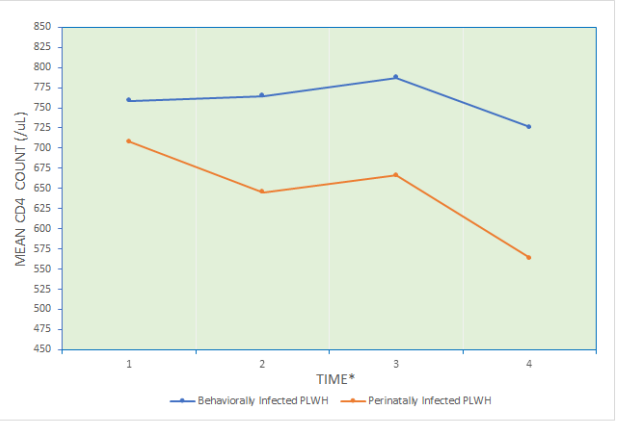
A Comparison of Outcomes Over Time Between Perinatally Infected PLWH vs. Behaviorally Infected PLWH

OUTCOME	Time*	PERINATAL			BEHAVIORAL		
		n	n %	Mean (SD)	n	n %	Mean (SD)
VIRALLY UNSUPPRESSED	1	10	27.8	-	6	12	-
	2	7	21.9	-	3	8.1	-
	3	7	26.9	-	4	10.5	-
	4	4	28.6	-	2	8.7	-
ART NONADHERENCE	1	15	44.12	-	8	19.05	-
	2	6	23.08	-	5	17.2	-
	3	4	19.1	-	4	12.5	-
	4	3	30	-	5	22.7	-
CD4 COUNT (/uL)	1	38	-	708.06 (356.03)	51	-	758.72 (376.03)
	2	32	-	645.50 (349.70)	39	-	764.81 (341.25)
	3	27	-	666.42 (315.22)	39	-	787.29 (311.84)
	4	14	-	563.50 (229.83)	25	-	725.83 (324.75)

*New York Department of Health Aids Institute guidelines recommend patients have an HIV care visit at least once in the first half of the year and another in the second half of the year. We used the specified time periods so that we could capture every patient's biannual visits. 1=Baseline clinic visit; 2= Earliest visit that is 180-359 days from the baseline visit; 3=Earliest visit that is 360-539 days from the baseline visit; 4=Earliest visit that is 540-719 days from the baseline visit.
Notes. SD=Standard deviation.

Observed Changes in CD4 Count Over Time, Compared by Mode (Perinatally Infected PLWH vs. Behaviorally Infected PLWH)



*1=Baseline clinic visit; 2= Earliest visit that is 180-359 days from the baseline visit; 3=Earliest visit that is 360-539 days from the baseline visit; 4=Earliest visit that is 540-719 days from the baseline visit.

Conclusion. Despite differences in reported ART adherence, perinatally and behaviorally infected PLWH had similar rates of HIV viral load suppression and comparable absolute values and trends in CD4 count.

Disclosures. **All Authors**: No reported disclosures

1033. One year of Bictegravir in Mexico City: Differences in the Neuropsychiatric Adverse Events vs. Efavirenz

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Session: P-47. HIV: Treatment

Background. In Mexico, Efavirenz (EFV) was considered as first-line regimen for several years. However, the Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) had a history neuropsychiatric effects such as depression, suicidal thoughts, insomnia, hypersomnia, impairment cognition, impairment in quality of life, these adverse events cause poor adherence and abandon EFV regimens. Since June 2019, bictegravir (BIC) in a single tablet regimen was introduced in Mexico as a first-line treatment. Therefore, the objective of the study was to compare the presence of depressive and cognitive symptoms, suicidality, sleep disturbances, quality of life between BIC and EFV regimens.

Methods. Prospective cross-sectional study, non-probability sample, both groups BIC and EFV were matched according to age. Patients were recruited from June 2019 to May 2020 in Condesa Specialized Clinic in Mexico City. All the patients had 1 to 4 months from starting treatment. The evaluation test used were Medical Outcomes Study Short Form-36 (SF-36), Beck Depression Inventory (IDB-IA), Center for Epidemiologic Studies-Depression Suicidal Ideation subscale (CES-D IS), State Impulsivity Scale (SIS) and Pittsburgh Sleep Quality Index (PSQI).

Results. One thousand six hundred patients, 800 in BIC group and 800 in EFV group. The mean age 37 years. Non-statistical difference was found in sociodemographic and HIV-related variables. Statistically significant differences were found between BIC and EFV groups (t = 1.91 - 15.28, p < 0.03). The largest differences were seen in cognitive symptoms such as impulsivity, quality of life mental score and suicidal ideation (t > 10.61). No differences were found in physical role and sleep disorders.

BIC & EFV groups comparison

Variable	BIC n= 800		EFV n= 800		t	p
	Mean	±	Mean	±		
PCS	78.53	25.18	77.6	26.94	5.05*	p<.01
MCS	65.7	20.42	64.09	22.14	10.61*	p<.01
SF-36	72.12	19.87	70.84	21.45	8.65*	p<.01
PF	89.54	18.58	88.13	19.97	9.87*	p<.01
PR	67.52	38.53	67.00	40.79	1.84	p>.05
MH	67.78	21.45	65.83	23.45	12.13*	p<.01
VT	63.62	23.57	62.34	24.83	7.42*	p<.01
BDI-I	5.77	5.73	6.09	5.05	2.18*	p<.03
CES-D SI	1.85	0.98	2.20	1.12	10.80*	p<.01
Impulsivity SIS	7.1	6.41	7.78	7.50	15.28*	p<.01
SQ	1.23	0.77	1.26	0.78	4.57*	p<.01
SL	1.28	0.94	1.30	0.94	5.15*	p<.01
SD	1.39	1.09	1.40	1.11	2.73*	p<.01
SE	0.97	0.61	0.99	0.64	0.51	p>.05
SDs	1.45	0.64	1.46	0.65	0.76	p>.05
SM	1.76	1.38	1.77	1.39	2.25*	p<.03
DD	1.21	0.91	1.23	0.90	1.12	p>.05
PSQI	7.5	3.73	7.67	3.80	1.91*	p<.03

*statistically significant differences. ± standard deviation. **BIC:** bictegravir. **EFV:** efavirenz. **PCS:** Physical component of SF-36. **MCS**: Mental component of SF-36. **SF-36**: Medical Outcomes Study Short Form-36. **PS**: Physical Functioning. **PR:** Physical Role. **MH**: Mental Health. **VT**: Vitality. **BDI-I**: Beck Depression Inventory, HIV adapted. **CES-DIS**: Center for Epidemiologic Studies-Depression Suicidal Ideation subscale. **SIS**: State Impulsivity Scale. **SQ**: Perceived Sleep Quality. **SL**: Sleep Latency.**SD**: Sleep Duration. **SE**: Sleep Efficiency. **SDs**: Sleep Disturbances. **SM**: Sleep Medication **DD**: Daytime Disfunction. **PSQI**: Pittsburgh Sleep Quality Index

Conclusion. In this study we found BIC group have fewer neuropsychiatric events than EFV group. The principal differences were in cognitive symptoms, suicidality, functionality associated with central nervous system symptoms. We suggest having a long-term follow-up of the sleep quality variables, to observe patient's adaptation to treatment for a period over to 12 months.

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1034. Patient Perspectives on Implementation of a Long-Acting Injectable Antiretroviral Therapy Regimen in HIV US Healthcare Settings: Interim Results from the CUSTOMIZE study

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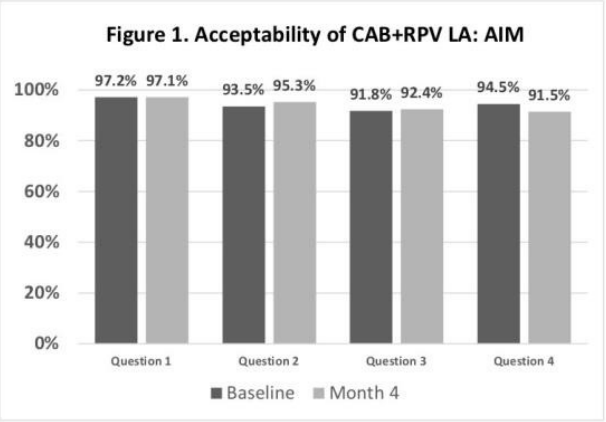
Session: P-47. HIV: Treatment

Background. Cabotegravir and rilpivirine long-acting (CAB+RPV LA) administered by monthly injection demonstrated non-inferiority compared to standard daily oral antiretroviral therapy (ART) at 48 weeks. This novel treatment offers a less frequent dosing alternative to daily oral pills but requires more frequent clinic visits. Patient perspectives on implementation of CAB + RPV LA in US healthcare settings were evaluated in an innovative Hybrid III implementation-effectiveness study (CUSTOMIZE).

Methods. This single-arm study enrolled virologically suppressed patients to receive monthly CAB+RPV LA across eight diverse US clinics. Patients were surveyed at Baseline (BL) prior to the first injection and at Month 4 (M4) prior to the fourth injection to evaluate clinic implementation of CAB+RPV LA, including Acceptability of Intervention (AIM) and Intervention Appropriateness (IAM) Measures. Subgroups were compared with Fisher's exact test.

Results. A total of 109 and 105 patients completed BL and M4 surveys, respectively, and were 87% male; 59% Caucasian and 35% African American; 27% Hispanic/Latino; mean age 39 years (range 20-65). At BL, 33% reported hiding their oral ART from others, 22% reported problems remembering to take daily ART (female 43% > male 19%, p< 0.05), while 47% reported no problems with daily ART (male 51% > female 21%, p< 0.05). Patient "interest in a more convenient treatment option" (83%) was a top reason for choosing CAB+RPV LA treatment. Acceptability and appropriateness of CAB+RPV LA were high at BL and M4 (Figures). At M4, 84% of patients reported that monthly clinic visits were very/extremely acceptable and 66% reported no logistical challenges to clinic administered CAB+RPV LA. Injection pain/soreness was the most common worry at BL (58%); at M4, 28% reported injection pain/soreness as a concern. For Months 2-4, 95% of injections were within a +/-7-day dosing window (5% were early, -7 to -14 days). No patients missed an injection or required oral bridging.

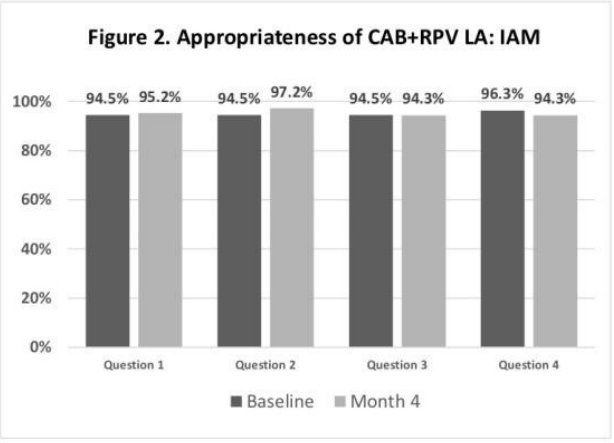
Figure 1. Acceptability of CAB+RPV LA: AIM



AIM utilizes a five-point Likert Scale (1=Completely Disagree to 5=Completely Agree). Bars represent the proportion of patients who Agreed (4) or Completely Agreed (5) with each statement.

AIM Question 1: CAB+RPV LA meets my needs for treating my HIV
AIM Question 2: CAB+RPV LA is appealing to me
AIM Question 3: I like CAB+RPV LA for treating my HIV
AIM Question 4: I welcome CAB+RPV LA for treating my HIV

Figure 2: Appropriateness of CAB+RPV LA: IAM



IAM utilizes a five-point Likert Scale (1=Completely Disagree to 5=Completely Agree). Bars represent the proportion of patients who Agreed (4) or Completely Agreed (5) with each statement.

IAM Question 1: CAB+RPV LA is fitting for my life
IAM Question 2: CAB+RPV LA is suitable for my life
IAM Question 3: CAB+RPV LA is applicable to my life
IAM Question 4: CAB+RPV LA is a good match for my life

Conclusion. Most patients found CAB+RPV LA to be acceptable and appropriate, and a majority reported monthly appointments were highly acceptable. Initial implementation data suggest CAB+RPV LA is a convenient, appealing alternative treatment option for patients, with few reported logistical challenges.

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1035. Patient-Reported Outcomes on Long-Acting Cabotegravir + Rilpivirine as Maintenance Therapy: FLAIR 96-Week Results

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Session: P-47. HIV: Treatment

Background. In the phase 3 FLAIR study, switching to monthly injectable long-acting (LA) cabotegravir (CAB) + rilpivirine (RPV) was noninferior to continued daily oral dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) for the maintenance of virologic suppression over 96 weeks in adults with HIV-1. Key patient-reported outcomes (PROs) through Week 96 are presented.

Methods. In FLAIR, ART-naive adult participants received induction therapy with oral DTG/ABC/3TC for 20 weeks. Those with HIV-1 RNA < 50 c/mL at 16 weeks were randomized (1:1) to continue DTG/ABC/3TC or receive monthly CAB + RPV LA injections after a 4-week lead-in with daily oral CAB + RPV through Week 96. Treatment satisfaction (HIV Treatment Satisfaction Questionnaire status version [HIVTSQs]) and acceptability of injections (Perception of Injection [PIN] Questionnaire) up to Week 96 were secondary endpoints.

Results. A total of 566 participants were randomized (median age, 34 years; 22% female); baseline characteristics were similar between treatment groups. At Week 96, significantly greater improvement from baseline in total treatment satisfaction score was observed in the CAB + RPV LA vs DTG/ABC/3TC treatment group (adjusted mean difference, 2.3 [95% CI, 1.1-3.5]; $P< 0.001$), further increasing from Weeks 24 (2.1 [0.9-3.3]) and 44 (0.7 [−0.4, 1.9]). Key drivers for the difference in HIVTSQs between treatment groups were items assessing convenience, flexibility, and satisfaction to continue with LA therapy. In participants receiving CAB + RPV LA, mean score for the "Acceptability of ISRs" dimension of PIN (scale, 1-5) significantly decreased (improved) from Week 5 to Weeks 41, 48, and 96 (2.08 to 1.71, 1.66, and 1.71, respectively; $P< 0.001$ for all). In addition, 82% and 85% of LA participants, respectively, rated pain and local reactions due to injections as "totally" or "very acceptable" at Week 96.

Conclusion. At Week 96, FLAIR participants receiving LA therapy reported greater improvement in treatment satisfaction compared with participants continuing on daily oral medication as well as overall good acceptability of injections with improvement over time. Overall, these results support monthly CAB + RPV LA as an alternative to daily oral regimens for adults with HIV-1.

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1036. Persistence of Guideline-Recommended Antiretroviral Therapy Regimens among Persons Living with HIV Newly Initiating Treatment in the US

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Session: P-47. HIV: Treatment

Background. Discontinuation of first-line antiretroviral therapy (ART) may lead to poor outcomes for persons living with HIV (PLWH). While single-tablet regimens (STRs) have been associated with greater persistence compared to multi-tablet regimens (MTRs), few real-world studies have assessed persistence with current guideline-recommended ART regimens. The study aims to assess persistence among treatment-naïve PLWH initiating guideline-recommended ART regimens

Methods. Longitudinal pharmacy claims were extracted from IQVIA's US LRx database for PLWH initiating ART between Jan 1, 2016 - Jul 31, 2019 (index period), with the observational period up to Jan 31, 2020. Index date was defined as the date of the first ART claim for STRs, or the date of the last filled drug of 1st set of claims for MTRs. Persistence was measured as the number of days until treatment discontinuation (≥ 90-day gap in therapy) and presented via Kaplan-Meier curves. Risk of discontinuation was assessed via Cox proportional hazards models, with BIC/FTC/TAF used as the reference ART regimen.

Results. Overall, 90,949 PLWH initiated STRs and 20,737 initiated MTRs. Average (SD) age was 43 (14) years, 75% were male, and 75% had commercial insurance. At 6 months of follow-up, 71% of PLWH initiating STRs and 56% initiating MTRs remained on their ART regimen. The proportion remaining on their index regimen at 6 months of follow-up was 79% for BIC/FTC/TAF, 73% for EVG/COBI/FTC/TAF, 71% for DTG/ABC/3TC, 69% for DTG + FTC/TAF, 67% for EFV/FTC/TDF, 62% for EVG/COBI/FTC/TDF, and 38% for DTG + FTC/TDF. Risk of discontinuation was higher for MTRs compared to STRs (hazard ratio [HR]: 1.63, 95% CI: 1.61 - 1.66). Compared to the referent BIC/FTC/TAF, risk of discontinuation was higher for EVG/COBI/FTC/TAF (HR: 1.54, 95% CI: 1.48 - 1.60), DTG/ABC/3TC (HR: 1.58, 95% CI: 1.52, 1.65), DTG + FTC/TAF (HR: 1.83, 95% CI: 1.74 - 1.93), EFV/FTC/TDF (HR: 2.31, 95% CI: 2.21 - 2.41), EVG/COBI/FTC/TDF (HR: 2.58, 95% CI: 2.47 - 2.70), and DTG + FTC/TDF (HR: 6.20, 95% CI: 5.83 - 6.59).