Current and upcoming challenges using long-acting agents

BREACH Spring Symposium 2025

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BREACH

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Long-acting agents in 2025…

Approved agents

Injectables

- Ibalizumab (Q2W)
- CAB/RPV Q1M
- CAB/RPV Q2M 
- Lenacapavir Q6M (SC)

Long acting agents in 2025… and beyond

Approved agents

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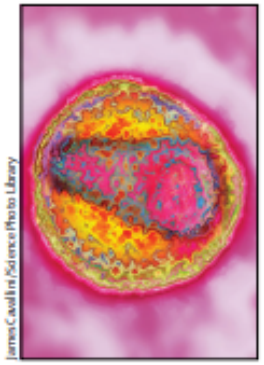
Drug pipeline

Table 1: HIV pipeline 2025 including new data presented at Glasgow 2024

Compound/combination	Class	Phase	Company	Refs
Daily oral tablet				
Lenacapavir + bictegravir	CI + INSTI	Ph 2/3	Gilead	2–7
Doravirine + islatravir	NNRTI + NRTTI	Ph 3	MSD	8
Once-weekly oral tablet				
Islatravir + lenacapavir	NRTTI + CI	Ph 3	MSD + Gilead	9–12
Islatravir + ulonivirine	NRTTI + NNRTI	Ph 2b	MSD	13
GS-1720 and GS-4182	CI + INSTI	Ph 2/3 ongoing	Gilead	14, 15, 16, 17
GS-5894	NNRTI	Preclinical	Gilead	19
Two-monthly injectable				
VH4011499 (VH-499)	CI	Ph 2a	ViiV	18
CAB-LA + lenacapavir	INSTI + CI	Off-label use only so far	ViiV + Gilead	19, 20, 21
Three-monthly injectable				
GS-1614 (ISL prodrug) and GS-6212	NRTTI and INSTI	Ph 1b completed	Gilead	22
Four-monthly injectable				
Ultra long-acting (ULA) cabotegravir + rilpivirine	INSTI + NNRTI	Ph1 reported	ViiV + Janssen	19, 23
Six-monthly injectable or infusion				
VH-184 (VH4524184)	INSTI	Ph1 reported	ViiV	24
VH-310 (CAB prodrug)	INSTI	Ph1 2025	ViiV	1
N6LS (VH3810109) with rHuPH20 *	bNAb	Ph 2	ViiV	19, 25, 26
Teropavimab (TAB, 3BNC117/GS 5423) and zinlirvimab (ZAB, 10-1074/GS 2872) plus lenacapavir	bNAbs + CI	Ph 2	Gilead	27, 28

Long-acting injectable ART: next revolution in HIV?



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S0140-6736(17)31962-1

See Articles page 1499

In the two decades since the arrival of triple antiretroviral therapy (ART),[1,2] there have been multiple breakthroughs including new drugs in new classes, simplification from complex, restrictive regimens to single fixed-dose multiclass tablets, and major improvements in tolerability and toxicity.[3-5] There is even an emerging re-examination of the triple therapy paradigm itself. Studies have shown that some dual-therapy combinations appear to confer the same success as conventional triple regimens, whether in individuals who are naive to ART or as a switch strategy.[6-8]

Despite all the activity and success, the job remains unfinished. In the absence of a cure or effective vaccine we must rely on ART for HIV treatment and prevention. In this context, there is an understanding that we need to create and develop a set of interventions that suit the many and various preferences of those infected with HIV and those at risk. 2 years ago David Margolis and colleagues[9] reported the outcomes of the LATTE study, showing that an oral dual-drug ART regimen of cabotegravir and rilpivirine successfully maintained virological suppression in people receiving cabotegravir with either tenofovir disoproxil fumarate–emtricitabine or abacavir–lamivudine fixed-dose combination tablets.

Now in *The Lancet*, David Margolis and colleagues report the results of the follow-up LATTE-2 study.[10] LATTE-2 is a randomised, open-label, phase 2b study of long-acting injectable cabotegravir and rilpivirine in adults with HIV-1 infection. This study used a suppression-maintenance approach with participants naive to ART initiating therapy with an oral version of cabotegravir 30 mg plus abacavir–lamivudine 600–300 mg once daily for the first 20 weeks. Once HIV suppression to less than 50 copies per mL was achieved, participants were randomly assigned to either continue the same oral regimen or to switch to long-acting cabotegravir and rilpivirine at 4-week intervals (long-acting cabotegravir 400 mg plus rilpivirine 600 mg; two 2 mL injections) or 8-week intervals (long-acting cabotegravir 600 mg plus rilpivirine 900 mg; two 3 mL injections). After 96 weeks of randomised therapy, viral suppression was maintained in 47 (84%) of 56 patients

Boyd et al. Lancet 2017

Long-acting injectable ART: next revolution in HIV?

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CURRENT OPINION

Implementation challenges for long-acting antivirals as treatment

Diane Havlir and Monica Gandhi

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Havlir et al. Curr Opin HIV AIDS 2015

Expected challenges (in 2015)

FDA-equivalent approval process in countries outside the USA and endorsement by global recommendation guidelines
Determination of which patient populations to prioritize, both in resource-rich and constrained settings, for long-acting ART based on patient characteristics, adherence level, inadequate virologic suppression rates, cost constraints and accurate cost projections, cold chain requirements, etc.
Requirement for clinic or hospital infrastructure (clean needles, trained staff) for provider administration
Need for steady supply chains for the injectable forms of ART
Likely requirement for cold chain for transport of nanoparticle long-acting ART and refrigeration at site
Possible requirement for HIV drug resistance testing prior to use, laboratory monitoring (including for safety and HIV viral load) during use
Decentralization of care (including mobile health units) to minimize prolonged travel to clinic sites with capability to administer long-acting ART
Requirement for education programs to inform providers/clinics of the evidence behind long-acting ART, as well as bolstering systems as above to prescribe long-acting ART and monitor its outcomes
Current knowledge gaps in use of long-acting ART in children, pregnant and breastfeeding women, those on prevalent-use concomitant medications such as contraceptives, hepatitis C drugs
Individual-level challenges to implementing long-acting ART
Possible injection site reactions or other possible side effects
Possible increase in stigma from receiving injections at HIV-associated site
Patient preference and acceptability of injection-based therapy; loss of perceived "control" associated with not taking oral medications
Insurance status and cost
As with all chronic diseases, patient understanding of the need for the medication and commitment to adherence

Havlir et al. Curr Opin HIV AIDS 2015

Expected challenges (in 2015)

Drug-related challenges

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Expected challenges (in 2015)

Drug-related challenges

Patient-related challenges

Healthcare (system)-related challenges

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Determination of which patient populations to prioritize, both in resource-rich and constrained settings, for long-acting ART based on patient characteristics, adherence level, inadequate virologic suppression rates, cost constraints and accurate cost projections, cold chain requirements, etc.
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Havlir et al. Curr Opin HIV AIDS 2015

Challenges with current LA-drugs

CAB/RPV limitations

Table 1. Summary of Key Requirements for Widespread Use of Antiretroviral Therapy

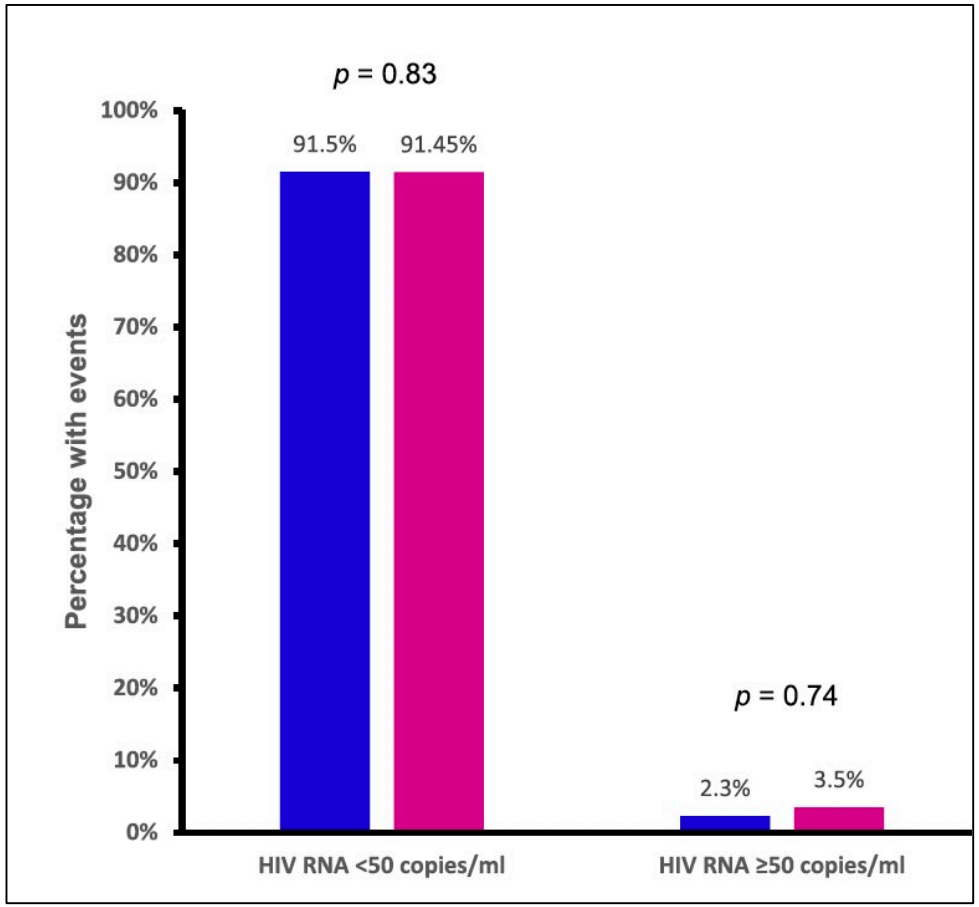
	Benchmark	TDF/3TC/DTG	DOR/ISL	CAB/RPV
1	Efficacy in treatment-naive individuals	Unsurpassed	Likely noninferior to DTG + 2NRTI	Noninferior to DTG + 2NRTI
2	High genetic barrier to resistance	Yes	No	No
3	Safe in hepatitis B coinfection (hepatitis B surface antigen or hepatitis B virus DNA positive)	Yes	No	No
4	Effective against human immunodeficiency virus type 2	Yes	No	No
5	Safely coadministered with anti-tuberculosis medication	Yes	No	No
6	Acceptable safety in pregnancy	Yes	Insufficient data	Insufficient data
7	Course price per person per year	<45 (generic)	DOR $22 673–$5966 (no data for ISL)	$20 643–$11 771
8	Availability in long-acting formulations	Under investigation	Studies held: ISL with lenacapavir under investigation	Available in injectable monthly or 2-monthly formulation

Abbreviations: 3TC, lamivudine; CAB, cabotegravir; DOR, doravirine; DTG, dolutegravir; ISL, islatravir; NRTI, nucleoside reverse-transcriptase inhibitor; RPV, rilpivirine; TDF, tenofovir-disoproxil.

9. Use in virologicaly uncontrolled patients	Yes	Appears useful – not yet recommended

Fairhead et al. Clin Infect Dis 2024 – Hickey et al. Clin Infect Dis 2025

CAB/RPV efficacy in RCTs

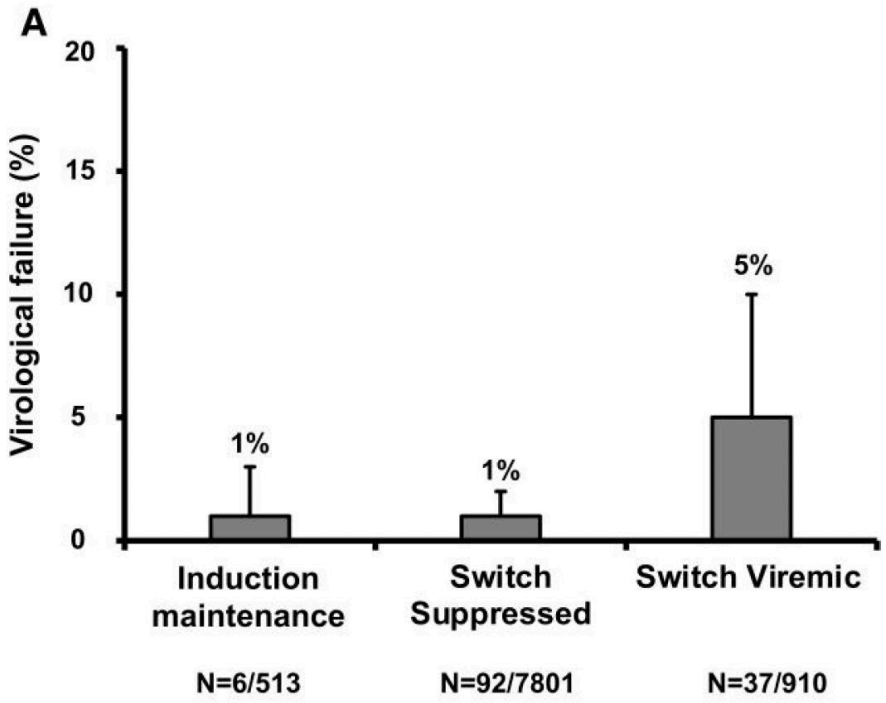


- High level of efficacy in RCTs
- Small number of virological failures (VF) ~ 1%
  - LATTE-2: 2/230
  - SOLAR: 3/454
  - CARES: 2/255
  - ATLAS 2M: 10/1045
  - CARISEL: 1/430
  - FLAIR: 4/283

Manalu et al. J Antimicrob Chemother 2024 – Perez-Navarro et al. Clin Infect Dis 2025

Virologic Failure and Emergent Integrase Strand Transfer Inhibitor Drug Resistance With Long-Acting Cabotegravir for HIV Treatment: A Meta-analysis

Andrea Perez Navarro,[1] Cameron T. Nutt,[2,3] Mark J. Siedner,[2,3,4] Suzanne M. McCluskey,[2,3] and Andrew Hill[5]



RCTs and real-life data support low risk of VF

Perez-Navarro et al. Clin Infect Dis 2025

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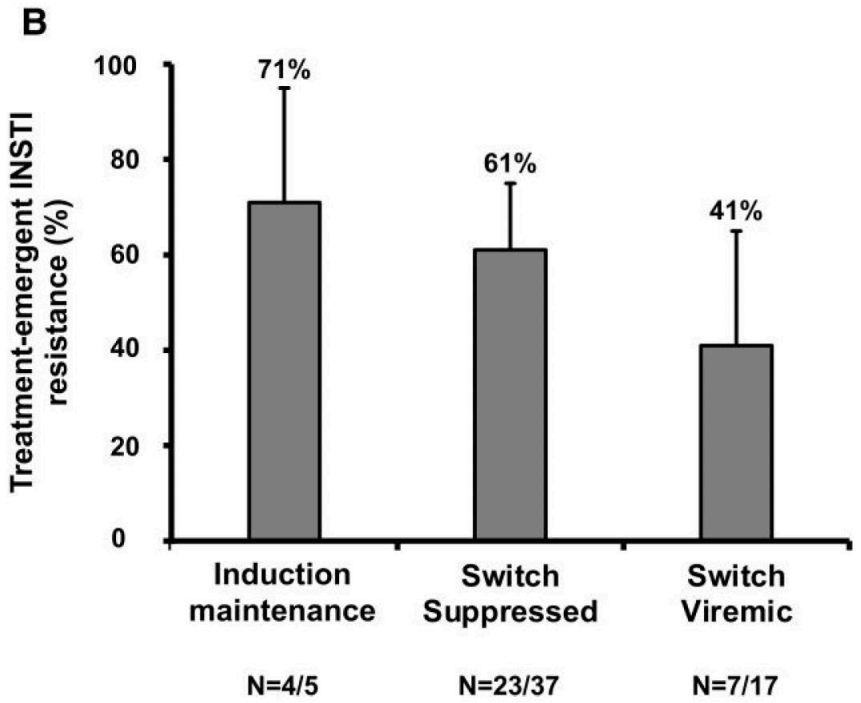

The true challenge : treatment-emergent resistance

Perez-Navarro et al. Clin Infect Dis 2025

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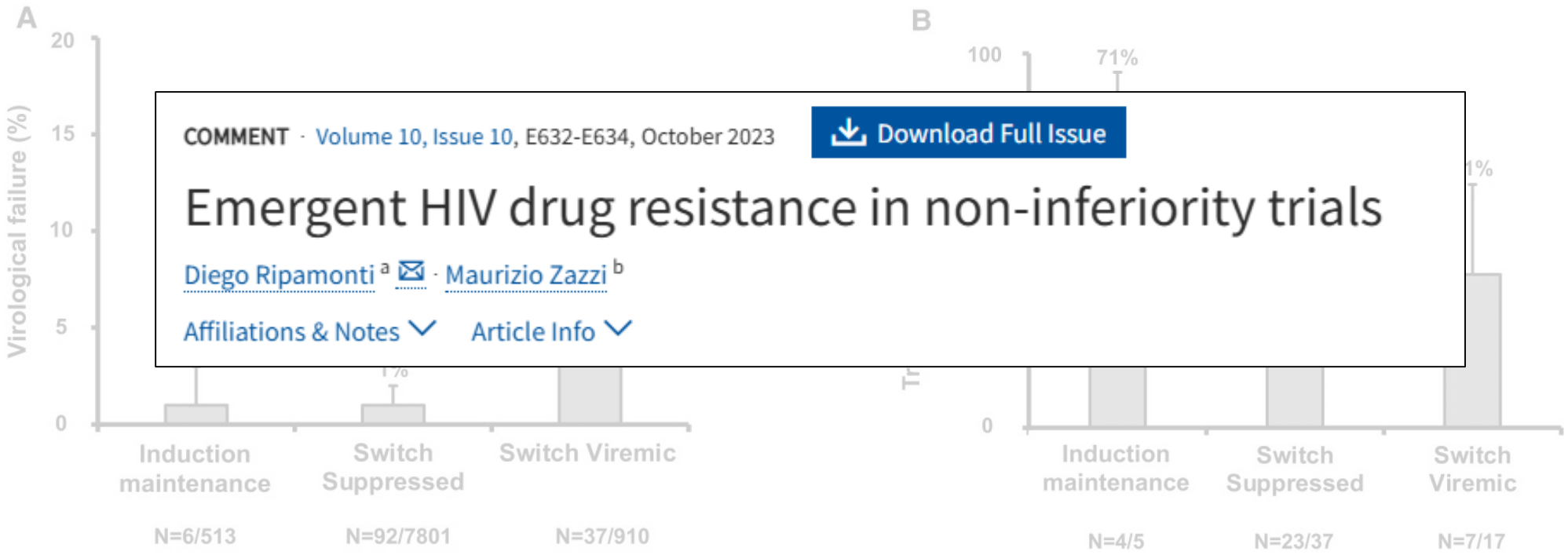


RCTs and real-life data support low risk of VF

The true challenge : treatment-emergent resistance

Perez-Navarro et al. Clin Infect Dis 2025

Defining the optimal monitoring of LA-CAB/RPV

- Frequency of viral load monitoring?

BHIVA British HIV Association

- We recommend the following viral load monitoring:
  - Two-monthly HIV RNA quantification (Grade 1A);
  - Prompt recall for repeat testing and resistance testing if viral rebound occurs (GPP).

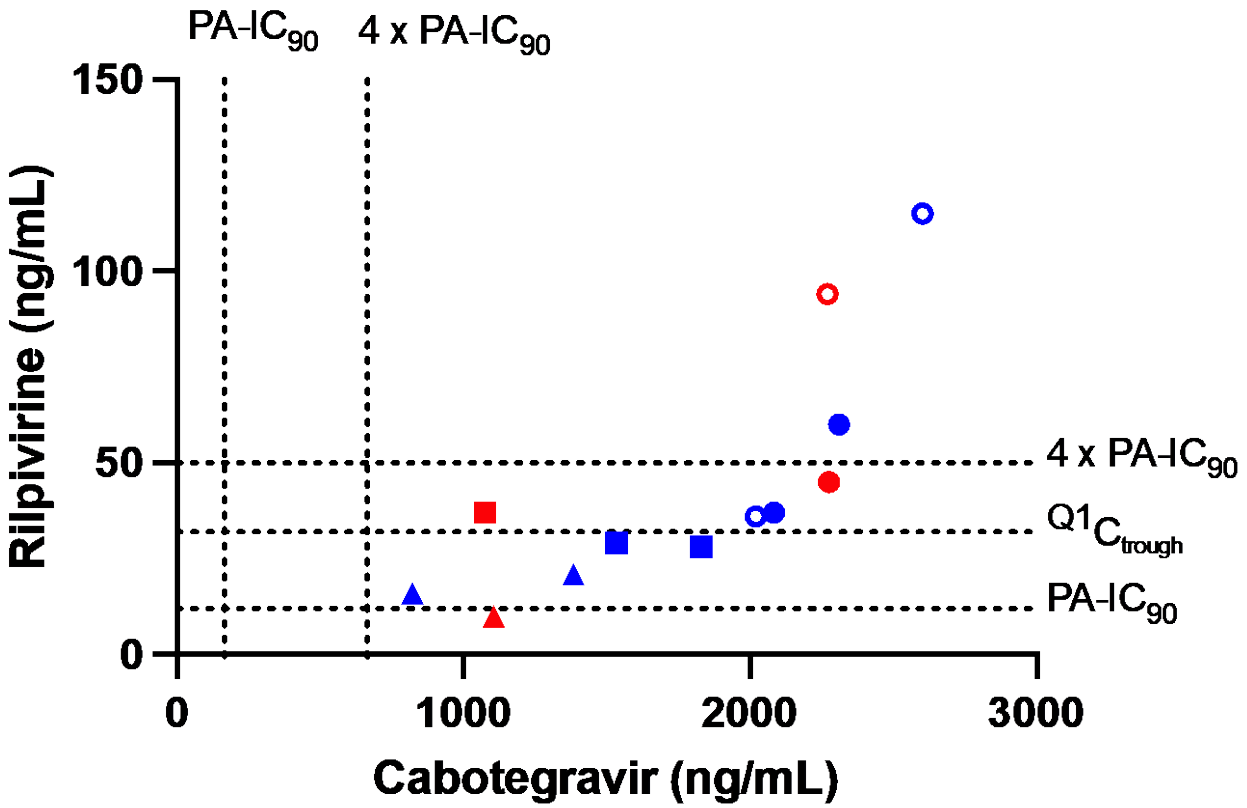
EACS European AIDS Clinical Society

Assessment	At HIV diagnosis	Prior to starting ART	Follow-up frequency
Plasma HIV VL	+	+	3-12 months

Defining the optimal monitoring of LA-CAB/RPV

- Frequency of viral load monitoring?
- Is there a role of TDM?
  - If yes, in which cases ?

Interpreting CAB/RPV TDM



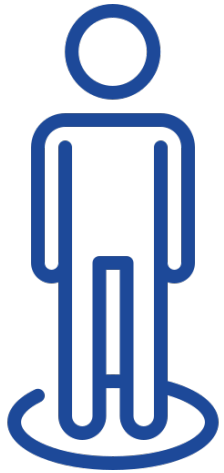
Cases = failing
Controls = success

No difference of drug plasma levels between cases and controls

Defining the optimal monitoring of LA-CAB/RPV

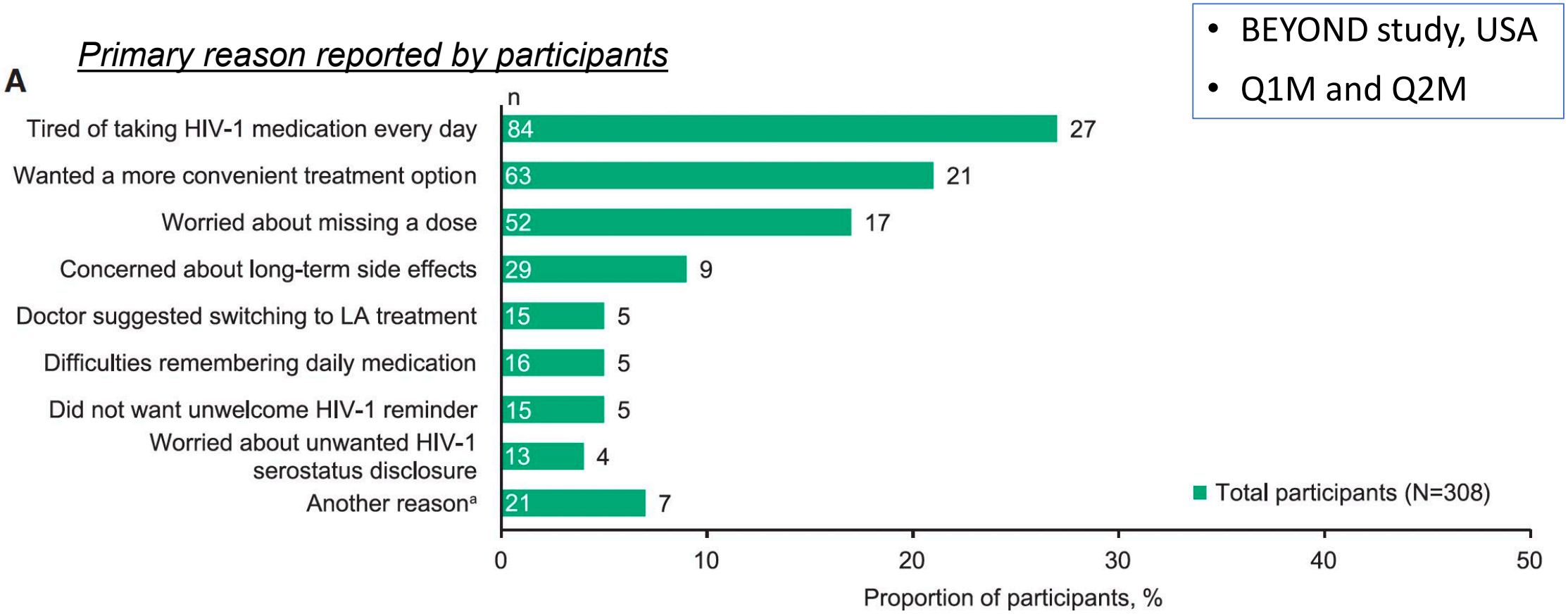
- Frequency of viral load monitoring?
- Role of TDM?
- The role of patient-reported outcomes (PROM) and experience measures (PREM)?

PLWH expectations and challenges with the use of LA-agents



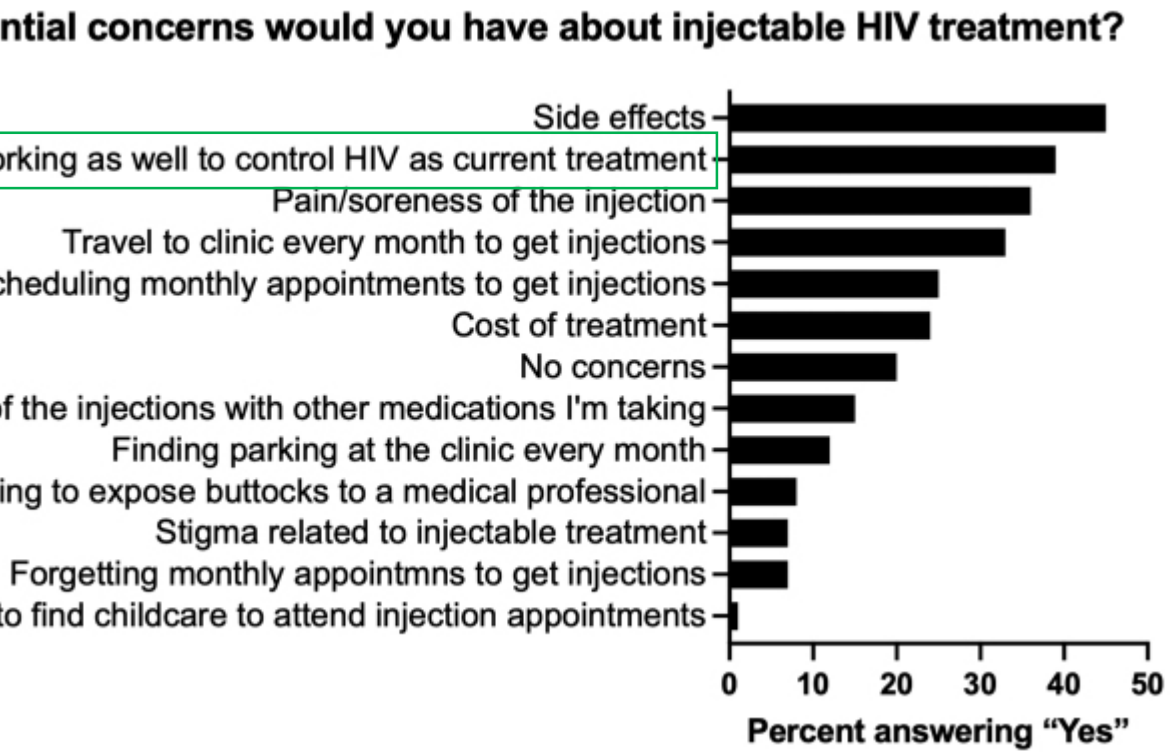
Why do patients initiate LA-CAB/RPV ?

- BEYOND study, USA
- Q1M and Q2M



Dandachi et al. Open Forum Infect Dis 2025

Injection-naïve patients' concerns



Efficacy

N = 160

Survey of PLWH **receiving oral cART**, South Carolina, USA

Adekunle et al. AIDS Patient Care and STDs 2023

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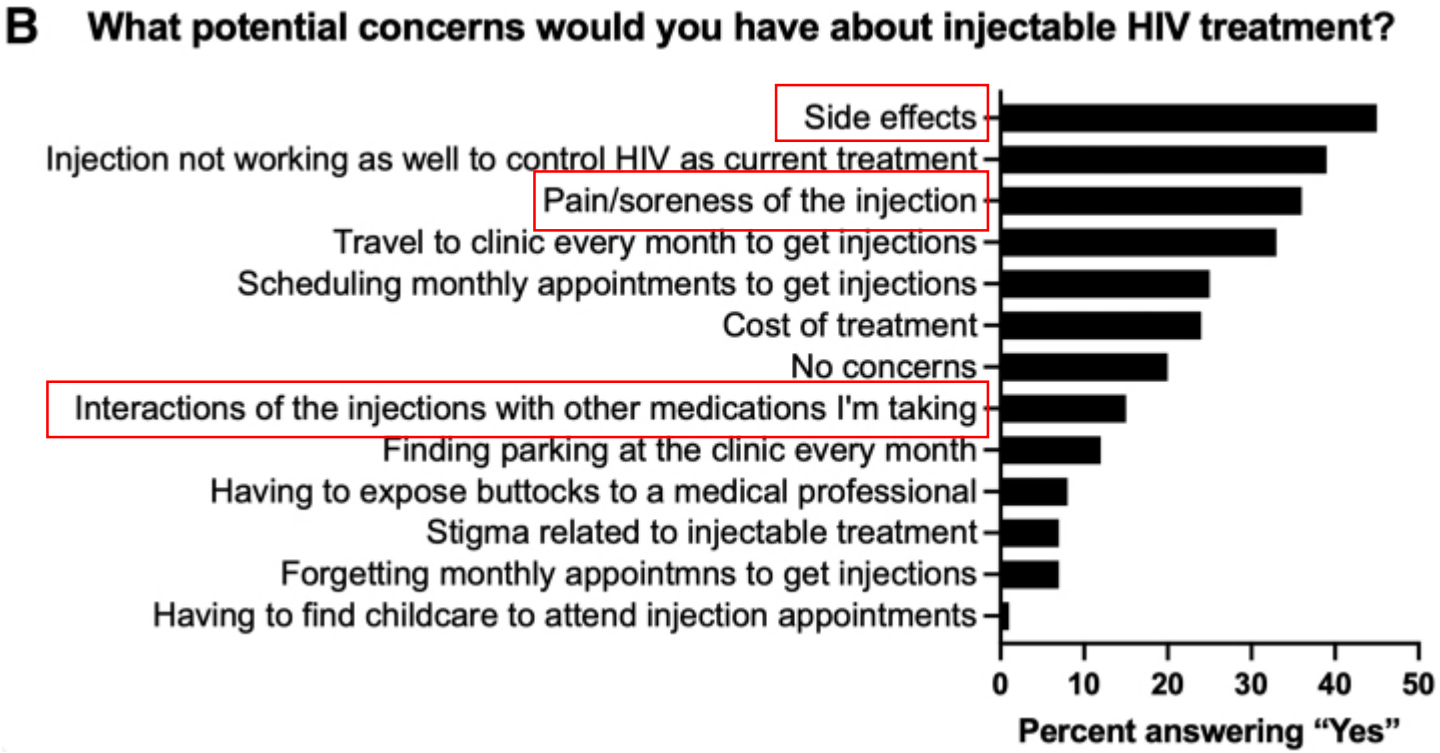

Efficacy

Safety

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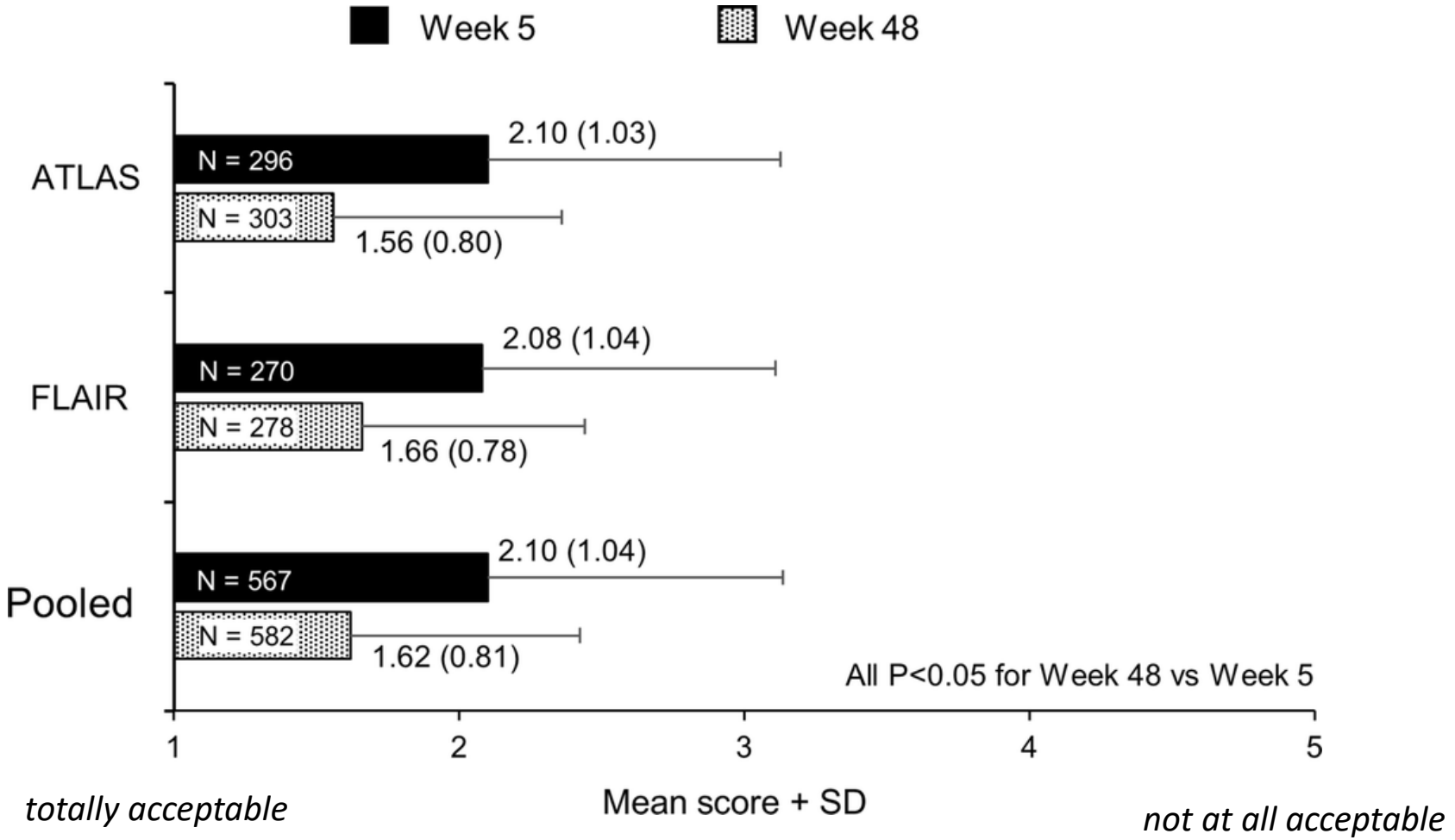
Adekunle et al. AIDS Patient Care and STDs 2023

Acceptability of injection-site reactions

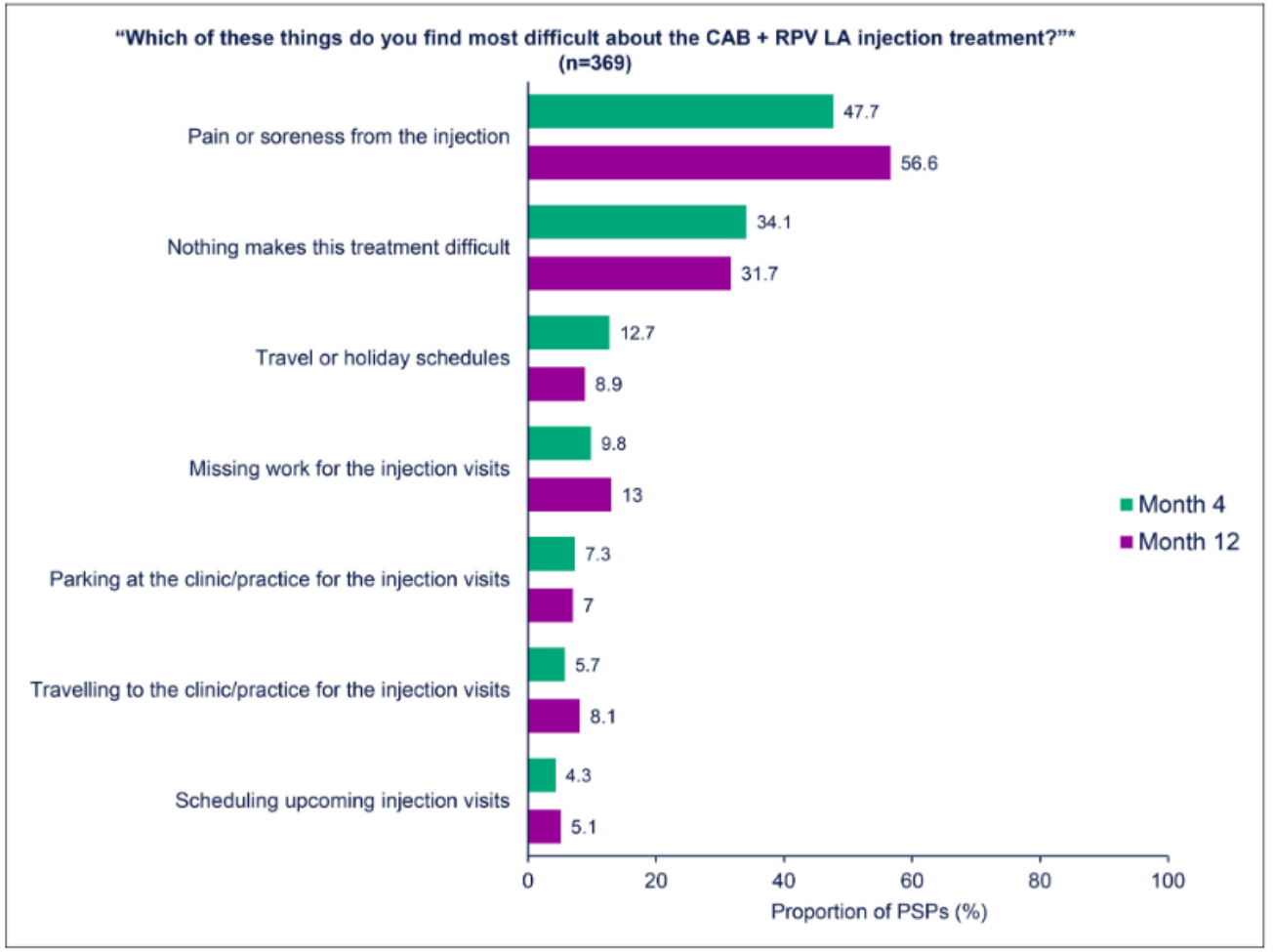


Murray et al. AIDS Behav 2020

LA-CAB/RPV Q8W: patients' perspectives

CARISEL study (12M)

- 54 (13%) participants discontinued treatment prematurely – with AE (mainly ISR) as main reason
- Participants found CAB + RPV LA Q2M to be an acceptable, appropriate, and feasible treatment option.



Jonsson-Oldenbütte et al. J Acquir Immune Defic Syndr 2024 - J Gutner et al. Int Assoc Provid AIDS Care. 2024

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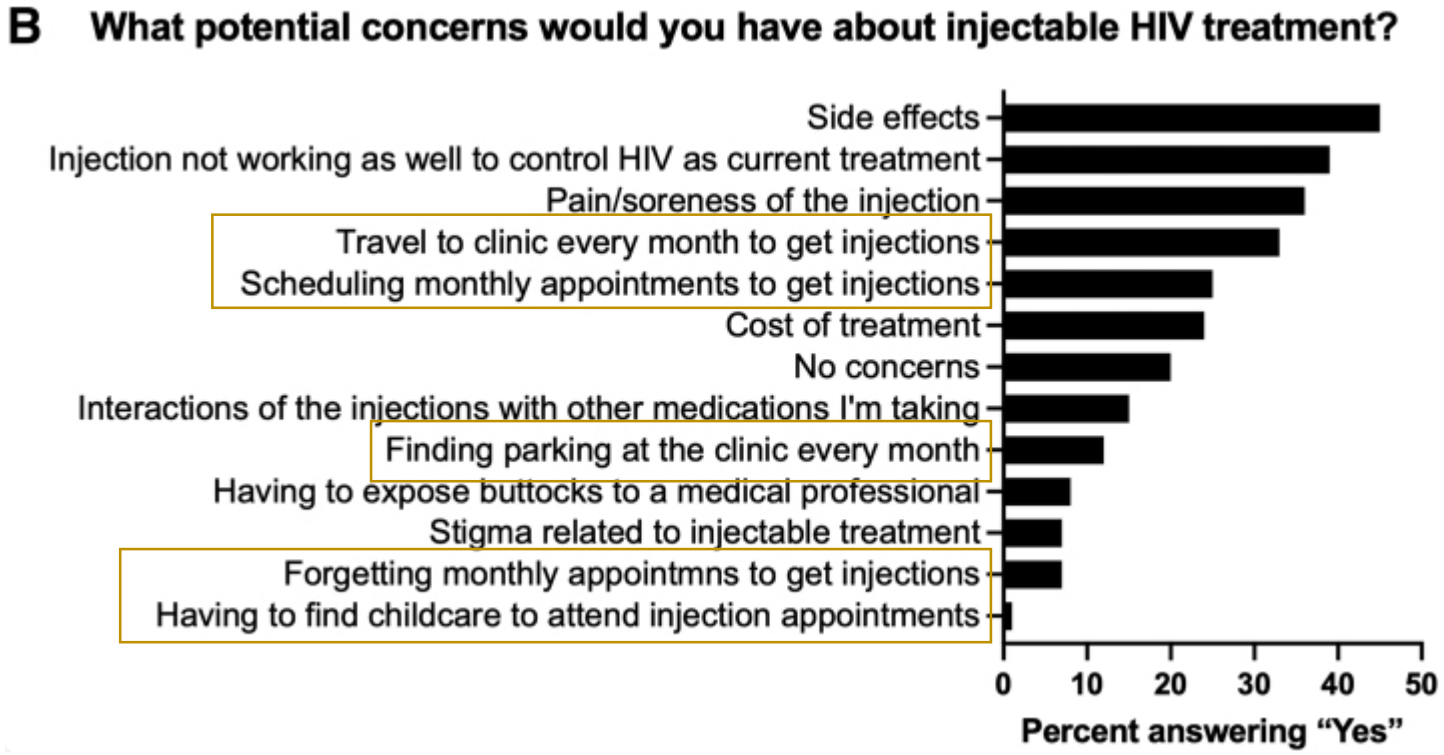

Efficacy

Safety

Organisationnal

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Adekunle et al. AIDS Patient Care and STDs 2023

BREACH cross-sectional study

- Preliminary results (~ 33% recruitment)

How convenient is it for you to come to the clinic and receive your injections every 2 months

Convenient - 65.5%

Somewhat convenient - 23.1%

Neither convenient nor inconvenient (neutral) - 5.9%

Somewhat inconvenient - 3.6%

Inconvenient - 1.9%

Courtesy of R. Nasreddine

CAB/RPV real world adherence

BEYOND study (US)

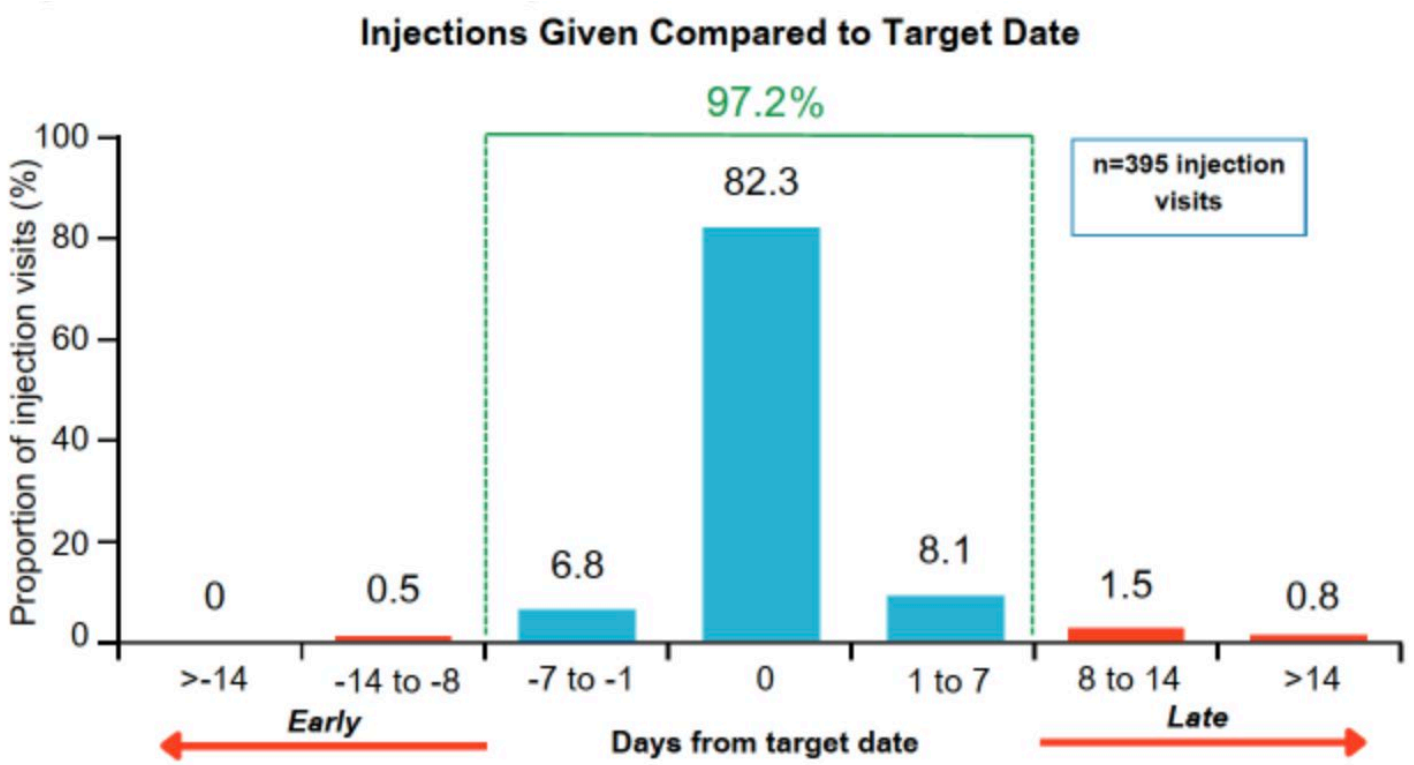
- 3% (of 2101) injections missed
  - *Oral bridging in half of missed injections*

- 90,5% of received injections were within +/- 7 days of target date
  - 4,5% early injections (~12 days before target)
  - 5% late injections (~11-14 days after target)

Dandachi et al. Open Forum Infect Dis 2025

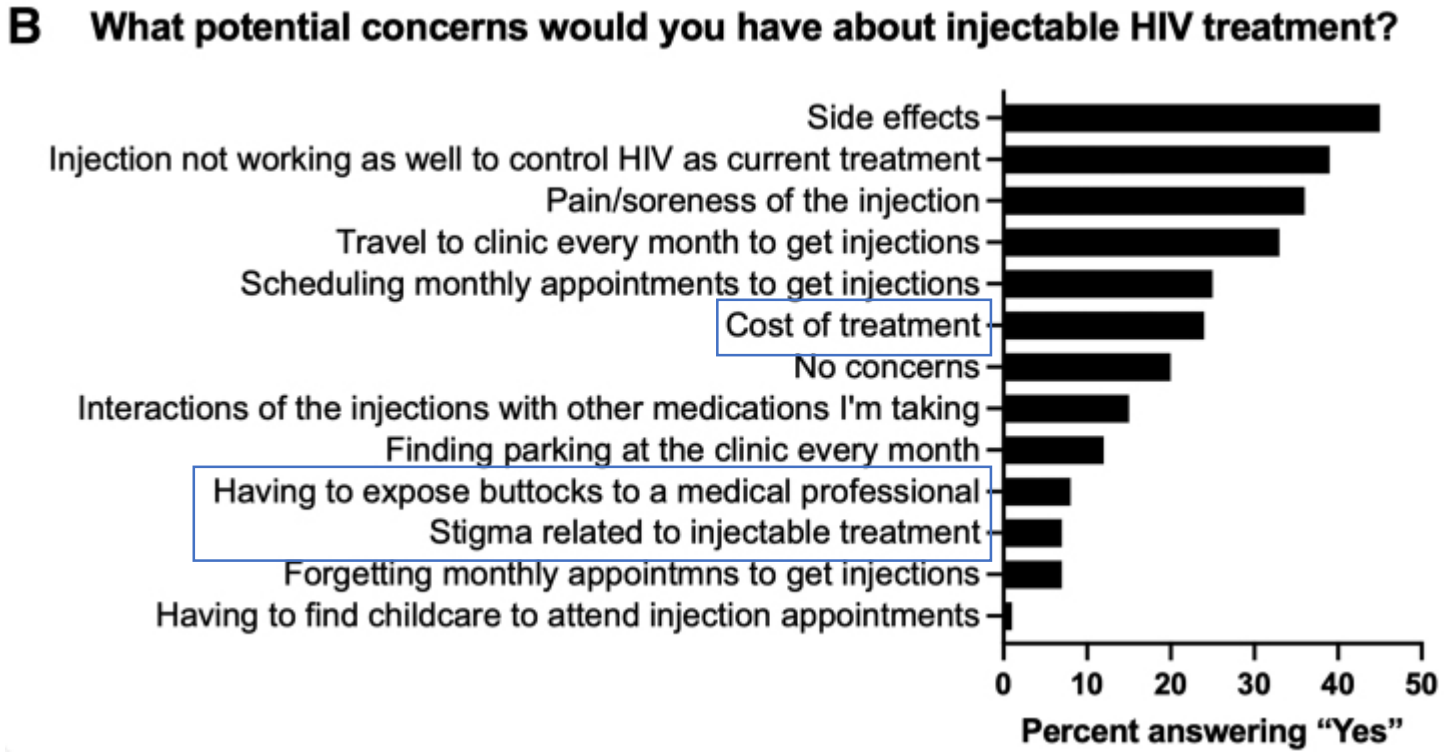
CAB/RPV real world adherence

- ***Implementation study of CAB/RPV in vulnerable populations with complex needs***
  - *Single center, Australia*
  - *60 participants*
  - *Involvement of multidisciplinary health service (social worker, HIV nurse, welfare assistant)*



Levin et al. IAS con ference 2023

Injection-naïve patients' concerns



Efficacy

Safety

Organisationnal

Others

N = 160

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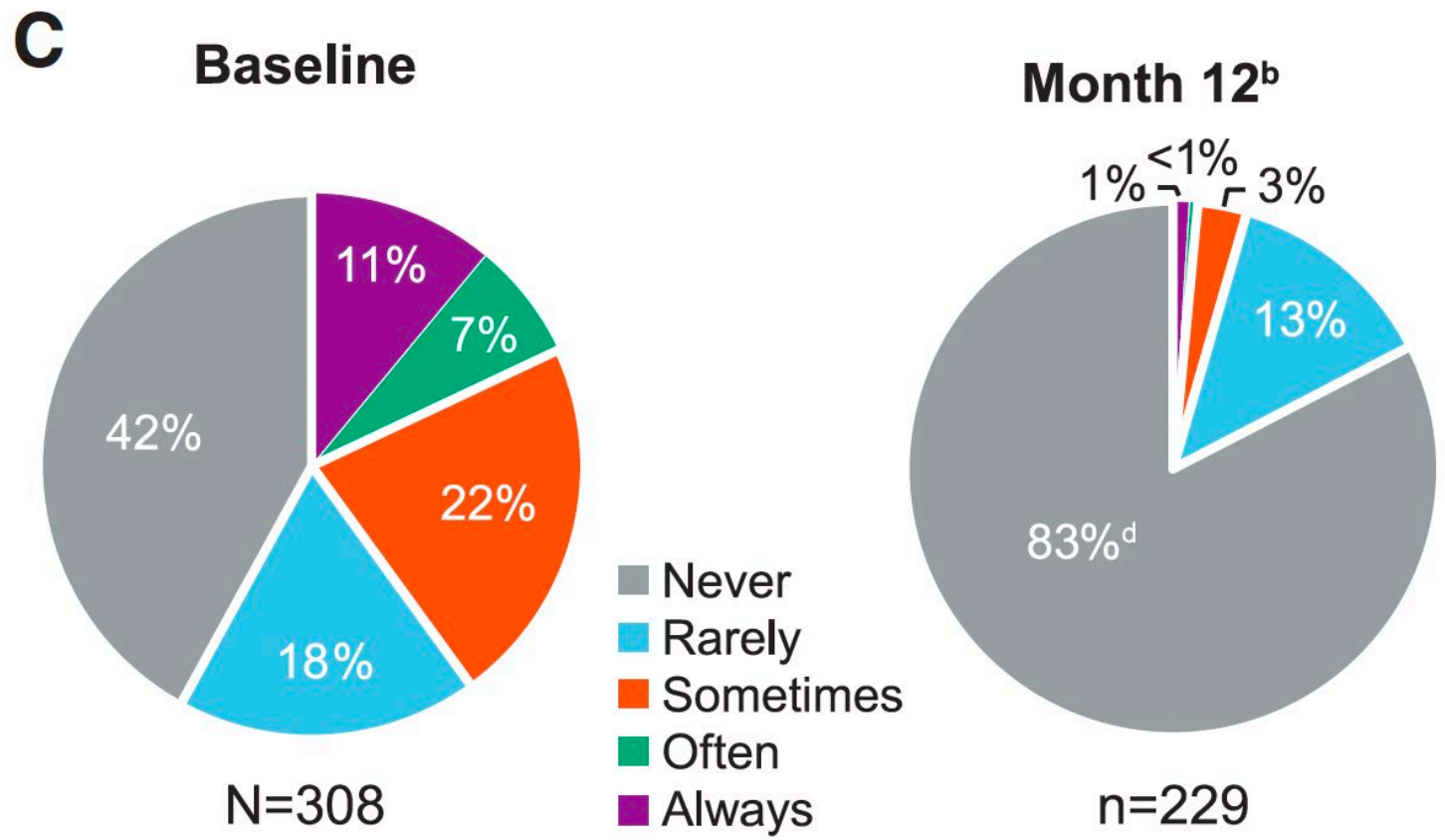
Adekunle et al. AIDS Patient Care and STDs 2023

Stigma and CAB/RPV-LA

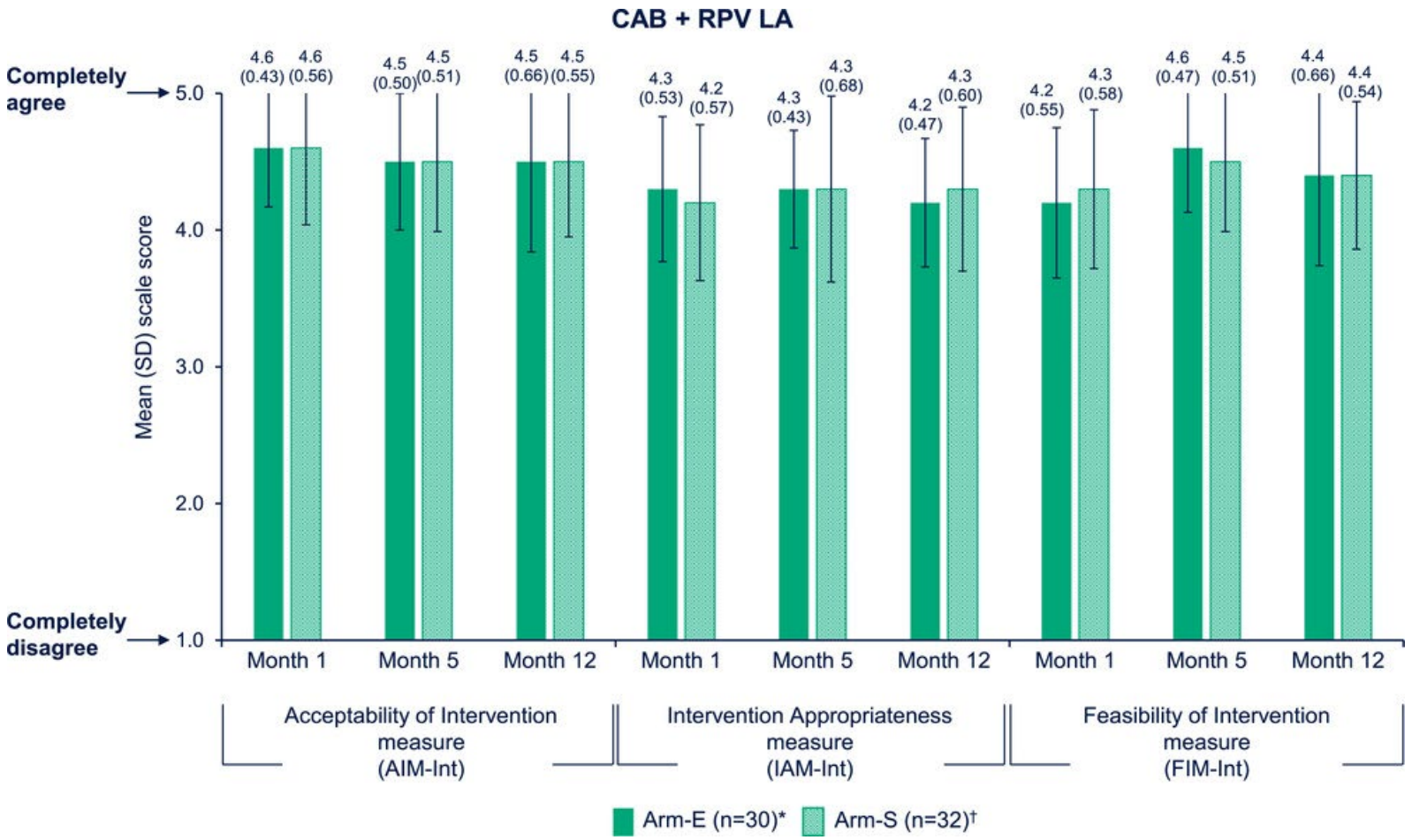
Proportion of participants feeling stigmatized by HIV-1 treatment



Dandachi et al. Open Forum Infect Dis 2025

Health-care providers/system and LA-agents: challenges and future directions

Implementation of LA-CAB/RPV Health care providers' perspective

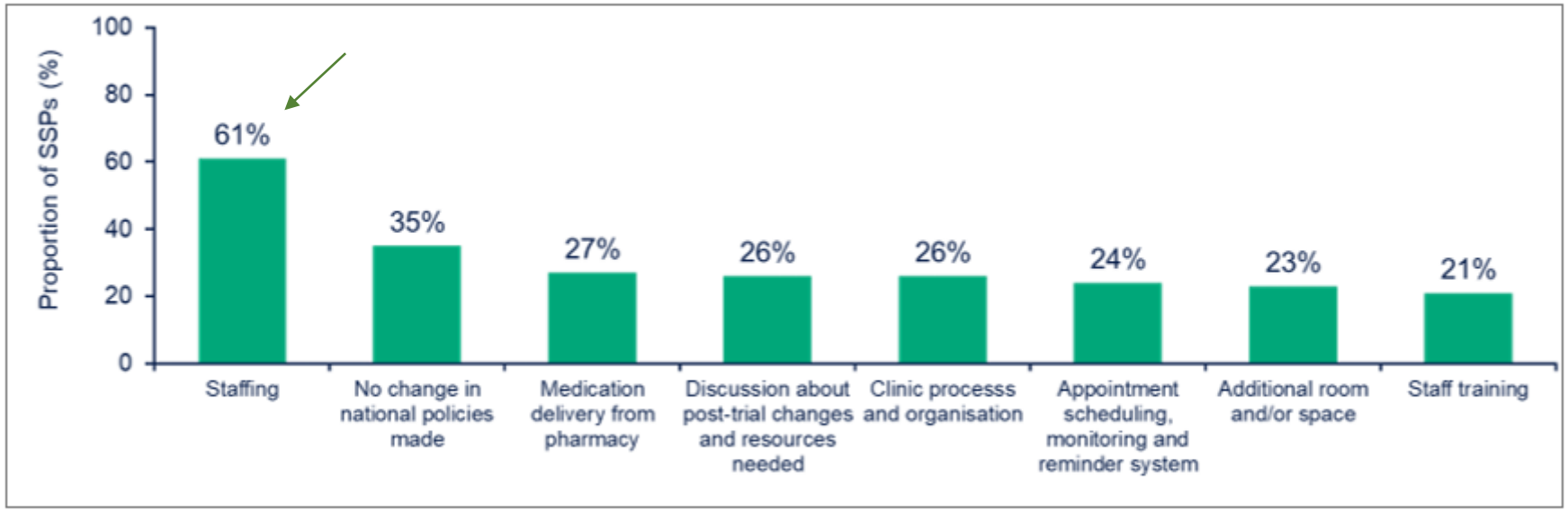


- CARISEL study
- Similar acceptability, appropriateness and feasibility found for standard vs enhanced implementation strategies

Gutner et al. J Int AIDS Soc 2024

Challenges with CAB/RPV Q2M

Figure S2. Anticipated Post-Trial Implementation Needs Identified in Month 12 Qualitative Interviews*



*n=62. Those reported by >20% of participants are shown.

SSP, staff study participant.

Gutner et al. J Int AIDS Soc 2024

Future directions
Alternative LA therapies

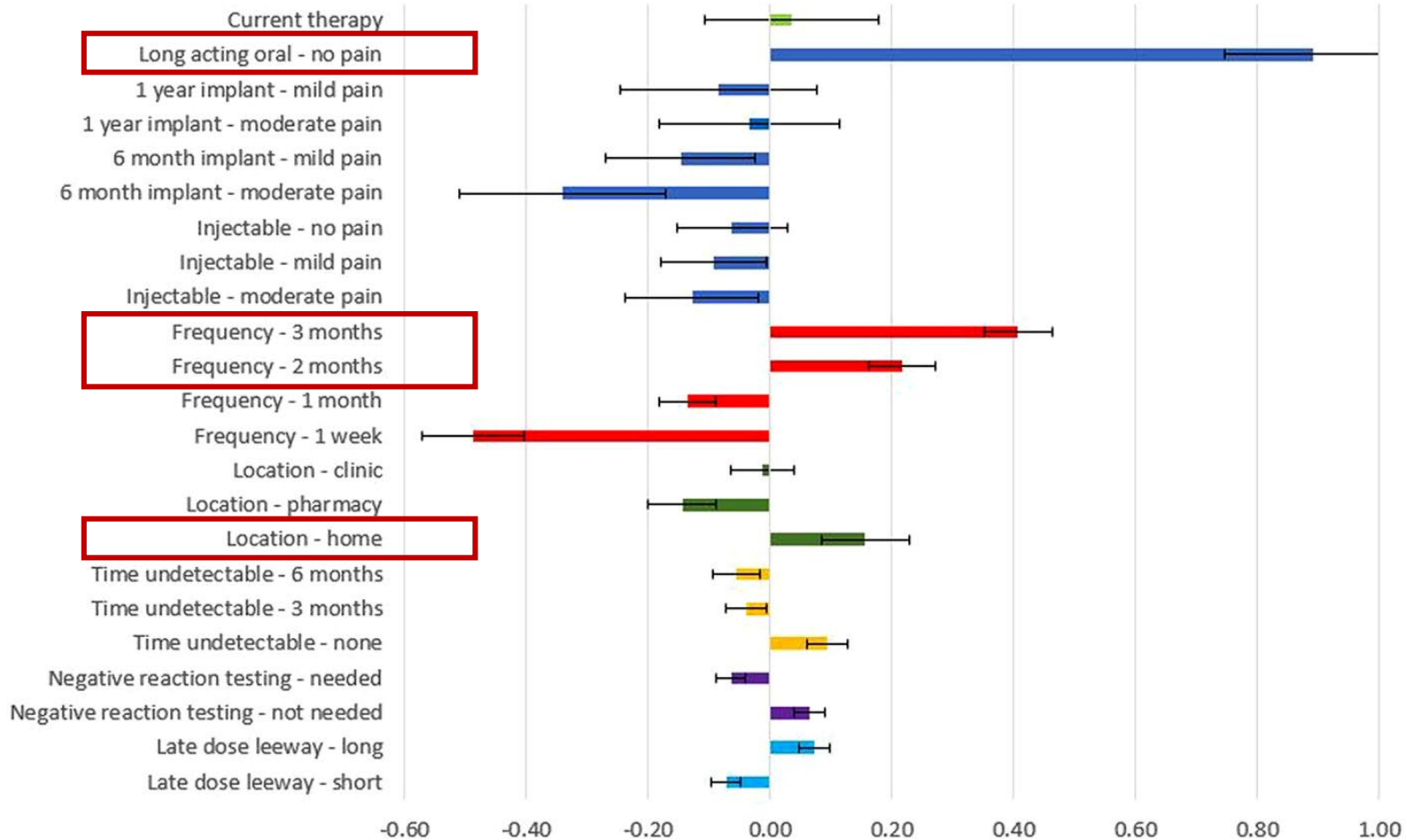
Who Wants to Switch? Gauging Patient Interest in Novel Antiretroviral Therapies

Table 1. Distribution and Correlates of Interest in Switching to Novel ART Regimens (n = 263)

	1 Pill Once a Week	2 Shots Every Other Month	2 Implants Every 6 Months
Interest in switching, No. (%)			
Not at all interested	38 (14)	100 (38)	152 (58)
Somewhat interested	52 (20)	60 (23)	61 (23)
Very interested	173 (66)	101 (39)	5 (18)
No.	263	261	261

Derrick et al. OFID 2018

U.S. patient preferences for long-acting HIV treatment: a discrete choice experiment



Graham et al. J Int AIDS Soc 2023

BREACH cross-sectional study

- Preliminary results (~ 33% recruitment)

How helpful would it be to receive your injections outside of your usual clinic?

Very helpful - 27.6%

Somewhat helpful - 27.6%

A little helpful - 13.8%

Not helpful - 31%

Courtesy R. Nasreddine

BREACH cross-sectional study

- Preliminary results (~ 33% recruitment)

Where else would you consider receiving your injections?

Same day care in the hospital - 42.9%

Pharmacy - 28.6%

Mobile vehicle - 10.7%

Nurse coming to your home - 32.1%

General practitioner/Family physician - 39.3%

Courtesy R. Nasreddine

Comparison of At-home vs. In-clinic Receipt of Long-Acting Injectable Cabotegravir/Rilpivirine

Kirk et al., 2024 | *Clinical Infectious Diseases*

IDSA
Infectious Diseases Society of America

BACKGROUND: With potential perceived benefits to receiving injectable HIV therapy at-home, this non-randomized observational study examined whether home health administration of LA CAB/RPV by a healthcare provider would be safe, effective, and associated with patient satisfaction relative to in-clinic administration.

COHORT:
Enrolled participants who were prescribed LA CAB/RPV by their primary HIV provider chose to receive each LA CAB/RPV injection either at-home with a healthcare provider or in-clinic over a 12-month period.

STUDY LOCATION & DEMOGRAPHICS:
The Medical University of South Carolina is an academic medical center in Charleston, SC. The thirty-three persons who enrolled in the study were predominantly male (73%) and Black (64%).

At-home (n = 15)

LA CAB + RPV was shipped from the pharmacy directly to participants homes and stored in their personal refrigerator until time of home health visit. One LPN performed all at-home injection visits.

VERSUS

In-clinic (n = 18)

LA CAB + RPV was shipped from the pharmacy to the clinic and was stored there until administeration by rotating nursing staff during scheduled clinic times.

RESULTS AND CONCLUSION: All participants were virologically suppressed and retained in care at the end of study. Home health administration of LA CAB/RPV was observed to be comparably safe, effective and associated with high participant satisfaction relative to in-clinic administration.

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In conclusion, at-home receipt of LA CAB/RPV was safe, effective, and associated with high participant satisfaction. Although many participants valued and wanted to continue at-home LA CAB/RPV, real world limitations and lack of insurance coverage to cover the cost for at-home receipt of treatment made continuation of this effort impractical after study completion. Benefits of the effort were somewhat offset by the extensive time and coordination efforts from clinical team members needed to support at-home LA CAB/RPV, which may be difficult to reproduce, sustain, afford, and implement in clinical practice. Nonetheless, this work serves as a proof of concept in support of continued efforts to make LA CAB/RPV accessible in non-clinical settings.

Perspectives of people with HIV on implementing long acting cabotegravir plus rilpivirine in clinics and community settings in the UK: results from the anti-sexist, anti-racist, anti-ageist ILANA study

Orkin et al., 2024 | *Clinical Infectious Diseases*

IDSA Infectious Diseases Society of America

BACKGROUND: The equity-focused ILANA study evaluated feasibility, acceptability, appropriateness of delivering on-label two-monthly cabotegravir and rilpivirine (CAB+RPV) injections for HIV-1 therapy in clinics and community settings.

PARTICIPANTS: Of 114 participants, 54% were female, 70% racially minoritised and 40% aged >50. 24% chose to receive injections in community settings. The two groups were broadly similar, although a larger proportion of community participants were white, aged <50, employed, and more financially secure.

METHODS

At six UK sites, injections were delivered in clinic (months 1-6), and in clinic or community settings (patient choice, months 6-12). Community settings included: home visits (at 3 sites), HIV support organisations (at 2 sites), community clinic (at 1 site). Surveys were completed at baseline, M4 and M12, and 14 participants completed interviews at baseline and M12.

- ✓ Adult aged 18+
- ✓ Virally suppressed (VL<50 copies/mL) for 6+ months
- ✗ No resistance to NNRTIs or INSTIs
- ✗ Not co-infected with HBV

Implementation outcomes	Only attended CLINIC	Attended COMMUNITY at least once	p-value
Agree attending community setting is feasible at M12 (FIM=/>4) (%)	24/69 (34.8)	21/26 (80.8)	<0.01
Agree attending community setting is acceptable at M12 (AIM=/>4) (%)	23/69 (33.3)	19/26 (73.1)	<0.01
Agree attending community setting is appropriate at M12 (IAM=/>4) (%)	24/69 (34.8)	21/26 (80.8)	<0.01
Treatment Satisfaction (HIV-TSQs) (mean difference M0-12, SD)	+4.65 (SD 11.15)	+11.46 (SD 10.66)	0.01

CONCLUSION: When offered the choice to receive CAB+RPV injections in the community, most participants declined. Key concerns identified in interviews related to anticipated stigma, inconvenience, and loss of access to their trusted healthcare provider. However, those who chose community delivery found it highly acceptable.

Orkin et al. Clin Infect Dis 2024

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Thank you !