

Long-acting injectable antiretroviral therapy: pursuing equity of access through shared decision-making

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BACKGROUND Long-acting injectable antiretroviral therapy (LA) offers people living with HIV an effective alternative to daily oral therapy. This is in all respects an innovative therapeutic choice that should be offered to all individuals, net of well-known exclusion criteria, following a standardised decision-making process, without prejudice, in compliance with the principles of equity of access and prioritising patient choice.

METHODS To evaluate LA suitability fairly and proactively for our outpatient population, we developed an electronic screening tool to be applied to all individuals attending follow-up, regardless of any interest already expressed by the individual. The tool considers factors associated with virological failure (previous NNRTI or INSTI failure or resistance [including archived mutations], HIV subtype A6/A1, BMI \geq 30 kg/m²) and the current viral load to identify eligible individuals, strictly non-eligible individuals, and individuals requiring in-depth review to exclude or confirm eligibility. Through collegial discussions, we take a holistic approach that considers the overall risk/benefit for the individual, identifying individualised action points, and recording the discussion with the patient, including reasons for declining LA when offered. Our programme is ongoing. Here we present the data for July - November 2023.

RESULTS Across a cohort of 785 adults with HIV, to date, 270 (34%) have been proactively evaluated for LA. The median age was 49 years (IQR 40-57) and most were male at birth (75%) and native Italian (75%), contracted HIV sexually (83%), and were on triple ART regimens (75%), which were typically INI-based (74%). Of the 270 participants screened (Table 1), 56 (21%) were eligible, 84 (31%) were non-eligible (Fig 1), and 130 (48%) needed risk/benefit review (Fig 2). Among the 56 individuals who screened eligible, 11 (20%) started LA immediately; 21 (37%) declined the offer of LA; and a further 24 (43%) are waiting, typically pending completion of HBV vaccination (Table 1). Other common delaying factors included waiting for HIV-1 DNA sequencing to determine HIV subtype and/or archived resistance, and having no access to long needles for BMI >30 Kg/m². To date, 28/270 (10%) individuals started LA. Of these, one discontinued LA due to adverse events and one due to pregnancy; no virological failures have occurred to date.

Table 1. Outcomes of proactive screening for CAB RPV LA eligibility

Total number	270
Screened eligible, n (%)	56 (21)
Screened non-eligible, n (%)	84 (31)
Required risk/benefit review, n (%)	130 (48)
Started LA immediately post-screening, n (%)	11 (20)
Did not start LA immediately, n (%)	45 (80)
Not yet offered	8 (14)
Declined by PLWH	21 (37)
Prefers oral ART due to habit and greater autonomy	13 (23)
Q2M attendance difficult due to working patterns	2 (4)
Prefers to avoid restrictions on travel	1 (2)
Anxious about changing ART regimen	1 (2)
Not stated	2 (4)
Undecided, prefers to take time to consider	2 (4)
Postponed	16 (29)
HBV non-immune, requiring vaccination	13 (23)*
Waiting to complete clinical trials	7 (13)*
Total started LA, n (%)	28 (10)
Discontinued LA, n (%)	2 (7%)
Virological failure (confirmed VL >50 cps/mL), n (%)	0 (0)

*not mutually exclusive

Figure 1. Long Acting not eligible PLWH, n. 84/270.

NNRTI, Non-Nucleoside Reverse Transcriptase Inhibitor; INI, Integrase Inhibitor; ART, Antiretroviral Therapy; VF, Virological Failure.

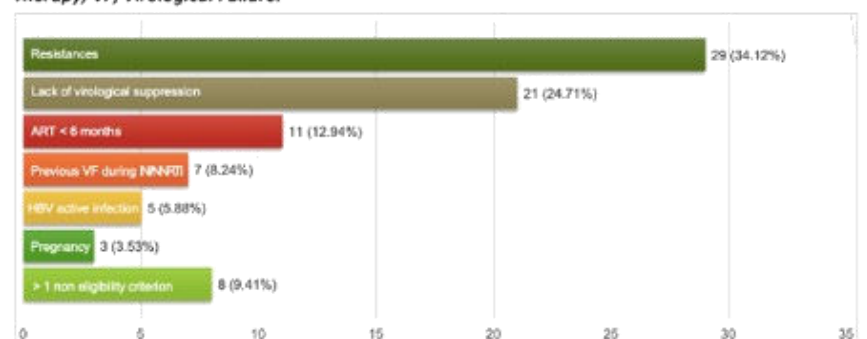
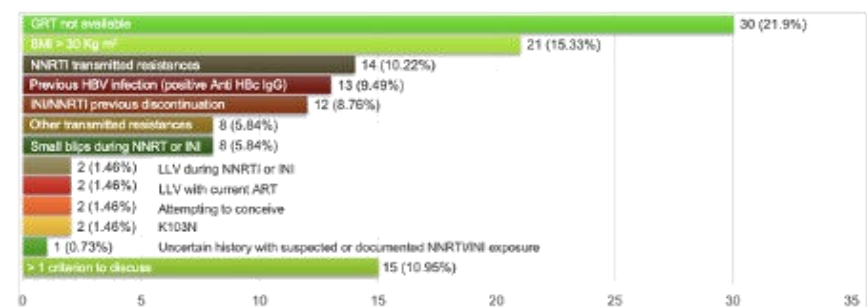


Figure 2. PLWH who need discussion, n. 130/270.

GRT, Genotype Resistance Test; BMI, Body Mass Index; NNRTI, Non-Nucleoside Reverse Transcriptase Inhibitor; INI, Integrase Inhibitor; ART, Antiretroviral Therapy; LLV, Low-Level Viremia: confirmed viremia 50-200 cps/mL.



CONCLUSIONS Implementing a proactive, patient-centred, collegial decision-making process which fully considers risk/benefit for the individual is essential to ensure equity of access to LA. Our findings highlight several practical barriers to implementation. As processes improve, the hope is that LA can be offered to an increasingly large cohort, giving people the option to choose a different approach to ensure clinical and psycho-social wellbeing.