

## **Evaluating pharmacist preparedness of administering long-acting injectable antiretroviral treatments in the community pharmacy setting**

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## **Background**

According to the Centers for Disease Control and Prevention (CDC) in 2016, an estimated 1.1 million people aged 13 and older were living with Human Immunodeficiency Virus (HIV) infection<sup>1</sup>. The goal of HIV antiretroviral therapy (ART) is to maximally and durably suppress the viral load and secondarily to preserve immune function. Antiretroviral therapy utilizes oral medications with distinct mechanisms of action such as targeting cellular entry, cellular transcription and virion assembly. The Department of Health and Human Services (DHHS) HIV guidelines recommends two Nucleotide Reverse Transcriptase Inhibitors (NRTIs) plus one Integrase Strand Transfer Inhibitor (INSTI) as an initial regimen for most people living with HIV<sup>2</sup>. Despite the lack of a cure for HIV, antiretroviral therapy has dramatically reduced HIV-associated morbidity and mortality<sup>2</sup>. Antiretroviral oral therapy efficacy is dependent on virus drug susceptibility and patient adherence.

The New Drug Application (NDA) for the first ever long-acting antiretroviral therapy (LAI-ART) has been submitted to the Food Drug and Administration (FDA) in 2019 by Viiv Pharmaceuticals<sup>3</sup>. The LAI-ART is a combination of cabotegravir (CAB, an INSTI) and rilpivirine (RPV, a NNRTI) administered intramuscularly in the gluteus medius every four weeks<sup>4</sup>. ATLAS and FLAIR were two clinical trials that evaluated the viral load suppression between the traditional oral regimen (2 NRTI + INSTI) and LAI-ART (CAB/RPV)<sup>4,5</sup>. In a non-inferiority study, ATLAS, patients were switched from stable ART therapy to LAI-ART administered every 4 weeks. On the other hand, FLAIR was a non-inferiority study in patients who were treatment naïve comparing traditional ART therapy with LAI-ART every 4 weeks. Both studies have shown that once-a-month LAI-ART is safe, efficacious, and non-inferior to the currently available oral triple therapies<sup>4,5</sup>. Furthermore, a phase 3 ATLAS-2M study at the end of week 48 showed that the antiviral activity and safety of LAI-ART (CAB/RPV) administered every 8 weeks was non-inferior when compare to the administration every 4 weeks<sup>6</sup>.

However, in December 2019, the FDA submitted a complete response letter denying approval of CAB/RPV. The denial was related to the chemistry manufacturing and controls (CMC) processes. Viiv Pharmaceuticals is working very closely with the FDA to clarify issues regarding CMC processes. Hence, the approval of the LAI-ART is postponed till the end of 2020<sup>7</sup>.

Medication adherence to antiretroviral therapy remains unsatisfactory and varies between 27% and 80% across different population in various studies, compared with the required level of 95%. This new route of administration of HIV ART may increase patient adherence while providing similar therapeutic outcomes as oral triple ART by suppressing viral load<sup>5</sup>. LAI-ART would drastically decrease pill burden for patients on oral ART regimens. To promote patient adherence and accessibility to LAI-ART, it is important to identify appropriate settings for administration. A clinical study, CUSTOMIZE, aimed to identify and evaluate appropriate implementation of once-a-month LAI-ART in clinical practice settings<sup>3</sup>. The study was conducted in a combination of nine university-affiliated hospitals, private, and public clinics across the United States. Educational items, training aids, and planning tools such as appointment reminders were provided to the clinics by the study authors<sup>3</sup>. As opposed to implementation of LAI-ART studies in clinics, there is no current medical literature on implementation of LAI-ART in the community pharmacy setting.

Albertsons pharmacy is a grocery chain community pharmacy operating in several states across the United States. The pharmacy provides numerous clinical services such as immunization and medication administration, medication therapy management, pharmacogenomic testing, diabetes education, and point-of-care testing for cholesterol and A1C. Where permitted by law, the company's medication administration program allows all pharmacists to administer intramuscular (IM) medications in the deltoid and has specially trained pharmacists to administer medications in muscles other than deltoid. Pharmacists have been successful in administering LAI antipsychotics medications where permitted by law. According to the National Alliance of State Pharmacy Associations (NASPA) and the College of Psychiatric and Neurologic Pharmacists (CPNP), pharmacist administration of long-acting injectable (LAI) antipsychotic medications has increased access to patients who need the therapy<sup>8</sup>. With the anticipated arrival of LAI-ART, it was important to assess if pharmacists were prepared to administer LAI-ART in community setting. Because special training was needed to administer medications in muscles other than deltoid, it was important to identify preferred training methods in anticipation of pharmacists being able to administer LAI-ART.

## **Objectives**

The primary objective of the study was to evaluate pharmacists' preparedness with injecting LAI-ART who have experience administering IM treatment in the community pharmacy setting. The secondary objective was to identify preferred training methods for pharmacists injecting LAI-ART in the community pharmacy setting.

## **Methods**

This project was a multicenter survey-based research study conducted at multiple Albertsons Pharmacies across the United States. Inclusion criteria included Albertsons pharmacists who have an active pharmacist license in the states that they practice, permission to administer injectable medications and have experience with IM

treatment. Exclusion criteria included Albertsons pharmacists who have only administered immunizations. An anonymous online survey was sent to all Albertsons pharmacists who met the inclusion criteria. The survey consisted of multiple-choice questions, yes/no questions and Likert scale questions. These questions measured pharmacist preparedness in injecting LAI-ART and counseling patients on LAI-ART. The preparedness was measured through Likert scale questions in which participants indicated their level of agreement (Strongly agree to strong disagree). Questions determined preparedness of pharmacists with injection technique, concern of HIV transmission, workflow and store characteristics. In addition, the survey asked if pharmacists have previously administered injectable medications. Other questions determined preferences of training methods for administering LAI-ART (i.e. printed manuals, interactive online videos, or live training sessions).

Demographic questions included number of years practicing in a community setting, number of years since graduating pharmacy school, graduate degree of PharmD versus RPh, completion of residency program, and prior experience with administering injectables other than vaccines.

The results of the survey were entered into a spreadsheet and interpreted by a statistician. Descriptive statistics were used to evaluate survey data. Descriptive statistics was used to analyze and summarize data collected and the frequency of responses for each survey question. Survey data included discrete data points from Likert scale questions ranging from agreement to disagreement. Analysis of variance with multiple comparisons using Bonferroni correction and two-sample t-tests were also utilized. The study results assessed if community pharmacists were prepared to administer LAI-ART. The results also identified preference for training methods for community pharmacists in administering LAI-ART. Pharmacists who completed the survey were entered in a raffle for gift cards worth \$100 each which helped increase survey completion rates. This research received a APhA incentive grant for \$1,000.

## **Results**

Data collection was conducted from January 2020 until February 2020. For the pharmacist's population, 127 of participants completed the survey; 71 of the participants met the inclusion criteria and their results were analyzed.

### *Preparedness to administer LAI-ART*

Approximately 57.3% of pharmacists felt prepared to administer LAI-ART in the community setting (Table 1). Preparedness to administer LAI-ART varied based on the number of years in practice. Pharmacists who had less than 10 years of work experience (54.8%), 10-30 years of work experience (67.7%), 30-50 years of work experience (50%), and more than 50 years of work experience (53.3%) felt prepared to administer LAI-ART. Furthermore, patient care pharmacists and residents felt more

prepared to administer LAI-ART compared to pharmacy managers and staff pharmacists (P-value = 0.047).

Pharmacists were also asked about their experience with administering ventrogluteal (VG) injections. Pharmacists who had administered less than 10 (53.2%), 10-30 injections (78.6%), 30-50 injections (58.3%), and more than 50 injections (77.8%) felt prepared to administer LAI-ART.

In addition, 59% of the pharmacists agreed about having sufficient space at the pharmacy to administer IM VG therapy. Pharmacists agreed about having appropriate equipment to administer IM VG therapy in the community setting (56.3%). An estimation of 71% of the pharmacists agreed that they have a private area to provide IM VG therapy in the pharmacy. Moreover, pharmacists were also asked about the concerns with possible safety issues such as needle sticks while administering LAI-ART in the pharmacy. Most of the pharmacists (43.7%) disagreed with having potential safety issues.

### *Preferred training materials*

Overall, most pharmacists preferred live in person training (84%) (Table 1). Some of pharmacists preferred live webinar (57%) and written handouts (75.7%). In addition, about 30.3% of pharmacists strongly disagreed to being adequately trained to administer IM VG injections. Of all the pharmacists that expressed more training, 97.1 % of pharmacists preferred either live sessions or written training materials

### *Demographics*

The general demographics for the participants are summarized in Table 2. Most of the pharmacists received PharmD (77%). About 22% of the pharmacists received B.S. Pharmacy and 14% of the pharmacists completed 1 year of post graduate residency. An estimate of 84% of the pharmacists did not received any additional advance credentials. Some of the participants had received advance certificates such as American Academy of HIV Pharmacist (AAHIVP – 6%), American Academy of HIV Expert (AAHIVE – 1%), Board Certified Ambulatory Care Pharmacist (BCACP – 1%), Board Certified Pharmacotherapy Specialists (BCPS – 3%) and other certificates (5%). When asked about the position in the company, most participants were pharmacist-in-charge (53.5). Others included staff pharmacist (28.2%), floater pharmacist (5.6%), and other (12.7%).

Furthermore, the participants had varying work experience, 33.8% of the pharmacists had less than 5 years of work experience, 35.2% of the pharmacists had 5 to 15 years of work experience, 8.5% of the pharmacists had 15 to 25 years of work experience and 22.5% of the pharmacist had greater than 25 years of work experience. All the participants had administered intramuscular (IM) injections other than vaccines.

21.1% had administered greater than 50 IM deltoid injections and 4.2% had administered greater than 50 IM VG injections.

## **Conclusion**

Most community pharmacists feel prepared to administer LAI-ART in the community setting. Additional training to administer IM VG injections should utilize live sessions or video materials. LAI-ART for patients living with HIV can be provided in the community pharmacy setting.

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Table 1: Pharmacists preparedness to administer LAI-ART & preferred training materials

Characteristics	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<b>Pharmacists preparedness to administer LAI-ART</b>					
Community pharmacist should administer LAI-ART	35.2	32.4	19.7	4.2	8.5
Comfortable with administering IM VG therapy	19.7	26.8	18.3	16.9	18.3
Sufficient space at pharmacy to administer IM VG therapy	38	21.1	15.5	11.3	14.1
Appropriate equipment at the pharmacy to administer IM VG therapy	33.8	22.5	14.1	14.1	15.5
Private area to provide IM VG therapy	42.3	28.2	8.5	5.6	15.5
Concerns about potential safety issues (e.g needle sticks)	15.5	19.7	21.1	16.9	26.8
<b>Preferred training materials</b>					
Written handout	43.7	32.4	8.5	7	8.5
Video	46.5	35.2	3.7	4.2	7
Live webinar	32.4	25.4	22.5	12.7	7
Live in-person training	66.2	18.3	7	5.6	2.8

Table 2: General demographics of the participants

Characteristics	Number of Pharmacists (N = 71)
<b>Education</b>	
B.S. Pharmacy	16
PharmD.	55
<b>Advance credentials</b>	
AAHIVP (American Academy of HIV Pharmacist)	4
AAHIVE (American Academy of HIV Expert)	1
BCACP (Board Certified Ambulatory Care Pharmacist)	1
BCPS (Board Certified Pharmacotherapy Specialists)	2
None	60
Other	4
<b>Position in the company</b>	
Pharmacist in-charge	38
Staff pharmacist	20
Floater pharmacist	4
Per diem pharmacist	0
Other	9
<b>Work experience</b>	
Less than 5 years	24
5 to 15 years	25
15 to 25 years	6
Greater than 25 years	16
<b>Post-graduate training</b>	
1 year of residency	10
PhD	1
<b>Amount of IM deltoid injections administered, other than vaccines</b>	
Less than 10	29
10 to less than 30	17
30 to less than 50	10
Greater than 50	15
<b>Amount of IM VG injections administered, other than vaccines</b>	
Less than 10	59
10 to less than 30	7
30 to less than 50	2
Greater than 50	3