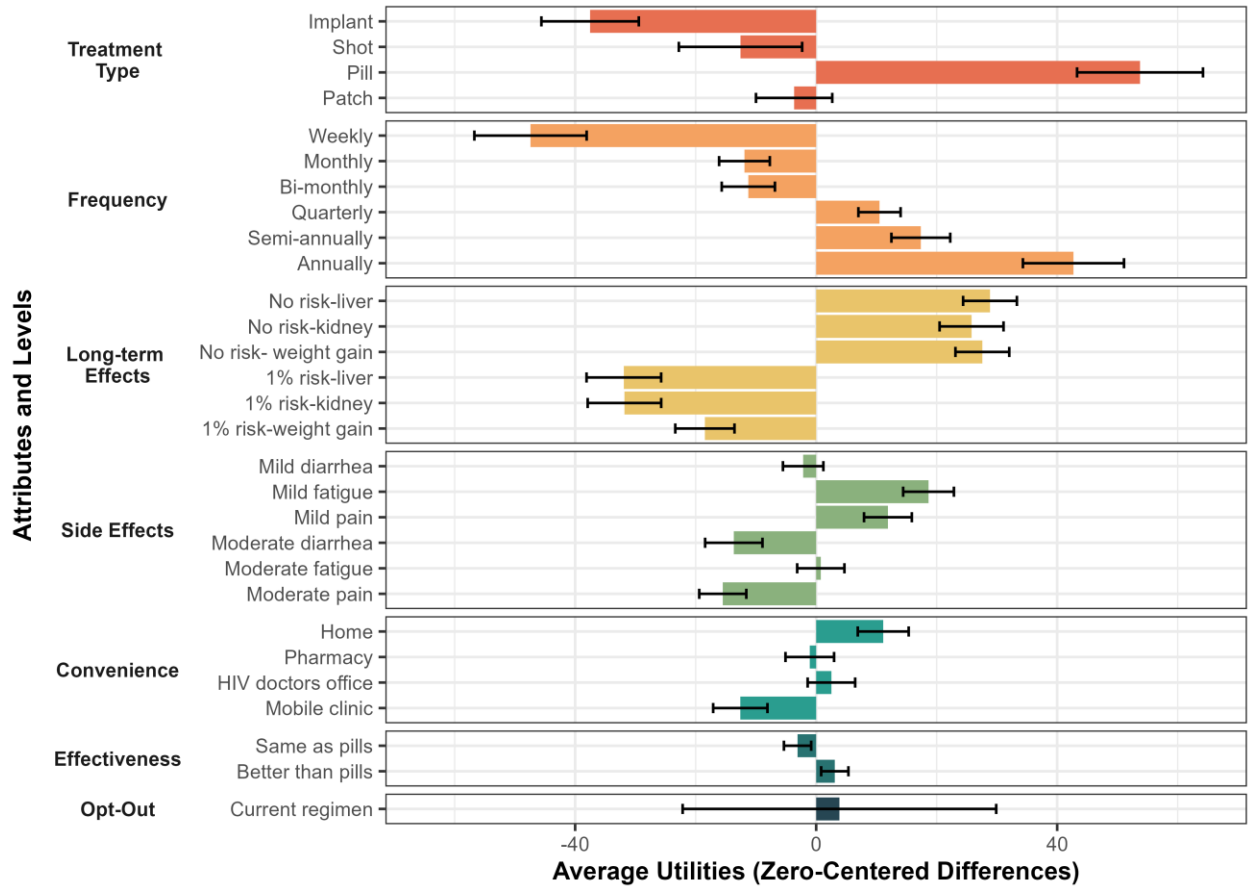
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## Figure Legends

**Figure 1. Average Zero-Centered Utilities for Long-Acting ART Attribute Levels among Florida Cohort Participants (n=208)**

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*Positive utilities indicate more preferred levels and negative utilities indicate less preferred levels. Error bars mark the 95% confidence intervals. Comparisons can be made within attributes and with the utility of their current regimen (i.e., the opt-out option), but not between levels in different attributes.*

### List of Supplemental Digital Content

SDC1.png

Supplemental Digital Content 2.docx

Supplemental Digital Content 3.docx

## Tables

**Table 1. Florida Cohort Participants who completed the ART Preference Module (n=208)**

Characteristic	Participants n (%)
Age	
18-34	34 (16.3%)
35-49	51 (24.5%)
50+	123 (59.1%)
Race/Ethnicity	
Non-Hispanic White	67 (32.2%)
Non-Hispanic Black	100 (48.1%)
Hispanic	25 (12.0%)
Other/Multiracial	14 (6.7%)
Sex Assigned at Birth	
Male	113 (54.3%)
Female	95 (45.7%)
Education	
Did not complete high school	42 (20.2%)
High school or more	165 (79.3%)
Income	
<\$10,000	72 (34.6%)
\$10,000-\$29,999	83 (39.9%)
\$30,000+	53 (25.5%)

Experienced being unhoused in the past 12 months	
Yes	24 (11.5%)
No	183 (88.0%)
Region <sup>a</sup>	
North Florida	95 (45.7%)
Central Florida	96 (46.1%)
South Florida	17 (8.2%)
Years since HIV diagnoses median (IQR)	18 (11–25.5)
ART Regimen	
Daily oral pills	190 (91.3%)
LAI	13 (6.3%)
Not on ART	4 (1.9%)
ART Adherence	
<90%	20 (10.5%)
90%+	169 (88.9%)
Missed HIV Care Appointment in past 12 months	
Yes	38 (18.3%)
No	169 (81.2%)
Viral Suppression	
Not Suppressed	25 (12.0%)
Suppressed	183 (88.0%)
<sup>a</sup> North Florida includes Alachua, Columbia, Duval, and Marion counties. Central Florida includes Brevard and Hillsborough counties. South Florida includes Miami-Dade and Palm	

Beach counties.

ACCEPTED