

# Socio-structural Factors Surrounding Long Acting Injectable ART: A Qualitative Study Among PLHIV Participating in a Phase II Study of Cabotegravir + Rilpivirine (LATTE-2) in the US and Spain

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## INTRODUCTION

- Adherence to HIV antiretroviral therapy (ART) is important for treatment success; however, patients face challenges in maintaining adherence, including the fear of disclosure, forgetfulness, not understanding the benefits of treatment, difficult regimens, and lack of access<sup>1</sup>
- Stigma and discrimination associated with HIV have also been identified as important risk factors for nonadherence, particularly in young patients<sup>2,3</sup>
- Long-acting injectable (LAI) ART is a novel delivery mechanism that may address barriers to daily oral adherence and facilitate individual health
- Two antiretroviral drugs, cabotegravir and rilpivirine, are currently being studied for use as LAI ART, with the LATTE-2 phase IIb trial having now completed primary analyses<sup>4</sup>
  - Cabotegravir and rilpivirine met the primary endpoint, demonstrating a similar ability to maintain levels of viral suppression after oral induction with combination ART compared with the combination daily oral regimen

## OBJECTIVE

- To qualitatively explore the views and experiences of people living with HIV (PLHIV) and their providers participating in the LATTE-2 trial in the United States and Spain to inform future research and potential programmatic rollout of LAI ART across settings

## METHODS

- This was a cross-sectional, qualitative study of participants and providers from the LATTE-2 trial, a phase IIb study on the safety, tolerability, and acceptability of LAI cabotegravir and rilpivirine for the treatment of HIV<sup>4</sup>
  - Participants initially received an oral induction regimen of cabotegravir, abacavir, and lamivudine for 20 weeks
  - Those who achieved viral suppression and tolerated oral therapy during the induction period were randomized to receive LAI cabotegravir and rilpivirine every 4 weeks or every 8 weeks, or to continue the daily oral regimen
- Qualitative interviews were conducted with 27 PLHIV (25 men, 2 women) and 12 clinical providers participating in the LATTE-2 study at 3 US sites and 3 sites in Madrid, Spain
  - US sites were smaller, with an average of 55 patients per month compared with 650 patients per month at the sites in Spain
- Data collection occurred between November 2015 and January 2016
- All subjects had completed a minimum of 32 weeks of LAI ART when interviewed. In-depth interviews explored attitudes, experiences, and the context of daily oral and LAI ART. Interviews were analyzed using a thematic content analysis approach
- Clinicians were recruited to obtain the perspective of providers regarding the prescription and clinical management of LAI ART

## RESULTS

### Baseline characteristics

- A total of 27 patients participated in this qualitative study; most patients were male (93%), men who have sex with men (85%), and Caucasian (70%; Table)

Table. Select Demographic and Behavioral Characteristics of Trial Participants

	Characteristics of qualitative study sample									
	Age, mean (range), y	Males	Sexual orientation, n (%)			Race/Ethnicity, n (%)				
			MSM	Heterosexual male	Heterosexual female	Caucasian	African	Asian	Haitian	Latino/South American
United States (n=11)	38 (24-59)	10 (91)	9 (82)	1 (9)	1 (9)	6 (55)	2 (18)	2 (18)	1 (9)	0
Spain (n=16)	37 (25-51)	15 (94)	14 (88)	1 (6)	1 (6)	13 (81)	0	0	0	3 (19)

MSM, men who have sex with men.

### Interview results

#### Simplification of daily life

Eliminating the daily reminder that is associated with taking pills can reduce internalized stigma.

“It’s less and less stigmatized with the injection, because I don’t feel like I’m reminding myself of [HIV]...with the injection you go through days and weeks...two months not having to worry about that, so it’s less stigmatized.”

Female participants described LAI ART as having the potential to reduce stress and pressure associated with one more thing they had to worry about.

“I love it because I don’t have to take a daily medication, so that’s just one less thing on my plate that I have to worry about...”

#### Convenience

PLHIV have the ability to live more freely and uninhibited because of the length of time between injections.

“In reality, taking the pill every day keeps it [HIV] present...and the shot is just once a month...you remember it when you come in and the rest of the time you can basically forget it.”

Travel becomes less stressful and less restricted because of the elimination of pills and fear that luggage searches might lead to undesired disclosure to immigration officials, which can affect the ability to enter the country.

“If you go on a trip, you don’t have to bring your pills or take anything at all along. You follow your ‘normal life.’”

#### Potential concerns about LAI ART

The need for more visits to the clinic to receive LAI ART concerned some participants because of the possibility of unwanted disclosure of HIV status to people who are aware of the frequent visits (eg, coworkers).

“Even my carpool buddy asked a couple of times, ‘Wow. You go to the doctor a lot.’ Then I started saying, ‘Well, I just have an appointment for my roofer’...I stopped saying I was going to the doctor so much.”

Healthcare providers are in favor of the LAI ART option but voiced greater concerns for those who miss multiple injections than for those who miss pills.

“My concern with injections is this: when you have someone who’s just not compliant. If they’re not compliant and they miss 2 or 3 oral doses, it’s not the end of the world. If you’re not compliant with every 8 weeks, that could be an issue.”

#### Visit location preferences

There was some disagreement on the appropriate venue in which to administer LAI ART (ie, primary vs HIV-specific care), although there was general agreement that LAI ART must be administered by a “trained” professional such as a doctor or nurse rather than someone at a pharmacy or community center.

#### Differences in perspectives – Spain versus the United States

Spain has a single-payer, government healthcare system, and the large HIV clinics would be busier if many people receive LAI ART, leading to concerns about the upkeep of patients receiving this therapy. The concern for those in the United States, with a smaller number of clinic visitors, was about keeping LAI ART in stock.

## CONCLUSIONS

- Elements of the socio-structural environment, including stigma and the healthcare system, emerged as critical factors that may influence the rollout of LAI ART to PLHIV
- Differences between the two countries indicate the importance of further cross-context research to inform rollout

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