



“Understanding the Treatment Experience: A Qualitative Study of people living with HIV who transitioned from Oral Antiretrovirals to Cabotegravir/Rilpivirine Injectable Therapy”

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Nova Southeastern University Barry and Judy Silverman College of Pharmacy

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Disclosure:

Kalumi Ayala, PharmD, AAHIVP, TTS- ViiV Healthcare Post
Fall Conference-Virtual Advisory Board (Advisory Board Member-
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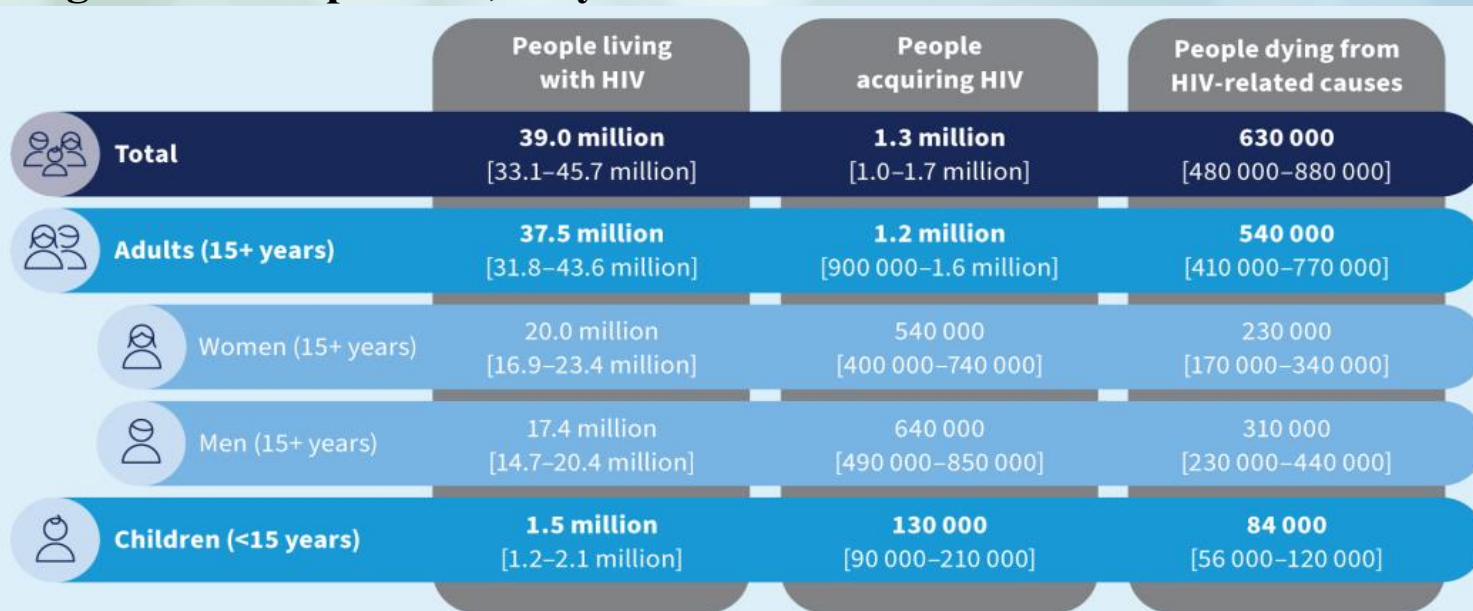
The rest of the authors of this presentation declare no conflicts of interest or financial disclosures. We have no relevant affiliations or financial involvement with any organization or entity with a financial interest in the subject matter discussed in this presentation.

Background:

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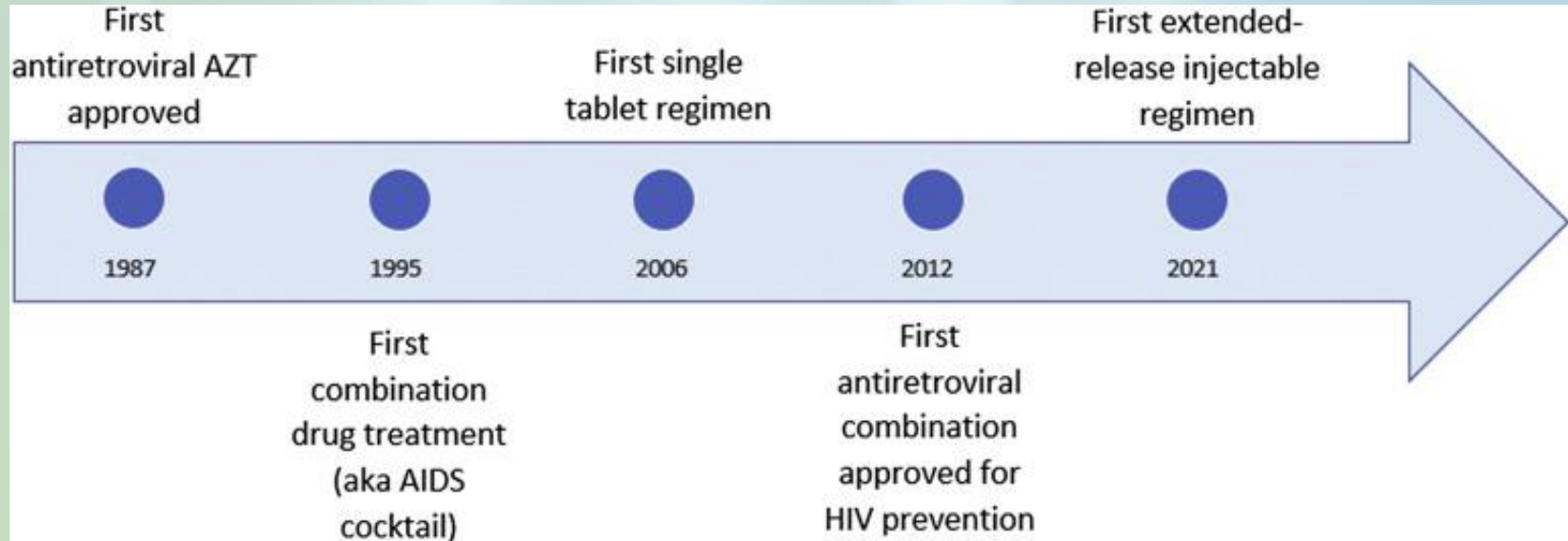
Summary of the global HIV epidemic, July 2023:



Source: UNAIDS/WHO estimates



The timeline of milestones in FDA approval of antiretroviral therapy (ART):

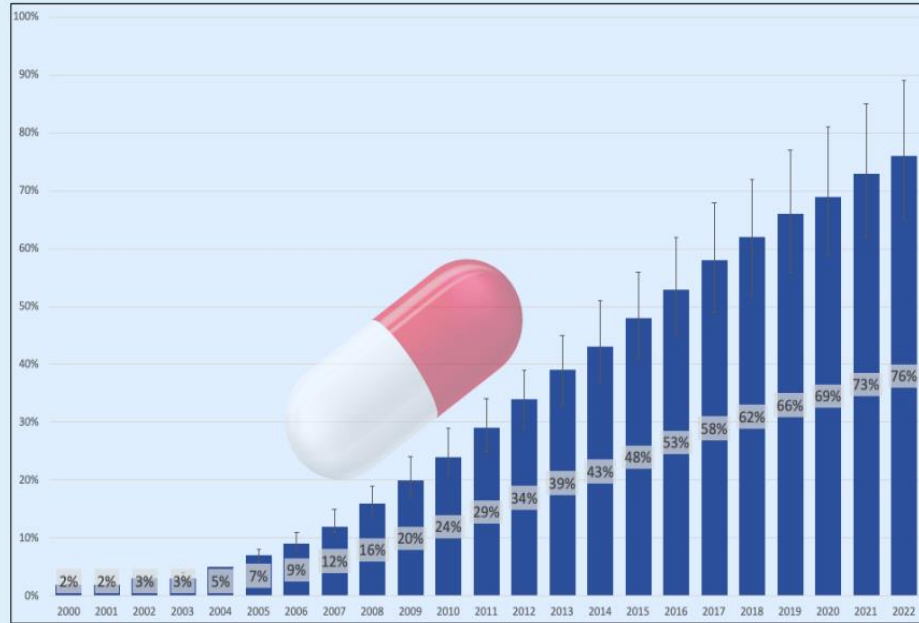


Significance of ART:

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Global antiretroviral therapy coverage over time, global, 2000–2022



Source: UNAIDS/WHO estimates



Benefits:

- Viral suppression
- Extended Lifespan
- Prevention

Challenges:

- Medication Adherence
- Side effects
- Drug resistance
- Disparities in access to treatment



Long-acting injectable CAB/RPV as an alternative to oral ART challenges?

LATTE-2 Trial¹

- HIVTSQs mean increase from baseline at week 44: 5.68 points higher (95% CI, 4.37 to 6.98) in the long-acting–therapy group vs the oral ART
- At week 48: 97% of participants preferred the injectable over the oral ART.

FLAIR Trial²

- Adjusted HIVTSQc mean difference: 4.1 points (95% CI, 2.8 to 5.5)
- Exploratory Question: 257/259 (99%) preferred the LA over the previous oral therapy

Qualitative insights³

- LATTE-2 Trial: Participants described the convenience of LA injections versus daily pills and emotional benefits such as minimized potential for HIV disclosure and eliminating the “daily reminder of living with HIV.”

1- Swindells et al. (2020). New England Journal of Medicine, 382 (12):1112-1123

2- Orkin et al. (2020). New England Journal of Medicine, 382(12), 1124–1135. <https://doi.org/10.1056/nejmoa1909512>

3- Mantsios, et al. (2018) PLoS ONE 13(1): e0190487



Purpose

- This study aims to explore the treatment experience of persons living with HIV who have transitioned from conventional oral ART to long-acting antiretroviral therapy using Cabotegravir/Rilpivirine (LAI-CAB/RPV) in Puerto Rico.
- By exploring the personal narratives of these participants, we seek to gain a deeper understanding of their journey, challenges, and successes in adapting to this novel treatment approach.



Methods

Study design:

- Qualitative study following an interpretative phenomenological analysis.

Question guide:

- The question guide was developed by a panel of experts and based on the literature. It was piloted with a potential participant.
- The question guide sought to elicit responses from the participants about their experiences as people living with HIV who transitioned from oral to long-acting injectable ART.
- Questions about HIV diagnosis, experience with oral ART, and experience and meaning of the transition to LAI-CAB/RPV ART were asked.

Ethics:

- This study was approved by the Nova Southeastern University Institutional Review Board.



Methods

Study participants: (n=10)

- Sample: purposive homogeneous sampling
- ≥ 21 years old
- PLWHIV who have undergone the transition from oral ART to LAI- CAB/RPV and have been on the injectable medication for a minimum of six months.

Venue/Site

- Centro Ararat San Juan/Ponce: A non-profit organization, founded in 2001 that offers primary health services in five clinics located in Ponce, San Juan and Arecibo.

Interviews

- The ten interviews were audio recorded, transcribed, and coded by three researchers.
- The interviews lasted from 30 to 35 minutes.



Data Analysis

Reading & Re-Reading

Participants become the center of the analysis

Exploratory Noting

Aim is to produce a detail and comprehensive sets of notes and comments on the data.

Experiential Statement

Aim is to reduce the volume of detail.

Produce a summary of what is important

Searching for connection

Develop a mapping of how the statements fits together.

Personal Experiential Themes (PET)

Each of the clusters of experiential statement giving a title to described its characteristics

Individual Analysis of other cases

Repeat the process above with all transcripts

Develop Group Experiential Themes

Aim is to look for patters of similarity and differences across the PET and create a Group Experiential Themes (GET)

Analysis

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Group Experiential Themes

Sub-themes

Receiving an HIV Diagnosis

- Emotional Response
- Social implication of dx
- Coping mechanism
- Relationship with healthcare provider

ART Experience

- Oral ART
- Transition to injectable ART

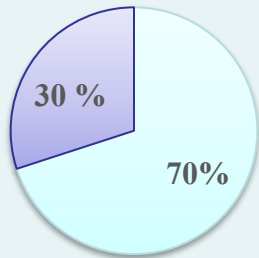
Understanding the transition from oral to long-acting injectable ART

Results: Socio-Demographics



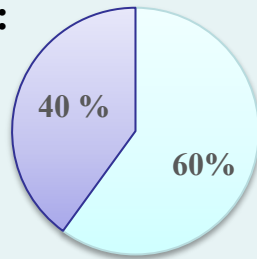
Age:
Mean: 67 years (SD=9)
Range: 46-81 years

Gender:



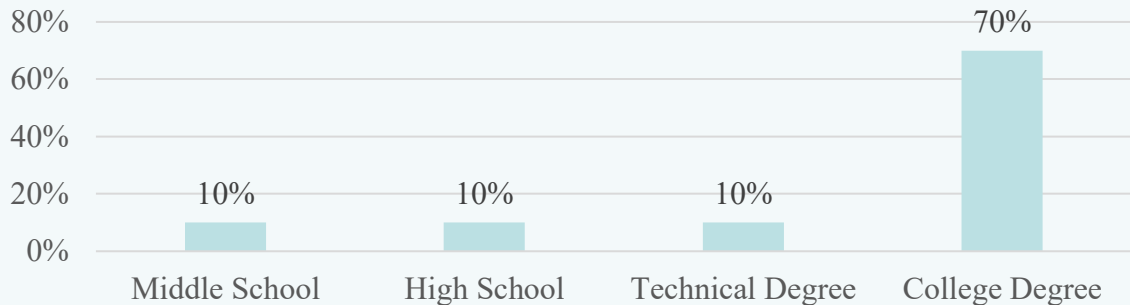
Male Female

Sexual identity:



Heterosexual Homosexual

Education:





Results

Characteristics	n (%)
Health insurance:	
Private health Insurance	3 (30 %)
Medicaid	8 (80 %)
Medicare	6 (60 %)
Years in oral ART:	
10- 15 yrs	3 (30 %)
16-20 yrs	1 (10 %)
21-25 yrs	1 (10 %)
26-30 yrs	4 (40 %)
≥ 30 yrs	1 (10 %)
Months in LAI CAB/RPV:	
6-11 mo	1 (10 %)
12-23 mo	4 (40 %)
≥ 24 mo	5 (50 %)



Results

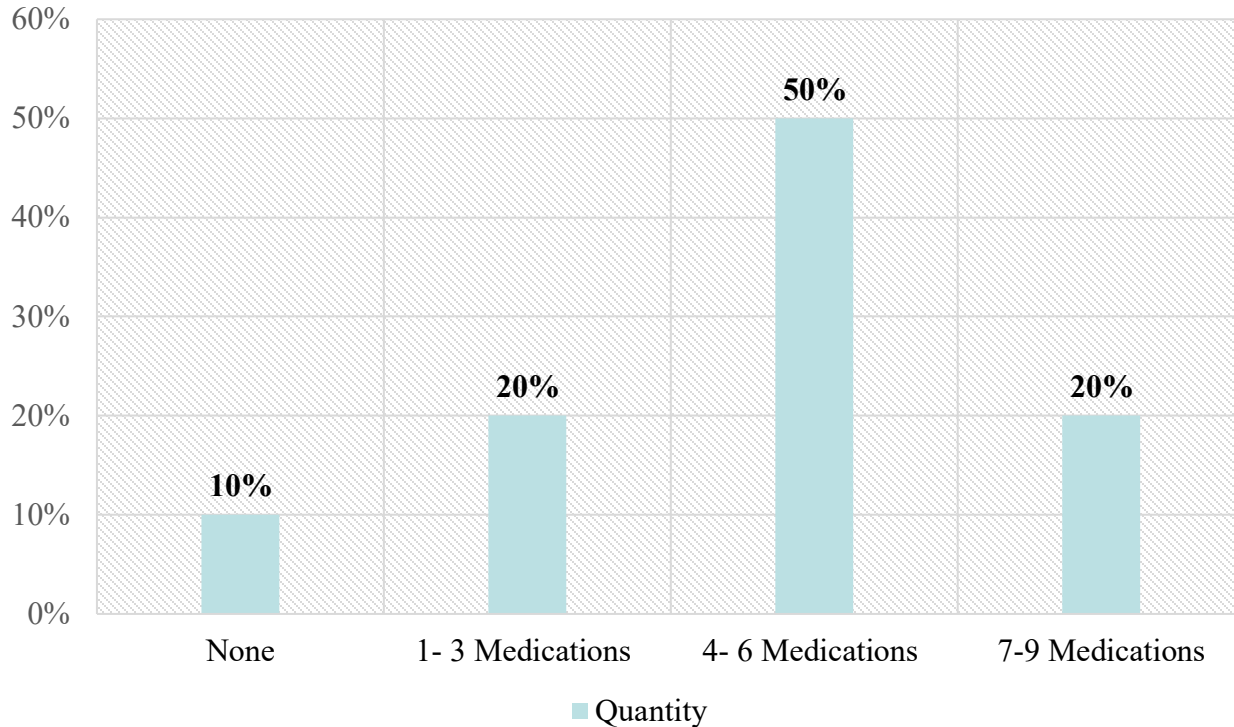
Comorbidities	n (%)
Hyperlipidemia	7 (70 %)
Hypertension	6 (60 %)
Hypothyroidism	4 (40 %)
DM-2	3 (30%)
GERD	3 (30 %)
Psychiatric Disorders	2 (20 %)
Sleep Disorders	2 (20 %)
COPD	1 (10 %)
ESRD	1 (10%)
CKD	1 (10 %)
Coronary artery disease (CAD)	1 (10 %)
Congestive Heart Failure (CHF)	1 (10 %)
Anemia	1 (10 %)
Diabetes type I	1 (10 %)
Endometriosis	1 (10 %)
Cervicalgia	1 (10 %)
Osteoarthritis	1 (10 %)
Atopic dermatitis	1 (10 %)
Dysphagia	1 (10 %)

Results

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Daily Oral Medications





Results

Characteristics	n (%)
Viral load: ≤ 50 cp/mL	10 (100%)
CD4 count: 250-499 cells/μL	4 (40 %)
500-999 cells/μL	4 (40 %)
1000-1499 cells/μL	0 (0 %)
≥ 1500 cells/μL	2 (20 %)



Qualitative Results: Themes

Receiving an HIV Diagnosis

- Emotional Response
- Social Implications
- Coping Mechanisms
- Relationship with healthcare providers

Experience with ART

- **Oral ART**
 - Initial regimen, adverse effect, adherence and social implications
- **Transition to injectable ART**
 - Relationship with healthcare providers, access, first dose experience, adverse effect, adherence, meaning and social implications



Experience with ART: Oral

Initial treatment:

- Complex regimens: multiple medications + multiple times a day.
- Pill burden affected participants' daily routines and social interactions.
- Some described feelings of frustration and social isolation.

"Back when I started... with oral medication, at that time, cocktails still existed. It was a cocktail of 10 to 15 pills, morning, noon, and night. So, how was I supposed to socialize, publicly, at work, and all that, having to gulp down those cocktails' morning, noon, and night?"

- Dennis, 65-year-old male



Experience with ART: Oral

Initial treatment:

- Lack of treatment options and limited efficacy of early medications

"Initially, they gave me a possible diagnosis, but at that time, there was no medication. There wasn't even AZT...When the AZT started, I did use it for a while, but then I wanted to go more towards natural methods. I saw that AZT wasn't doing anything, so I turned to natural remedies, until I got sick"

- July, 64-year-old male



Experience with ART: Oral

Adverse Effects:

- Ranges from gastrointestinal discomfort to psychological distress.
- Gastrointestinal disturbances were a common theme among participants.
- Some experienced more severe adverse reactions that led to the interruption of oral treatment.

"There was one, now I can't remember the name, that raised my liver enzymes a lot. They had to suspend the treatment. They raised them almost to a thousand. I didn't have any symptoms. It was when I did routine tests and that came out".

- Carlos Reiki, 68-year-old male



Experience with ART: Oral

Adverse Effects:

- Other participants struggled with psychological distress due to medication-induced adverse effects:

“... and I'll always remember that when the side effects started, like lipodystrophy, that really affected me emotionally, and now I know they're caused by the medication”.

- July, 64-year-old male



Experience with ART: Oral

Adherence:

- Adherence to oral ART varied among participants.
- Strategies used to facilitate adherence:
 - pill organizers
 - integrating medication routines into daily activities
 - prioritizing their treatment above all else

"Of course, I always kept the pill organizer handy, and I still do with routine medications. I have my pill organizer on the kitchen counter, and I take all my medications immediately after breakfast. Before sleeping, I keep them on the bedside table. This way, I never forget to take them".

- *Ernesto, 61-year-old male*



Experience with ART: Oral

Adherence challenges:

- Forgetting doses, intentionally skipping, and burden of medication intake.
- Some participants struggled with swallowing the pills due to their large size, which contributed to difficulties in adhering to the regimen.

"Swallowing them was horrible. First, they are quite large. So, swallowing that pill was difficult. I think also the fact that I was given so many medications the first time, and it was all like, here, take this, and twice a day. So, it was 14 medications. That traumatized me for my whole life".

- *Angélica, 46-year-old female*



Experience with ART: Oral

Adherence:

- The idea that “life depended on medication” was prevalent among some participants, instilling a sense of urgency and necessity for adherence.

"For me, my life depends on those bottles. If I don't take them, I will die. For a long time, I had to learn that I wouldn't die".

-Angélica, 46-year-old female



Experience with ART: Oral

Social Implications

- The requirement to take multiple doses throughout the day disrupted social activities, travel plans, and work commitments, leading to feelings of isolation and frustration.

“...at that moment, it made me nervous passing through customs or airport security, seeing a young person with so many pill bottles, because the medications were three huge bottles. Plus, with that concern of having to carry enough supply of the medications for every day, it creates tension.”

- CarlosReiki, 68-year-old male



Experience with ART: Oral

Social Implications

- Concerns about public perception and the need for secrecy led some participants to develop elaborate strategies to conceal their medication intake, such as hiding pills in the fridge or removing the prescription labels to avoid suspicion.

" There was a time when my sister lived with me. So, what I did was remove the label from the medication. And I would hide it, but I removed the label. I removed the label from all of them. And then I would open the bottles and put them in a pill organizer so they wouldn't be visible".

-Angélica, 46-year-old female



Experience with ART: Oral

Social Implications

- The act of taking medication itself became emblematic of the profound changes HIV diagnosis brought to their lives, symbolizing a constant reminder of their condition.

"It brings to mind the day when I laid them all out on my counter. With the paper bag. That paper bag used to cause me distress every time they handed it to me".

Angélica, 46-year-old female



Experience with ART: Transition to LAI

Access:

- Access to the injectable therapy was facilitated by healthcare providers who efficiently managed the paperwork and approval process.
- Participants were satisfied and happy with the support they received from the healthcare providers.

" Yes, that was a blessing... when the doctor approaches me, I say, yes, let's see if the medical plan approves it, and thanks to the Lord, I haven't had any kind of situation, they are very efficient, the pharmacist calls me and tells me, look, the medical plan has approved it, when is your appointment to receive the medication?, I mean, everything has flowed in a truly great way".

- *Ernesto, 61-year-old male*



Experience with ART: Transition to LAI

Access challenge:

- Delays with pharmacy services, particularly related to the timely delivery of the medication.
- These delays sometimes required proactive follow-up from patients to ensure that the medication was available for their scheduled appointments.

I mean the bureaucratic process of medical plans and the specialized pharmacy that is dedicated to distributing the medication... I have to keep pushing, as one says, the specialized pharmacy to ensure it arrives on time because it is very important for me, and I told them so... I mean, every two months I have to stay on top of it, and it creates tension for me.

- July, 64-year-old male



Experience with ART: Transition to LAI

First-dose experience:

- Feeling of excitement, hope, and enthusiasm. One participant compared the anticipation to a child's excitement on Christmas morning, describing it as a "gift of life".
- Concerns about potential side effects, the pain of the injection, and the unknown reactions were common.
- After the first injection the successful administration without severe side effects contributed to a sense of emotional relief.

"Like all new things, it creates a bit of anxiety. What are they going to inject me with? How am I going to react? And yes, I can't deny that I came with a lot of anxiety that day. But once I got the injection, my concern was, what will happen now? How will my results turn out, the cell count?"

- Ernesto, 61-year-old male



Experience with ART: Transition to LAI

Adverse Effects:

- Mild discomfort at the injection site, which typically subsided within a day.
- Few participants experienced mild symptoms such as body aches or chills, these effects were generally short-lived and manageable with over-the-counter pain relief medication like acetaminophen.
- Participants who reported more significant discomfort often compared it to the sensation experienced during routine vaccinations.

"Today, in addition to the pain in the area, I experience discomfort in my body that lasts about three days. But it doesn't make me nervous because I know it will alleviate, and I prefer the injection even though it causes pain over taking pills."

- July, 64-year-old male



Experience with ART: Transition to LAI

Adverse Effects:

- Participants demonstrated a high level of acceptance and adaptability to potential adverse effects with many emphasizing their willingness to tolerate discomfort in exchange for the benefits of injectable therapy.

"I do feel a little sore in the area if I touch it and such, but it wasn't something like I couldn't walk. But I didn't mind as long as I don't have to take a pill anymore, I'm happy."

- *Angélica, 46-year-old female*



Experience with ART: Transition to LAI

Adherence

- Participants' narratives show a high adherence level, highlighting the convenience of LAI.
- Participants consistently expressed satisfaction with the transition to receiving injections every two months, emphasizing the ease of attending clinic appointments.
- LAI allows them to have more flexibility and reduction in monthly clinic visits for oral medication refills

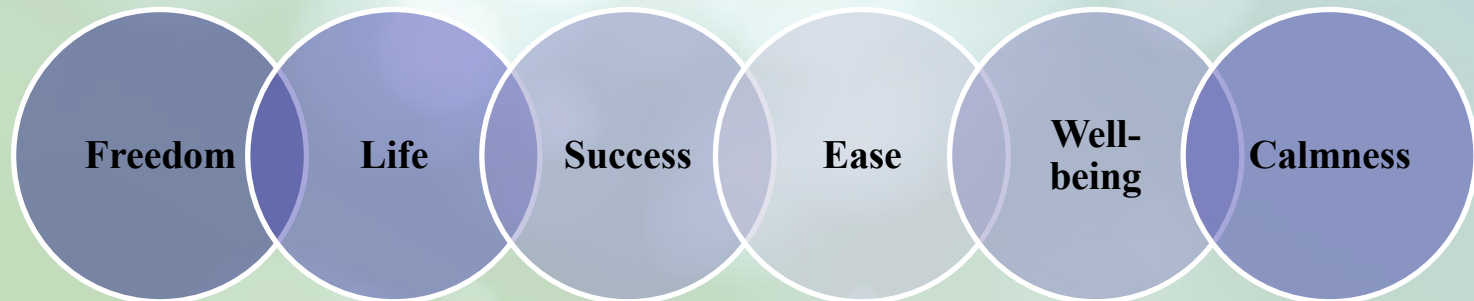


Experience with ART: Transition to LAI

Meaning:

- Injectable therapy has profound positive impacts on their lives.
- Many described the therapy as a transformative experience, emphasizing the sense of “*freedom*” and “*normalization*” it brought, allowing them to feel more “*like any other person*” without the constant worry of daily medication.

Key descriptive terms:





Experience with ART: Transition to LAI

Meaning:

“Freedom. It means freedom. I don't have to think, did I take it, did I not take it, where is the alarm? It's like normalizing my life. In other words, I feel more normal, more like any other person. Yes, I have a condition, but I come, I inject myself, and I leave. I go to my house, and when they call me, look, it's your turn again. That, for me, is my emotional freedom”.

Angélica, 46-year-old female

"Peace of mind, because I have to forget about taking medication every morning, whether I took it or not, making sure I have the correct amount to last for 30 days. Disconnecting, which is the best part".

- July, 64-year-old male



Experience with ART: Transition to LAI

Social implications:

- Positive and transformative change, enhancing their social interactions, reducing stress, and improving their overall life satisfaction.
- Improvement in their quality of life, citing the elimination of the daily burden of taking oral medications and the associated mental relief.
- Participants expressed a sense of freedom and normalcy with the injectable therapy

"Positively, as I repeat, it's quality of life... And now, thinking that I only have to come here every two months to get those two injections, which don't even hurt anymore, it's definitely very positive".

Ernesto, 61-year-old male



Conclusion:

- These insights highlight the importance of considering not only clinical outcomes but also the holistic impact of treatment modalities on patients' lives.
- The transition marked a profound positive change, participants described injectable therapy as synonymous with *freedom, improved quality of life, and a sense of relief*.
- Their positive experiences underscore the potential of LAI-CAB/RPV to revolutionize HIV management, enhancing both treatment adherence and quality of life.
- Further research is crucial to optimize HIV care and support patient-centered approaches in treatment decision-making.



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