Anti-racist, anti-sexist, anti-ageist implementation science study of long-acting injectable Cabotegravir and Rilpivirine in clinic and community settings: ILANA Primary Endpoint (M12) results

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Key Takeaways:

- **Most participants chose not to receive their CAB+RPV injections in the community, but those who did found it highly acceptable.**
- **The benefits of CAB+RPV and community delivery may not be felt equally across all people living with HIV, demonstrating the importance of equitable recruitment and study protocol design.**
- **The type of community setting offered should be carefully considered, and concerns around confidentiality, stigma, and access to HIV-specialist staff should be addressed.**

Background

- Limited evidence exists on community delivery of long-acting injectable cabotegravir and rilpivirine (CAB+RPV).
- Prior studies significantly underrepresented women, racially minoritised, and older people.
- ILANA is the first to deliver CAB+RPV-LAI in community settings using an inclusive protocol to recruit equitably.
- We present primary endpoint (M12), and pre-specified sub-group analyses (gender/race/age).

Methods

- Study sites were six large urban clinics in the United Kingdom, in London (n=4), Brighton (n=1) and Liverpool (n=1). Each site chose a community setting feasible for them, which included home visits (n=3), patient support organisations (n=2), and a community clinic (n=1).
- Injections were delivered on-label in the clinic (M1-6) and according to patient choice in clinic or community (M6-12).
- Quantitative surveys used validated measures: feasibility (FIM), acceptability (AIM) and appropriateness (IAM) of intervention measures and the HIV Treatment Satisfaction Questionnaire (HIVTSQs).
- Primary endpoint: FIM at M12 for the injection and community delivery
- Key secondary endpoints: AIM, IAM and HIVTSQs (baseline, M4, M12)
- Tertiary endpoints: virological and safety outcomes
- Demographic characteristics, survey data and virological data were summarised using descriptive statistics.
- FIM, AIM and IAM were analysed as continuous scores and grouped as agreement/complete agreement (mean score >4) versus other responses.

Results

- Of 145 people approached to participate, 114 were enrolled in the study (54% female; 70% racially minoritised and 40% aged >50 [Table 1])
- Overall, 114 (100%) initiated CAB+RPV and completed baseline surveys and 111 (97%) received at least one injection.
- 109 (95.6%) attended M4 visit and 106 (93.0%) completed questionnaires.
- 102 (89.5%) attended M12 visit and 95 (83.4%) completed questionnaires.
- By M12, 27 (23.7%) participants attended at least one community-setting visit: 19 received home visits and 8 attended a community-based organisation.
- Most common concerns about CAB+RPV at baseline M4 and M12 were potential side effects and efficacy rather than appointment logistics (Table 2). These diminished over the 12 months.

Table 1. ILANA participant characteristics (n=114)

Age (years)	
<50 (n, %)	68 (59.7)
≥ 50 (n, %)	46 (40.4)
Gender	
Cis-Woman (n, %)	60 (52.6)
Cis-Man (n, %)	52 (45.6)
Transgender woman (n, %)	2 (1.8)
Sexual orientation	
Heterosexual (n, %)	77 (67.6)
Gay / Bisexual / Queer / Same gender loving (n, %)	35 (30.7)
Prefer not to answer	2 (1.8)
Ethnicity and race	
Black, Black British, African, or Caribbean (n, %)	58 (50.9)
White British, European or Other (n, %)	34 (29.8)
Mixed / Other ethnic groups (n, %)	16 (14.0)
Asian or Asian British (n, %)	6 (5.3)
Participant clinical history	
≥2 medical conditions (n, %)	51 (44.7)
>2 concomitant medications (n, %)	54 (47.4)
Use of chems / recreational drugs (n, %)	7 (6.1)
Time since HIV diagnosis (median years, IQR)	13.0 (8.0, 19.0)
Time since starting ARVs (median years, IQR)	11.0 (7.0, 16.0)
Total number of regimens received (median, IQR)	3.0 (2.0, 5.0)
Previous ARV regimen exposure: NNRTI (n, %)	65 (57.0)
Previous experience of virological failure (n, %)	9 (7.9)

Table 2. Patient-reported concerns about CAB+RPV at baseline, M4 and M12

Which of the following concerns do you have about treatment with CAB RPV LA injections, if any? (multi-select)	Baseline (N=114)	M4 (N=109*)	M12 (N=102*)
Other side effects or possible long-term effects from the treatment (%)	50 (43.9)	26 (24.5)	26 (27.4)
Pain or soreness from the injection (%)	47 (41.2)	55 (51.9)	52 (54.7)
Impact on my viral load and/or CD4/ T-cell counts (%)	30 (26.3)	25 (23.6)	12 (12.6)
No concerns (%)	26 (22.8)	23 (21.7)	23 (24.2)
Scheduling my travel/holiday around my injection visits (%)	25 (21.9)	20 (18.9)	19 (20.0)
Privacy/confidentiality concerns going to the clinic/practice for my injection visits (%)	18 (15.8)	13 (12.3)	10 (10.5)
Clinic/practice hours for injection visits not fitting with my schedule (%)	18 (15.8)	14 (13.2)	6 (6.3)
Getting tired of the injections after a while (%)	17 (14.9)	12 (11.3)	15 (15.8)
Getting to the clinic/practice for the injection visits for example, difficulty missing work/school, finding childcare, costs of travel and/or parking (%)	17 (14.9)	13 (12.3)	6 (6.3)
Forgetting my appointments for the injection visit (%)	9 (7.9)	9 (8.5)	8 (8.4)
Other concerns (%)	2 (1.8)	2 (1.9)	3 (3.2)

** Total visit conducted. Missing not included in denominator for %.*

Clinical Outcomes

- At M12, **735/745 (98.7%) injections were given within the ±7-day window–641/651 (98.5%) in clinic; 94/94 (100%) in community settings.**
- 12/114 (10.5%) participants withdrew before M12, 3 during the oral-lead in.
- Reasons for withdrawal: unconfirmed viraemia [HIV-1 VL 50-200 (n=3)], injection-related reasons (n=3), participant choice (n=3), pregnancy (n=1), participant death (n=1), clinic transfer (n=1)
- 1 virologic failure (two consecutive VL> 200 c/mL) based on local bloods repeated at non-study visits around M3, re-suppressed at M4 and withdrew with viraemia 50-200 c/mL at M5 with no data on emergent resistance
- Two participants (1.8%) experienced SAEs (unrelated death; severe food poisoning).
- No reported adverse drug reactions.
- One pregnancy led to a healthy live birth.

Treatment satisfaction

- **HIVTSQ score was high at baseline (mean 54.99 (SD 10.09)), and improved by M12 (mean difference +6.52 (SD 11.38), p<0.01)** across all subgroup categories
- Women experienced a smaller increase than men (mean difference +4.35 [SD 10.61] vs. mean difference +9.5 [SD 11.85], p=0.03) as did Black vs non-Black participants (mean difference +3.76 (SD 10.44) vs mean difference +9.46 (SD 11.71), p=0.01) and clinic vs community (mean difference +4.65 [SD 11.15] vs mean difference +11.46 [SD 10.66], p=0.01)

Implementation outcomes for the injection

- Injection feasibility (FIM) at M12 (Table 3):
  - High overall; **79.0% (n=95) agreed or completely agreed (FIM≥4) CAB+RPV is feasible.**
  - Women scored lower than men (FIM≥4: 69.1% [n=55] vs. 92.5% [n=40], p=0.01), as did Black vs non-Black participants (FIM≥4: 65.3% [n=49] vs. 93.5% [n=46], p<0.01) and clinic vs community (FIM≥4: 71.0% [n=75] vs. 100.0% [n=27], p<0.01).
- Injection acceptability (AIM) at M12 (Table 3):
  - High overall: **85.3% (n=95) agreed/completely agreed (AIM≥4) that CAB+RPV is acceptable** and across all sub-groups.
- Injection appropriateness (IAM) at M12 (Table 3):
  - High overall: **87.4% (n=95) agreed/completely agreed (IAM≥4) that CAB+RPV is appropriate**.
  - Women had lower appropriateness scores than men (IAM≥4: 80.0% [n=55] vs 97.5% [n=40], p=0.01), as did Black vs non-Black participants (IAM≥4: 65.3% [n=49] vs 93.5% [n=46], p<0.01) and clinic vs community (IAM≥4: 82.6% [n=69] vs 100.0% [n=26], p=0.03).

Table 3. Proportion of participants who agreed/completely agreed that the injection was feasible (FIM≥4), acceptable (AIM≥4), and appropriate (IAM≥4) at baseline, M4 and M12, overall and by subgroup.

Tool	Timepoint	Overall (%)	Clinic[1] (%)	Community[1] (%)	p-value[2]	Women (%)	Men (%)	p-value[2]	Black (%)	Non-Black (%)	p-value[2]	Age <50 (%)	Age ≥50 (%)	p-value[2]
FIM	Baseline	93/114 (81.6)	68/87 (78.2)	25/27 (92.6%)	0.15	46/62 (74.2)	47/52 (90.4)	*0.03*	43/58 (74.1)	50/56 (89.3)	*0.04*	54/67 (79.4)	39/46 (84.8)	0.47
	M4	98/106 (92.4)	74/80 (92.5)	24/26 (92.3)	>0.99	54/60 (90.0)	44/46 (95.7)	0.46	49/54 (90.7)	49/52 (94.2)	0.72	62/64 (96.9)	36/42 (85.7)	0.06
	M12	75/95 (79.0)	49/69 (71.0)	26/26 (100.0)	*<0.01*	38/55 (69.1)	37/40 (92.5)	*0.01*	32/49 (65.3)	43/46 (93.5)	*<0.01*	48/57 (84.2)	27/38 (71.1)	0.12
AIM	Baseline	105/114 (92.1)	79/87 (90.8)	26/27 (96.3)	0.68	56/62 (90.3)	49/52 (94.2)	0.51	52/58 (89.7)	53/56 (94.6)	0.49	63/67 (92.7)	42/46 (91.3)	>0.99
	M4	95/106 (89.6)	71/80 (88.8)	24/26 (92.3)	>0.99	53/60 (88.3)	42/46 (91.3)	0.75	48/54 (88.9)	47/52 (90.4)	0.80	57/64 (89.1)	38/42 (90.5)	>0.99
	M12	81/95 (85.3)	56/69 (81.2)	25/26 (96.2)	0.10	46/55 (83.6)	35/40 (87.5)	0.60	39/49 (79.6)	42/46 (91.3)	0.11	49/57 (86.0)	32/38 (84.2)	0.81
IAM	Baseline	101/114 (88.6)	75/87 (86.2)	26/27 (96.3)	0.30	52/62 (83.9)	49/52 (94.2)	0.08	50/58 (86.2)	51/56 (91.1)	0.41	61/67 (89.7)	40/46 (87.0)	0.65
	M4	99/106 (93.4)	73/80 (91.3)	26/26 (100.0)	0.19	56/60 (93.3)	43/46 (93.5)	>0.99	50/54 (92.6)	49/52 (94.2)	>0.99	62/64 (96.9)	37/42 (88.1)	0.11
	M12	83/95 (87.4)	57/69 (82.6)	26/26 (100.0)	*0.03*	44/55 (80.0)	39/40 (97.5)	*0.01*	38/49 (77.6)	45/46 (97.8)	*<0.01*	53/57 (93.0)	30/38 (79.0)	0.06

Note: %s calculated excluding missing data ; 1) Location preference at 6 months not available for all participants; 2) p-values from chi-squared test

Implementation outcomes for the community setting

- Community setting feasibility (FIM) at M12 (Table 4):
  - Lower for the community setting than for the injection: **47.4% (n=95) agreed/completely agreed (FIM≥4) that the community setting is feasible.**
  - Black participants scored lower than non-Black (FIM≥4: 36.7% [n=49] vs. 58.7% [n=46], p=0.03), as did clinic vs community (FIM≥4: 34.8% [n=75] vs 80.8% [n=27], p<0.01).
- Community setting acceptability (AIM) at M12 (Table 4):
  - Lower for the community setting than for the injection: **44.2% (n=95) agreed/completely agreed (AIM≥4) that the community setting was acceptable.**
  - Black participants scored lower than non-Black for community setting (AIM≥4: 34.7% [n=49] vs. 54.4% [n=46], p=0.05), as did clinic vs community (AIM≥4: 33.3% [n=75] vs. 73.1% [n=27], p<0.01).
- Community setting appropriateness (IAM) at M12 (Table 4):
  - Lower for the community setting than for the injection: **47.4% (n=95) agreed/completely agreed (IAM≥4) that the community setting is appropriate.**
  - Black participants scored lower than non-Black on community setting appropriateness (IAM≥4: 36.7% [n=49] vs. 58.7% [n=46], p=0.03), as did clinic vs community (IAM≥4: 34.8% [n=75] vs. 80.8% [n=27], p<0.01).

Table 4. Proportion of participants who agreed/completely agreed that the community setting was feasible (FIM≥4), acceptable (AIM≥4), and appropriate (IAM≥4) at baseline, M4 and M12, overall and by subgroup

Tool	Timepoint	Overall (%)	Clinic (%)	Community (%)	p-value	Women (%)	Men (%)	p-value	Black (%)	Non-Black (%)	p-value	Age <50 (%)	Age ≥50 (%)	p-value
FIM	Baseline	56/114 (49.1)	33/87 (37.9)	23/27 (85.2)	*<0.01*	24/62 (38.7)	32/52 (61.5)	*0.02*	23/58 (39.7)	33/56 (58.9)	*0.04*	32/67 (47.1)	24/46 (52.2)	0.59
	M4	54/106 (50.9)	31/80 (38.8)	23/26 (88.5)	*<0.01*	30/60 (50.0)	24/46 (52.2)	0.85	23/54 (42.6)	31/52 (59.6)	0.08	36/64 (56.3)	18/42 (42.9)	0.18
	M12	45/95 (47.4)	24/69 (34.8)	21/26 (80.8)	*<0.01*	23/55 (41.8)	22/40 (55.0)	0.20	18/49 (36.7)	27/46 (58.7)	*0.03*	31/57 (54.4)	14/38 (36.8)	0.09
AIM	Baseline	54/114 (47.4)	30/87 (34.5)	24/27 (88.9)	*<0.01*	26/62 (41.9)	28/52 (53.9)	0.21	23/58 (39.7)	31/56 (55.4)	0.09	31/67 (45.6)	23/46 (50.0)	0.64
	M4	49/106 (46.2)	27/80 (33.8)	22/26 (84.6)	*<0.01*	26/60 (43.3)	23/46 (50.0)	0.50	21/54 (38.9)	28/52 (53.9)	0.12	32/64 (50.0)	17/42 (40.5)	0.34
	M12	42/95 (44.2)	23/69 (33.3)	19/26 (73.1)	*<0.01*	22/55 (40.0)	20/40 (50.0)	0.33	17/49 (34.7)	25/46 (54.4)	*0.05*	29/57 (50.9)	13/38 (34.2)	0.11
IAM	Baseline	52/114 (45.6)	30/87 (34.5)	22/27 (81.5)	*<0.01*	24/62 (38.7)	28/52 (53.9)	0.11	22/58 (37.9)	30/56 (53.6)	0.09	29/67 (42.7)	23/46 (50.0)	0.44
	M4	51/106 (48.1)	27/80 (33.8)	24/26 (92.3)	*<0.01*	26/60 (43.3)	25/46 (54.4)	0.26	20/54 (37.0)	31/52 (59.6)	*0.02*	32/64 (50.0)	19/42 (45.2)	0.63
	M12	45/95 (47.4)	24/69 (34.8)	21/26 (80.8)	*<0.01*	23/55 (41.8)	22/40 (55.0)	0.20	18/49 (36.7)	27/46 (58.7)	*0.03*	31/57 (54.4)	14/38 (36.8)	0.09

Conclusions

- CAB+RPV-LAI injections were considered highly feasible, acceptable and appropriate by this under-represented group of participants.
- Most participants chose not to receive treatment in the community. Those who did found it to be highly acceptable and feasible.
- The type of community setting offered should be carefully considered, and concerns around confidentiality, stigma, and access to HIV-specialist staff addressed.
- Further exploration of CAB+RPV delivery in alternative community settings such as primary care or pharmacies may be beneficial.

Presented at AIDS 2024, the 25th International AIDS Conference

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