Advancing Equity in the Delivery of Long-acting Injectable Antiretroviral Therapy: Preliminary Results of the IM-CAPABLE Study

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BACKGROUND

- Cabotegravir/rilpivirine long-acting (CAB+RPV LA) is the first complete long-acting regimen for HIV, given as intramuscular injections every one or two months.
- In Nebraska (NE), uptake has been concentrated among patients residing in urban areas and receiving care in a Ryan White-funded HIV clinic with on-site injection capacity, dedicated multidisciplinary program support.
- People with HIV (PWH) in rural and non-metropolitan (RNM) areas face long travel distances, few HIV specialists, and heightened disclosure concerns in small communities.
- Implementation data from RNM settings are limited, including how best to reach those who may considerably benefit from long-acting Antiretroviral therapy (ART).

OBJECTIVE

To evaluate acceptability, appropriateness and feasibility and early clinical effectiveness of a hybrid hub-and-spoke model that delivers CAB+RPV LA at a non-HIV clinic in a non-metropolitan community, supported by specialist care from an urban HIV hub.

METHODS, MEASURES & ANALYSIS

- Prospective hybrid type II implementation cohort study with site comparison.
  - Hub: UNMC Specialty Care Center, Omaha, NE: urban, Ryan White-funded HIV clinic.
  - Spoke: partnering non-HIV Nebraska Medicine clinic, Grand Island, NE: 150 miles from the hub.
- Acceptability (AIM), Appropriateness (IAM), Feasibility (FIM), reported as % "completely agree".
- HIV Treatment Satisfaction Questionnaire (HIVTSQ), 12 items scored 0–6.
- HIV Stigma Scale, 12 items scored 1–4; lower = less stigma.
- Injection-window adherence (±7 days of scheduled date) and viral suppression (HIV RNA <20 copies/mL).
- Paired t-tests for within-person change (n=34 with both timepoints); Fisher exact / t-tests for between-site comparison of change.

TABLE 1 · BASELINE CHARACTERISTICS

Characteristics	Grand Island (n=17)	Omaha SCC (n=23)	Total (n=40)	p
Age, mean (SD)	45.3 (12.6)	43.4 (10.6)	44.2 (11.4)	0.57
BMI, mean (SD)	30.2 (7.4)	28.5 (4.1)	29.2 (5.7)	0.39
Male	15 (88.2%)	19 (82%)	34 (85%)	1.00
White	16 (94.1%)	18 (78.13%)	34 (85%)	0.22
Hispanic	7 (41.2%)	4 (17.4%)	11 (27.5%)	0.15
High school education or less, n (%)	12 (70.6%)	15 (65.2%)	27 (67.5%)	1.00
Viral suppression (<20 copies/mL)	17 (100%)	23 (100%)	40 (100%)	—
Private/commercial insurance, n (%)	10 (58.8)	12 (52.2)	22 (55.0%)	0.75
Years since HIV diagnosis, median (IQR)	8 (6-12)	10 (8-14)	10 (6-14)	0.43
Years on ART, median (IQR)	7 (5-10)	10 (8-13)	9 (1-28)	0.29
Chose site closest to home, n (%)	17 (100%)	21 (91.3%)	38 (95%)	0.5
≥1 comorbidity, n (%)	12 (70.6%)	12 (52.2%)	24 (60%)	0.33
Discontinuations	1 (5.9%)	4 (17.4%)	5 (12.5%)	0.37

Continuous variables were compared using the Mann–Whitney U test; categorical variables were compared using two-sided Fisher's exact tests. Percentages are based on the enrollment-site denominator.

THE IM-CAPABLE HUB-AND-SPOKE DELIVERY MODEL

HUB · URBAN
UNMC Specialty Care Center
Omaha, NE

- Dedicated program support
  - HIV specialist prescribing & oversight
  - Patient Care Coordination and Medication Access Support
  - Telehealth visits with the patient at the spoke
  - Study coordination & protocol fidelity

Telehealth specialist visits
Provider training · HUB team travel to GI to deliver first injection and conduct patient education

Injection confirmation · Local labs
Adverse events · Scheduling updates

SPOKE · NON-METROPOLITAN
Partnering non-HIV clinic
Grand Island, NE (150 miles away)

- Local nursing staff administer the subsequent injection
- Local clinical champion on site
- Local labs and first-line adverse-event response
- Familiar, close-to-home care setting

1 BASELINE ASSESSMENT

- Patients: AIM / IAM / FIM, HIVTSQ, HIV stigma scale, treatment preferences
- Providers & staff:
  - Listening sessions/meetings
  - Acceptability, perceived feasibility, training needs
  - Site readiness: workflow mapping, storage capacity, staffing review

2 PRE-IMPLEMENTATION TRAINING

- Spoke staff trained by hub
  - Separate HIV 101 training with all clinic patient-facing staff
  - Training covered: CAB+RPV LA basics, gluteal IM technique, storage & cold chain, dosing window, oral bridging, missed-dose and adverse-events
- Local clinical champion designated to sustain the workflow

3 TELEHEALTH & CROSS-SITE COMMUNICATION

- Specialist visits delivered by telehealth while the patient is at the spoke
- Shared documentation and secure messaging between sites
- Recurring hub–spoke case review and injection-calendar tracking

4 PATIENT SUPPORT SERVICES (Hub-driven)

- Appointment reminder calls and text messages before every injection
- Care coordinator as a single point of contact
- Scheduling and travel support to keep visits in window
- Missed-visit tracking with rapid outreach and re-engagement

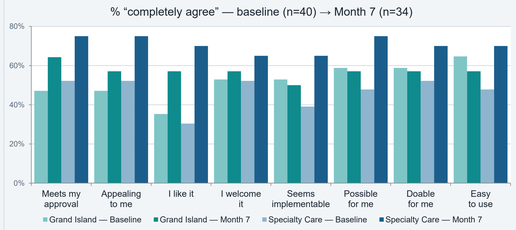
Injection-window adherence = injection received within the label-defined window around the target date. Both sites used the same protocol, assessments and reminder workflow.

PARTICIPANT FLOW & ANALYSIS POPULATIONS

Interim analysis — remaining participants had not yet reached the Month 9 timepoint at data cutoff.

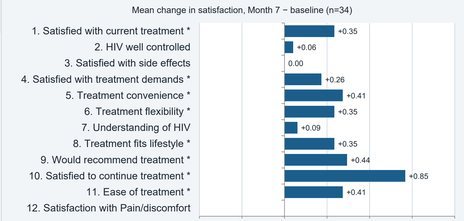
40 enrolled & initiated GI 17 · SCC 23 → 5 discontinued CAB+RPV LA → 34 Month 7 paired assessments GI 14 · SCC 20 → 35 Month 7 injections GI 15 · SCC 20 → 33 Month 9 viral loads GI 14 · SCC 19

ACCEPTABILITY & FEASIBILITY (AIM / FIM)



Displayed percentages use different denominators at the two timepoints; paired t-tests use the 34 participants with both assessments.

TREATMENT SATISFACTION (HIVTSQ)



p<0.05, paired t-test. 8 of 12 items improved and reached significance.
Item 12 "satisfaction with discomfort/pain" was not compared (patients still on ART at baseline)

IMPLEMENTATION OUTCOMES · SIGNIFICANCE

AIM / FIM item	Overall change†	Site difference‡	Direction
Meets my approval [Acceptability]	**p=0.007**	0.884	↑ Hub and Spoke improved
Appealing to me [Acceptability]	p=0.169	0.234	↑ Hub improved
I like it [Acceptability]	**p=0.001**	0.553	↑ Hub and Spoke improved
I welcome it [Acceptability]	p=1.000	0.239	↓ Spoke declined
Seems implementable [Feasibility]	p=0.133	0.079	↑ Hub improved · ↓ Spoke declined
Seems possible for me [Feasibility]	p=0.414	0.061	↑ Hub improved · ↓ Spoke declined
Seems doable for me [Feasibility]	p=0.571	0.094	↑ Hub improved · ↓ Spoke declined
Seems easy to use [Feasibility]	p=1.000	0.062	↓ Spoke declined

† Paired t-test, Month 7 vs baseline (N=34). t-test is on mean item score while cells show % completely agree
↑overall change in both sites *‡ Between-site comparison of change.*
High endorsement was sustained at both sites, with no significant site differences.

HIV STIGMA (12-ITEM SCALE)

Items with significant change at Month 7 (paired, n=34)

Stigma item	Baseline	Month 7	Change	p
Work to keep my HIV secret	3.02	2.76	**−0.21**	**0.017**
Careful whom I tell	3.45	3.12	**−0.27**	**0.027**

Scale 1 = strongly disagree to 4 = strongly agree; lower scores indicate less stigma and less secrecy.
The remaining 10 items showed no significant change (all p>0.05).
Reduction in careful disclosure differed by site: the Specialty Care Center showed the greater reduction (p=0.038).
Both significant changes are disclosure items rather than enacted-stigma items — consistent with removing the daily pill bottle as a visible marker of HIV status, and with six fewer occasions per year on which treatment must be explained or concealed.

KEY FINDINGS

100% of injections were received within the dosing window through Month 9 at both sites

100% of participants remained virologically suppressed at Month 9

8 of 11* HIVTSQ satisfaction items improved significantly

*Satisfaction with Pain/discomfort was not compared to baseline

CONCLUSIONS

- Delivering CAB+RPV LA at a non-HIV clinic 150 miles from the specialist hub was feasible and highly acceptable to patients at both sites.
- Injection timing held, and every injection was in window throughout Month 9.
- Virologic control was maintained at Month 9, with no between-site difference.
- Treatment satisfaction rose on eight of 12 items, most for willingness to continue treatment (Δ +0.85, p<0.001), convenience and ease of use.
- Disclosure-related stigma eased; At Month 7, mean satisfaction with injection-related discomfort (1st injection) was 5.24 (SD 1.10) on a 0-6 scale, with no significant site difference (p=0.073)

LIMITATIONS

- Single hub–spoke pair, 40 participants, no concurrent comparator.
- Interim analysis: 33 of 40 had a Month 9 viral load. Follow-up to Month 15 is ongoing
- Displayed percentages use different denominators at baseline (n=40) and Month 7 (n=34); paired tests use the 34 with both assessments.
- Participants elected long-acting therapy and were already on ART, a selected, motivated group.
- Item-level p-values are unadjusted for multiple comparisons

NEXT STEPS

Month-15 outcomes, staff time and cost analysis, and expansion to additional alternative sites of care.

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