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# JABS 48 week results: Implementation of long-acting cabotegravir and rilpivirine in vulnerable populations with complex needs

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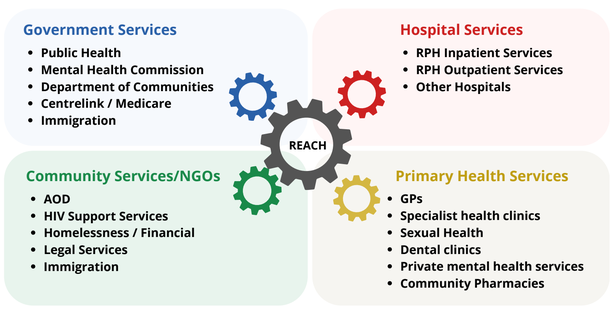
## Background

- Long-acting cabotegravir (CAB) + rilpivirine (RPV) is approved for use in virologically suppressed people living with HIV infection.
- The inJectable Antiretroviral feasiBility Study (JABS) evaluated the effectiveness of CAB+RPV in a large tertiary hospital ambulatory care setting in Perth, Western Australia.
- Participants with complex medical needs, social vulnerability and historical non-adherence, who are under-represented in registrational trials but may derive particular engagement and adherence benefits, were included in the enrolment.
- A multidisciplinary 'REACH' service comprising a Senior Social Worker, HIV Nurse Practitioner, and Immunology Welfare Assistant who liaise with the medical team as well as other agencies, provided individualised support to participants.

Figure 1. RPH REACH Service




## Methods

- **JABS** is a 48-week, single centre, single arm, open label study of long acting CAB 600mg plus RPV 900mg every 2 months to adults with treated HIV-1 infection.
- Oral lead in was included, as per recommendations at the time of study commencement.
- Primary endpoint: Proportion of attendances/delivery of injections within a fourteen-day dosing window over 12 months.
- Secondary and exploratory endpoints:
  - Missed/rescheduled appointments
  - Virological failures
  - Participant related outcomes
  - Oral bridging and discontinuations
  - Adverse events
  - Changes to service delivery
- Qualitative PRO data were obtained with questionnaires administered to participants at day 1, week 8, week 24 and week 48 as well as semi-structured interviews at Day 1 and week 48.
  - Questionnaires measured medication adherence (before JABS), treatment satisfaction pre and post commencing LA therapy, and injection experience (specifically surrounding pain, local reactions and acceptability). Semi-structured interviews discussed participants experiences with oral therapy and LA therapy, including challenges, facilitators, and suggestions for improvement.

Table 1. JABS Study Design

| Timeline | Day 1 | Week 4 | Week 8 | Week 16 | Week 24 | Week 32 | Week 40 | Week 48 |
|---|---|---|---|---|---|---|---|---|
| Treatment | Oral lead-in start | CAB + RPV LA Dose 1 | Dose 2 | Dose 3 | Dose 4 | Dose 5 | Dose 6 | Dose 7 |
| Data Collection | ♦ ■ ● ▲ | ● | ● ✕ | ● | ● ▲ | ● | ● | ■ ● ▲ ✕ |

♦ Medication adherence survey ■ Semi-structured interview ● Blood monitoring test ▲ Treatment satisfaction survey ✕ Injection experience survey

# Results

## Baseline Characteristics

Table 2. Participant Demographics (n=60)

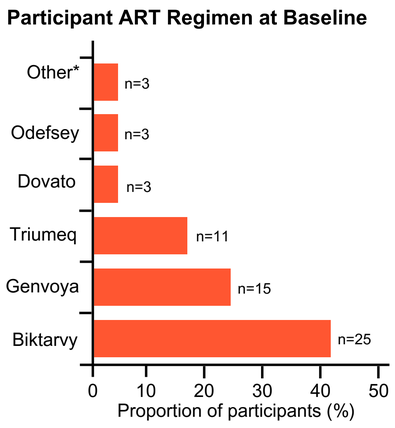
| Birth sex | ATSI Identifying | Country of birth | First language |
|---|---|---|---|
| 85% male (n=51) | 98.3% non-ATSI (n=59) | 43.3% Australia (n=26) | 75% English (n=15) |
| 15% female (n=9) | 1.7% ATSI (n=1) | 56.7% other country (n=34) | 25% Other language (n=45) |

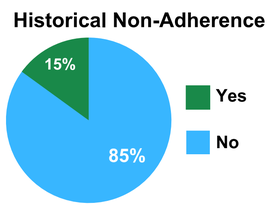
ATSI, Aboriginal and/or Torres Strait Islander

- 21.7% (n=13) African country of origin
- 15% (n=9) had BMIs above 30

| | Mean | StDev | Min | Max |
|---|---|---|---|---|
| Age | 41.5 | 10.17 | 18 | 63 |
| BMI | 26.22 | 4.17 | 18.75 | 39.85 |

Figure 2. Participant Treatment History (n=60)

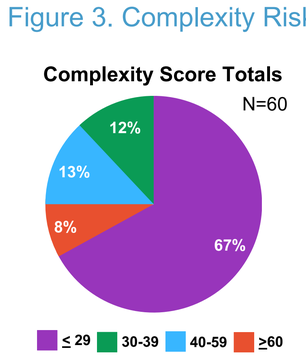


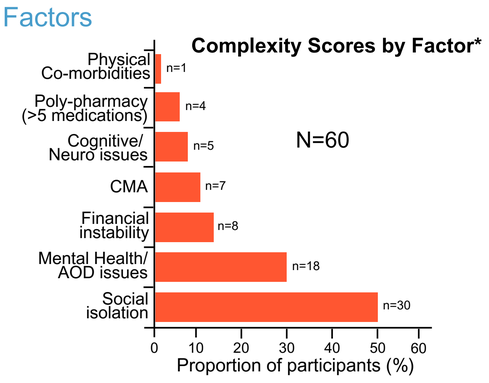




| | Mean | StDev | Min | Max |
|---|---|---|---|---|
| Years diagnosed | 9.75 | 7.46 | 1 | 32 |
| Years on treatment | 8.33 | 6.15 | 1 | 29 |

*Other included Descovy/Nevirapine; Descovy/Dolutegravir; Kaletra/Tenofovir/Lamivudine

Figure 3. Complexity Risk Factors

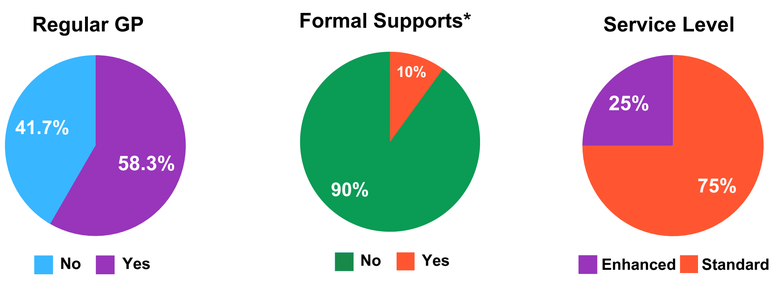



*Hepatitis C and/or Cancer also measured as factor but was reported by 0 participants
CMA, Crystal methamphetamine; AOD, Alcohol and Other Drugs

- Calculated using a validated complexity rating score[1]
  - This tool did not consider other factors which may impact complexity including housing status, family commitments, travel issues, work commitments (including fly-in-fly-out work).

Figure 4. Level of Engagement and Support (n=60)

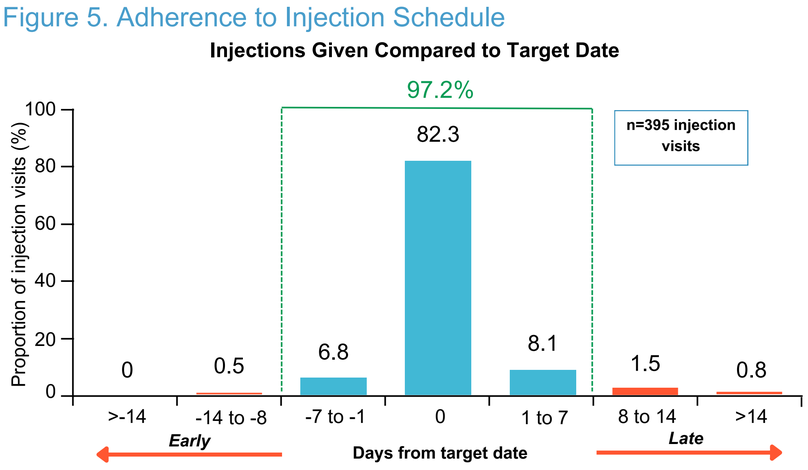



*Formal supports included Public Health, Mental Health or Community Case Management

- Staff assessed participants as requiring either a "standard" or "enhanced" service level based upon their previous adherence and engagement as well as complexity factors that were not considered in the complexity score tool.

## Adherence

Figure 5. Adherence to Injection Schedule

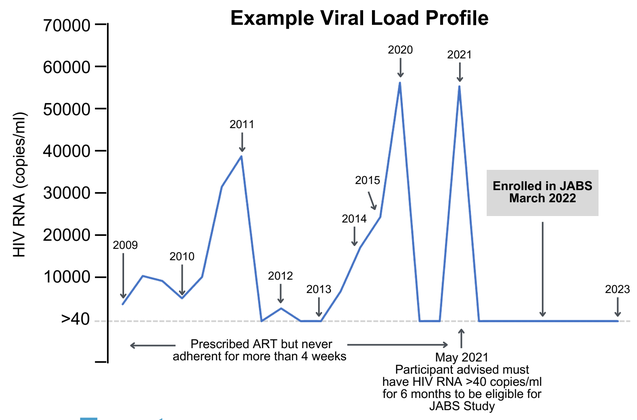



- Overall, 97.2% (n=384) of injections occurred within the dosing window, 97.7% (n=386) of occurred within the dosing window or earlier, and 2.3% (n=9) occured late.
  - Most common reason for late injections were being unable to attend due to work commitments (n=3) or being difficult to engage/contact (n=3)
  - Mean number of days from target date:0.4; range: 8-41 days
  - Dose administered 41 days after target date was due to an injection site reaction (hard lump) causing a delay in injection dose. Oral therapy (oral CAB+RPV) was used during this period.

## Virological Outcomes

- Participants who completed the study at week 48: n=54
- 98.15% of participants had HIV RNA <40 copies/ml at week 48 (n=53)
  - 1 participant had HIV RNA of 55 copies/ml at week 48
- No virological failures (>200 copies/ml) during course of entire study

Figure 6. Viral Load Profile




## Adverse Events

Table 3. Adverse Events

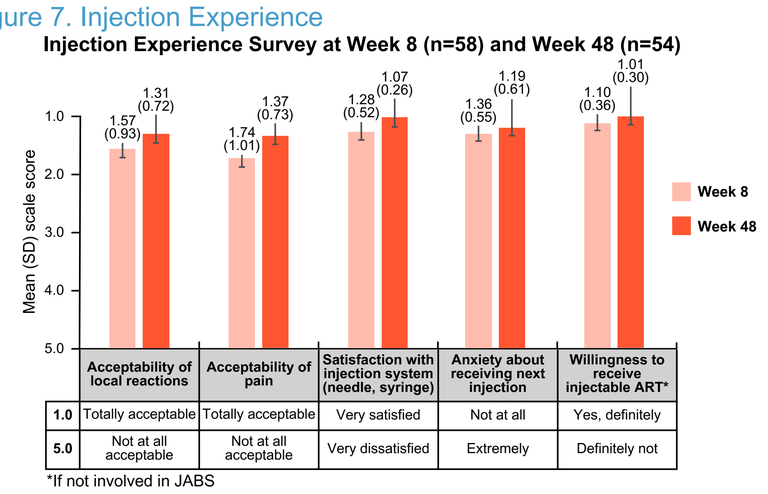
| | Grade | IM CAB + RPV (N=395) | Oral Lead In (N=60) |
|---|---|---|---|
| Drug-related adverse events | Grade 1-2 | 0 | 1(1.7%)* |
| | Grade 3 | 0 | 0 |
| Injection site reactions | Grade 1-2 | 115(29.1%) | N/A |
| | Grade 3 | 3(0.8%) | N/A |
| Discontinuation due to adverse events (n=2) | | 1(1.7%) | 1(1.7%) |
| Discontinuation for other reasons** (n=4) | | 4 (6.7%) | 0 |

*3 participants reported difficulties during the oral lead-in due to being unable to take their PPI medication (not considered a drug-related AE)
** Discontinuation due to anticoagulant therapy (1), hepatitis B diagnosis (1), fertility management (1), personal health beliefs (1)

- 1 participant discontinued during the oral lead-in, reporting difficulties sleeping (as well as effects of being unable to take PPI medication (for reflux). Unable to discern if drug-related as participant reported current stressors likely impacting their sleep.
- 1 participant discontinued due to ISR, reporting the injection site pain was interfering with their exercise regimen.

## Patient Reported Outcomes

Figure 7. Injection Experience

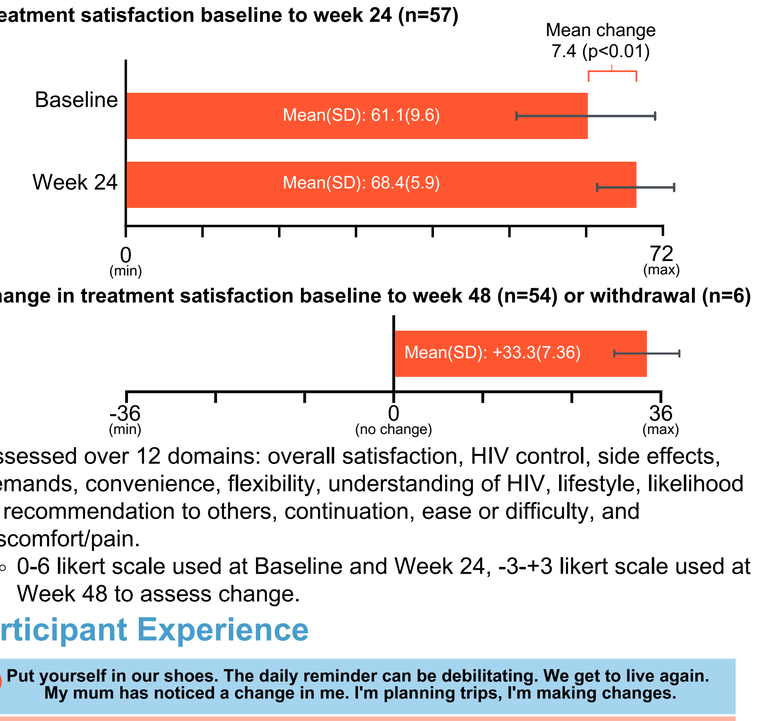



| | Acceptability of local reactions | Acceptability of pain | Satisfaction with injection system (needle, syringe) | Anxiety about receiving next injection | Willingness to receive injectable ART* |
|---|---|---|---|---|---|
| 1.0 | Totally acceptable | Totally acceptable | Very satisfied | Not at all | Yes, definitely |
| 5.0 | Not at all acceptable | Not at all acceptable | Very dissatisfied | Extremely | Definitely not |

*If not involved in JABS

- 21-question survey covering 5 domains: before/during the injections, after the injections, local reactions, pain, overall experience. Overall experience (questions 17, 18, 19, 20, 21) shown above.
- Completed at participants 2nd (week 8) and final (week 48) injection appointments.

Figure 8. Treatment Satisfaction




- Assessed over 12 domains: overall satisfaction, HIV control, side effects, demands, convenience, flexibility, understanding of HIV, lifestyle, likelihood of recommendation to others, continuation, ease or difficulty, and discomfort/pain.
  - 0-6 likert scale used at Baseline and Week 24, -3-+3 likert scale used at Week 48 to assess change.

## Participant Experience

> **Put yourself in our shoes. The daily reminder can be debilitating. We get to live again. My mum has noticed a change in me. I'm planning trips, I'm making changes.**
>
> **For the first time in 14 years, I celebrated my birthday without thinking about HIV at all.**
>
> **I will never go back to pills. I have freedom that I haven't had since before I was diagnosed.**
>
> **I never expected it to make a difference but it really has lifted a weight off my shoulders I didn't realise was there.**
>
> **Freedom of not having to think about diagnosis has changed everything. Friends have noticed I'm more like the old me. I even think I might start dating again.**
>
> **Being able to forget that I have HIV after being positive for 15 years is such a blessing.**

# Conclusions

- There is a high amount of interest in use of CAB+RPV among people living with HIV including those with risk factors for non-adherence to antiretroviral therapy
- Adherence to, and efficacy of, 2 monthly CAB+RPV in a real-world Australian population is comparable to those in phase III randomised clinical trials.
- People with identified complex needs, social vulnerability and historical non-adherence achieved the same levels of adherence, and virological suppression, as the wider study population.

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**References**: 1. Bulsara SM et al. Int J STD AIDS. 2019 Nov;30(13):1265-1274.
**Study approved** by Royal Perth Hospital Ethics Committee (HREC #RGS0000004857)

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