


Perceptions of Long-Acting Injectable Antiretroviral Treatment Regimens in a United States Urban Academic Medical Center

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Abstract

Patient acceptance of long-acting injectable antiretroviral (LAI-ARV) HIV-1 regimens will determine uptake. Although previous literature reports high satisfaction, these data stem from clinical trials subject to selection bias. This cross-sectional survey from the HIV practices of an urban academic medical center assessed perceptions and preferences using Likert scales toward overall acceptability, proposed frequencies, injection-site reaction durations, and distribution venue. 59% of surveys were completed resulting 202 respondents. 60% were male, 72% black, and the median age was 49 (IQR 36-58). 93% reported a once daily tablet frequency, 69% reported single tablet regimens, and 59% reported missing zero doses in the prior 30 days. Patients self-categorized as likely (57%) or unlikely (43%) to accept LAI-ARV. Both decreasing frequencies between injections and durations of injection-site reactions resulted higher acceptability scores. 57% of respondents preferred receiving an injectable from their clinician's office over other potential options. These data demonstrate positive LAI-ARV acceptance potential.

Keywords

HIV, perceptions, injectable, antiretroviral treatment

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Background

For many patients, antiretroviral therapy for the treatment of HIV-1 has progressed beyond taking multiple pills multiple times per day to a simplified regimen of 1 tablet taken once daily. Despite minimal pill burden, certain patients struggle with adherence posing a barrier to the 90-90-90 goal from the Joint United Nations Programme on HIV/AIDS.¹ Combination antiretroviral therapy (cART), in addition to modern HIV care-management, have increased life expectancies in persons living with HIV (PLWH) and are now similar to overall expectancy rates.² The increased duration of daily adherence demands have been associated with pill fatigue, spurring research toward alternative mechanisms of medication delivery.³

Alternative delivery mechanisms are not a new concept in the field of HIV-1. Enfuvirtide, a first in class HIV fusion inhibitor approved in 2003, is administered as a twice-daily subcutaneous injection as part of a complete antiretroviral regimen. Enfuvirtide is currently used sparingly in practice due to

significant injection-site reactions and alternative medication classes with fewer adverse drug effects.⁴ Ibalizumab-uiyk, a post attachment inhibitor, is administered as an intravenous infusion once every 2 weeks in addition to an optimized background regimen of oral antiretrovirals.⁵ Given that neither enfuvirtide nor ibalizumab-uiyk constitute a complete cART

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regimen, clinical use has remained limited to patients in which resistance patterns preclude the possibility of an all-oral agent regimen.

Many long-acting antiretrovirals administered through alternative mechanisms are under development. An intramuscular cART injectable of cabotegravir (CAB), a novel HIV integrase strand inhibitor, plus the non-nucleoside reverse transcriptase inhibitor rilpivirine (RPV), was approved in Canada in March 2020.⁶ Examples of other injectable agents under development are lenacapavir (a novel capsid inhibitor) and leronlimab (a novel viral entry inhibitor), both under study as subcutaneous injections. CAB-RPV remains under study with a less frequent dosing interval.⁷⁻⁹ Islatravir, a novel nucleoside reverse transcriptase translocation inhibitor, possesses an intracellular half-life of 100 hours and is under study in combination with other agents for HIV-1 treatment.¹⁰

Patient acceptability of and satisfaction with these long-acting alternative modes of medication delivery will be vital to their eventual uptake. Looking to historical precedent, acceptability of *twice daily* enfuvirtide injections was high in phase III clinical trials indicating relative ease of injection and limited effect on activities of daily living.¹¹ A later enfuvirtide study again demonstrated positive quality of life metrics, however >10% of patients discontinued the medication due to intolerance.¹²

Most CAB-RPV data exists from patients in clinical trials.¹³⁻¹⁶ Patients randomized to the injectable-containing arms of the phase 2b CAB-RPV LATTE-2 trial received administrations every 4 or 8 weeks. Study participants overwhelmingly reported injection site pain as an adverse effect, but also reported high rates of satisfaction of both study treatment and treatment continuation.^{13,14} Patient reported outcome measures at Week 48 of the follow-up phase 3 ATLAS and FLAIR trials again showed high rates of acceptance of injectable therapy, acceptability of injection-site reactions (including pain), and treatment satisfaction.^{15,16}

Data from clinical trials represent, by definition, a select group of participants, and may be subject to selection bias. Selection bias refers to a preferential selection/enrollment of individuals or groups such that there is both a lack of randomization in the studied population and that obtained data may not be truly representative of the population.^{17,18} Selection bias itself presents a threat to the external validity of findings, and can be minimized through mechanisms such as blinding or randomization. Therefore, study subjects who self-selected to enroll in the described clinical trials involving an injectable medication may not reflect overall acceptability of injectable medications in all populations living with HIV; data outside of the clinical trial environment may be instrumental to understanding real-world acceptability. While minimal data do exist in this area, none represent the full landscape of upcoming treatment options under development.¹⁹⁻²² Our study seeks to further describe patient acceptability of long-acting injectable antiretrovirals through the presentation of multiple formulation and delivery factors.

Methods

Study Design and Population

This anonymous, convenience sampling, cross-sectional study consisted of all PLWH presenting for an appointment at the combined HIV-treating practices of Temple Health (Philadelphia, PA). Patients were offered an English-only survey between March 11 and April 18, 2019, and then either an English or Spanish survey from September 23, 2019 through October 21, 2019. Patients seen by practice providers for reasons other than HIV (e.g., HIV Pre/Post Exposure Prophylaxis or Hepatitis C treatment) were excluded from survey offering.

Survey Instrument and Implementation

Adapting themes from a previously validated medication acceptability survey, this written, self-conducted survey included socio-demographic questions regarding age, gender, race/ethnicity, sexual orientation, endorsement of depressive symptoms, current antiretroviral usage, pill burden/frequency and missed doses.²³ Two yes/no questions were asked regarding knowledge of non-oral HIV treatment options both currently available and under development. A list of possible options for the preferred distribution site of a proposed injectable treatment regimen was presented, from which the participant was directed to choose his/her preferred option. A 1 (negative) to 10 (positive) Likert scale was then presented for 13 injectable medication formulation-specific statements regarding overall acceptability, cost, proposed frequency between injections, general comfort with the concept of self- or medical provider-administered injection, comfort with possible sites of injection, and continuation potential based on a proposed injection-site reaction duration. The 1-10 Likert scale was selected based on the proposed statistical analysis plan described below.

A patient care provider or a survey administrator invited patients attending their appointments to participate in survey completion. We obtained verbal consent and assigned each participant a unique study identifier. Although surveys were designed to be self-conducted, a patient could ask for assistance for survey completion from a survey administrator at any time. No personal identifying information was collected during survey administration. Study data were collected, managed, and secured using REDCap electronic data capture tools hosted at Temple University.²⁴

Statistical Analyses

Descriptive statistics summarized patient characteristics and survey responses. Summaries of categorical variables included counts and percentages, while medians and interquartile ranges were used for continuous variables. Survey participants were categorized into 2 groups for analysis using responses to the statement: "I am interested in an injection to treat my HIV." Participants who responded 1-5 on the Likert scale were categorized as "unlikely acceptors" and 6-10 were categorized as

“likely acceptors.” Likely acceptors were compared to unlikely acceptors by Fisher’s exact or Chi-Square tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. Linear regressions were used to test the trend in acceptability Likert scores of proposed frequency or injection-site reaction duration separately by likely and unlikely acceptors. Values were considered significant if P-values < 0.05. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Ethical Approval and Informed Consent

This study was approved under expedited review by the Institutional Review Board of Temple University (Protocol 25701). Consent was obtained from each patient prior to study initiation.

Results

Fifty-nine percent of offered surveys were completed yielding 202 unique responses. Zero surveys were excluded, therefore 202 completed surveys from PLWH were included to assess perceptions of long-acting injectable antiretrovirals. Table 1 lists demographic data. Participants’ ages ranged from 21 to 73 years with a median of 49 years old. Most respondents self-identified as male, however 38% identified as female and 2% identified as transgender. A large majority of survey respondents reported their race/ethnicity as Black, followed by Hispanic, White and other racial/ethnic identity designations. Approximately one-third of responses indicated that the person identified as Lesbian/Gay/Bisexual/Queer (LGBQ). Most participants endorsed a history of depression or depressive symptoms.

Two-hundred participants endorsed currently taking medications for HIV. A majority of regimens consisted of 1 tablet taken once daily and an overall tablet frequency (which may have consisted of multiple tablets) of once daily. A minority of participants endorsed experiencing side effects from their current antiretroviral regimen. While a majority of respondents endorsed missing 0, 1, or 2 doses in the previous 30 days, 12 surveys (6%) indicated that the participant missed 1 dose of medication per week. 16 surveys (8%) indicated that the participant missed more than 1 dose of medication per week. Attributions of missed doses were due to forgetfulness, medication acquisition difficulty, side effects, or other reasons.

Overall responses to the statement “I am interested in an injection to treat my HIV” resulted a median Likert score of 7 (IQR 3-10). One hundred-sixteen respondents (57%) were categorized as “likely acceptors” with a median Likert score of 10 (IQR 8-10), and 86 (43%) were categorized as “unlikely acceptors” with a median Likert score of 1 (IQR 1-5).

Mean Likert responses for acceptability of a proposed frequency between injections are shown in Figure 1. Scores for likely acceptors were uniformly greater than unlikely acceptors at each given time point with a trend seen toward higher Likert scores of acceptability as frequencies decreased (likely

Table 1. Demographic Factors of Survey Participants.

	n = 202
Age, years (IQR)	49 (36-58) n (%)
Sex/Gender	
Male	122 (60.4)
Female	76 (37.6)
Transgender	4 (2)
Race/Ethnicity	
Black	145 (71.8)
Hispanic	36 (17.8)
White	18 (8.9)
Other	3 (1.5)
LGBQ Identifying	
Yes	66 (32.7)
No	129 (63.9)
Other	7 (3.5)
Depressive symptoms (ever)	
Yes	109 (54)
No	87 (43.1)
Other	6 (3)
Antiretroviral pill burden	
1	140 (69.3)
2	31 (15.3)
3	16 (7.9)
4	5 (2.5)
More than 4	7 (3.5)
Unknown/Other	3 (1.5)
Antiretroviral pill frequency	
Once daily	188 (93.1)
Twice daily	11 (5.4)
Unknown/Other	3 (1.5)
Medication-related Adverse Effects (current)	
Yes	19 (9.4)
No	169 (83.7)
Other	14 (6.9)
Missed doses in the past 30 days	
Zero	119 (58.9)
1	25 (12.4)
2	28 (13.9)
Once per week	12 (5.9)
More than once per week	16 (7.9)
Other	2 (1)
Reason for missed doses	
I forgot	52 (25.7)
I had trouble getting my medication	9 (4.5)
I had a side effect	2 (1)
Other	139 (68.8)

Abbreviation: LGBQ = Lesbian, Gay, Bisexual, or Queer.

acceptors $p = 0.038$; unlikely acceptors $p = 0.004$). Mean Likert responses for acceptability of continuing a medication with a defined proposed injection-site reaction duration are summarized in Figure 2. Likert scores of acceptability for likely acceptors were again uniformly greater than unlikely acceptors at each given time point, and trends were seen toward lower Likert scores as proposed injection-site reaction durations increased (likely acceptors $p = 0.014$; unlikely acceptors $p = 0.02$). Associations between acceptor groups and remaining variables were analyzed (sex/gender, race/ethnicity, LGBQ

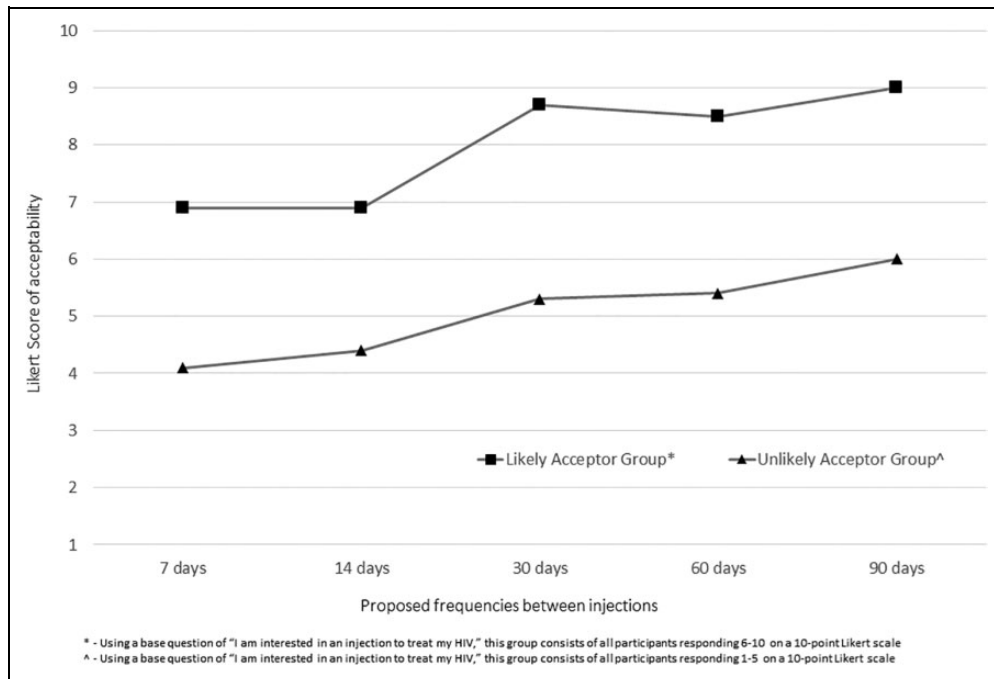


Figure 1. Likert Scores of long-acting injectable antiretroviral therapy acceptability by proposed frequency between injection administration.

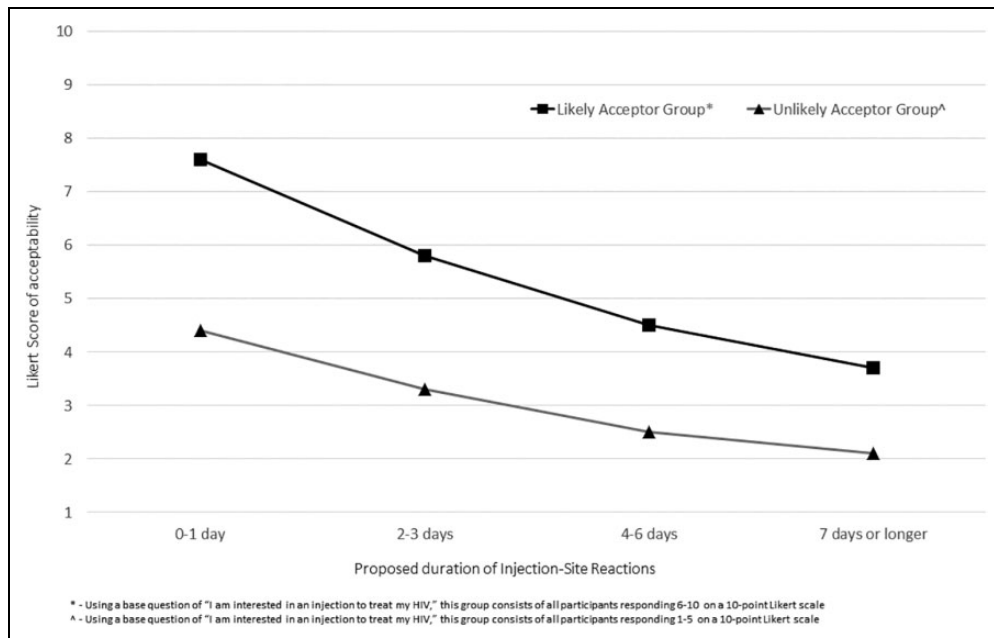


Figure 2. Likert scores of long-acting injectable antiretroviral therapy acceptability by proposed injection-site reaction duration.

identifying, self-reported depressive symptoms [ever], antiretroviral pill burden, antiretroviral tablet frequency, missed doses in the prior 30 days, and current antiretroviral-related side effect); no variables were statistically significant.

Among a list of presented options for primary preferred distribution venue for an injectable antiretroviral, a clear majority selected the clinician's office (115, 57%) as their preferred venue. Self-injection (44, 22%), assisted injection at home (18, 9%), pharmacy (7, 4%), and special injection

center (3, 2%) comprised the remaining responses (among those who selected a preference).

Participants were given the opportunity to express comfort regarding the idea of self- or medical provider-administered injections on the same Likert scale. Mean Likert scores of acceptability for medical professional-administered injections (likely acceptors 9.2 and unlikely acceptors 7.4) were greater than self-administered injection (likely acceptors 6.9 and unlikely acceptors 4.2).

Discussion

The availability of long-acting cART for the treatment of HIV-1 represents a paradigm shift for patients and providers of HIV care, and careful attention to acceptability, uptake, and implementation should guide future research. We believe that this study represents the most comprehensive data set of patient perceptions outside of a clinical trial to aid in describing attitudes toward injectable antiretroviral medications. We found no statistically significant variables that predicted acceptors versus unlikely acceptors of injectable agents but there were some noteworthy findings, such as the balance between accepting and non-accepting groups. These data differ from existing literature and underscore the importance of comparing real-world opinion to aforementioned acceptability data as part of clinical trials; high published acceptance may reflect selection bias inherent to clinical trials.¹³⁻¹⁶ These data are in agreement with positive attitudes toward shifting from daily medication taking to injectable options as reported by Khuong-Josses and colleagues.²² When comparing median Likert scores between groups, while the unlikely acceptor IQR spanned the entirety of the score range, the likely acceptor IQR was concentrated among top values. This suggests high likelihood of acceptability among some PLWH after medication approval, and indicates that providers should anticipate adoption of these medications into practice.²⁵

Expected trends among proposed longer intervals between injections and shorter duration of injection-site reactions demonstrate that these patient-friendly characteristics may affect eventual uptake. Of note, these trends were also present among respondents who initially categorized as unlikely acceptors. Although administration comfort with a medical professional was higher than from a self-administered injection, this study did not ask if self-injection would preclude uptake. These data align with previously published concerns toward general hesitation of injections and associated side effects from administration.²⁰

From distribution channel results, although physician's office and self-injection represent the largest category preferences, participants were only asked to choose 1 option. These data do not purport to compare preferences/attitudes between 2 proposed options, nor do they describe secondary preferences. Pharmacy-delivered injection may or may not be available to patients based on drug formulation, site of injection, and state-by-state regulation.²⁶

Study strengths and limitations. This cross-sectional, convenience-sampling study has multiple strengths, the largest being sample size and patient population. Given general underrepresentation of both minorities and women in HIV clinical trials, data from the population described here can be used to understand and implement these medications into clinical practice upon local approval.^{27,28} These data represent the most comprehensive known data set on this issue outside of a clinical trial to incorporate a range of possible HIV-1 injectable formulations/characteristics. These data are limited in that they come

from a single study site in an urban academic medical center and do not measure some social or psychological determinants of health which may affect results. Notably, Garris and colleagues reported favorable responses that a monthly injection for PLWH would make them feel both less ashamed or stigmatized from HIV. They additionally reported that such an injection may reduce chances that others would discover their diagnosis.²¹ Further study is needed on these social and environmental factors, which may prove advantageous when attempting to engage patients in challenging or highly-stigmatized locations and settings.

This study only characterizes patient-related attitudes and does not measure real-world barriers such as insurance authorization and procurement. Although we reduced selection bias by conducting this survey outside of a clinical trial, some bias remains due to convenience sampling methods; further implementation study is warranted.

Conclusion and Relevance

Injectable antiretrovirals, used as cART in the treatment of HIV-1 will require new approaches to treatment delivery. In a population enriched with female and minority persons, respondents were closely divided between likely and unlikely accepting groups. Although we found no specific variable predicting groupings, trends in patient-friendly characteristics, namely decreasing injection frequency and decreasing injection-site reaction duration may impact eventual uptake.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article. D.E.K has served on medical advisory panels for Gilead, Janssen, and Thera, and is an independent consultant for Abbvie and Gilead. The remaining authors have nothing to disclose.

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Previous Presentations

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