Patient reported outcomes
what tools do the clinicians have?

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PANDORA ID - 25
TIME TO WEBINAR IN INFECTIOUS DISEASES

Disclosures

- MM received research grants from Gilead Sciences, fee as speaker from ViiV Healthcare, Gilead Sciences, and MSD, and fee as advisory board member from ViiV Healthcare, Gilead Sciences, and MSD.

Introduction

- Shift towards patient-centered care in HIV treatment
- Importance of evaluating PROs
- Long-acting injectable regimens: a transformative option
- Define the role of PROs in the context of long-acting therapies
- Review available PRO measurement tools
- Provide practical recommendations for clinicians

Milestones in HIV prevention, treatment and care[1-8]

1982
Gay Men's Health Crisis (the first community-based AIDS service provider) is established in New York City[1]

1983
Treatment goals are focussed on preventing death and protecting healthcare professionals[2,3]

1987
First ART approved for the treatment of AIDS[1]

1991
International Council of AIDS Service Organisations is established as a network for nongovernmental and community-based organisations[1]

1995
HAART era begins[1]

2000
Durban Declaration, signed by 5,000 prominent clinicians and investigators, attests to overwhelming evidence that HIV causes AIDS, counteracting AIDS "denialism"[1]

2006
First single pill regimen approved[4]

2012
First approved daily oral regimen for PrEP[4]

2014
UNAIDS launches ambitious 90-90-90 targets to be achieved by 2020[5]

2016
U=U consensus statement issued[6]

2016
WHO updates treatment guidelines recommending treatment for all[7]

2021
First approved long-acting regimen for HIV treatment and first approved long-acting regimen for PrEP[8]

2021
UNAIDS targets for 2025 are 95-95-95[9]

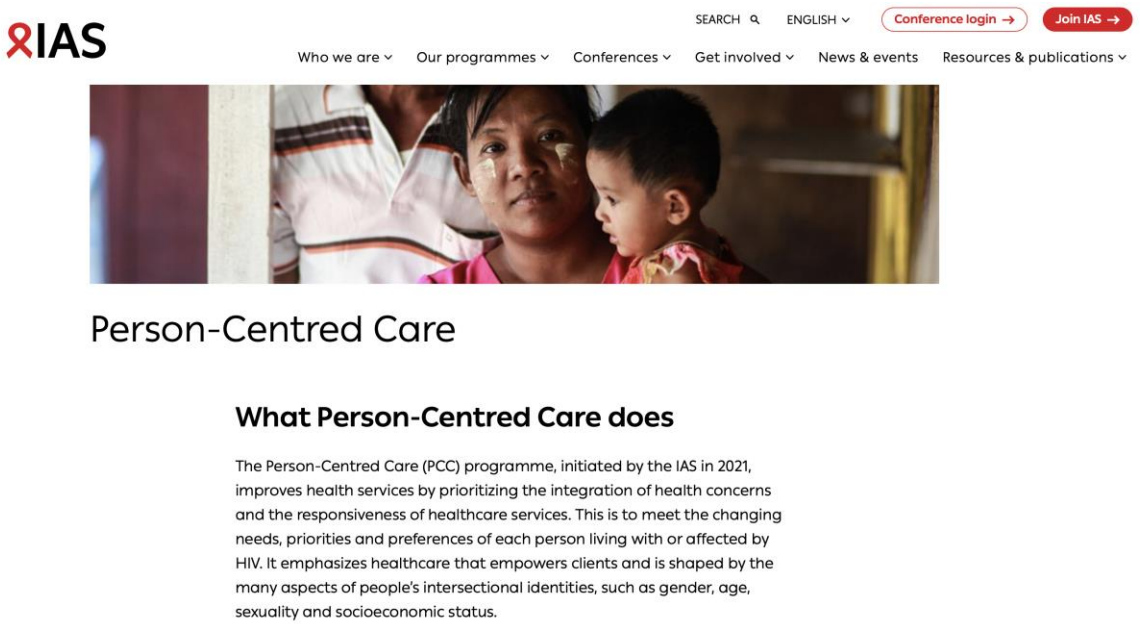
Adapted from Brandt AM, et al. N Engl J Med. 2013

Prolonging life | Evolving treatment goals | Holistic health

ART, antiretroviral; **HAART,** highly-active antiretroviral therapy; **PrEP,** pre-exposure prophylaxis **U=U,** Undetectable=Untransmittable; **UNAIDS,** Joint United Nations Programme on HIV/AIDS
WHO, World Health Organization

1. Brandt AM, et al. N Engl J Med. 2013;368:2149–52; **2.** HIV.gov. A timeline of HIV and AIDS. Available at: https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline. Accessed February 2022; **3.** Piot P, et al. Science. 1988;239:573–9; **4.** Tseng A, et al. Br J Clin Pharmacol. 2015;79:182–94
5. Levi J, et al. BMJ Global Health 2016;1:e000010; **6.** BHIVA. BHIVA encourages universal promotion of Undetectable=Untransmittable (U=U). Available at: https://www.bhiva.org/BHIVA-encourages-universal-promotion-of-U-U. Accessed February 2022; **7.** WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Available at: https://www.who.int/publications/i/item/9789241549684. Accessed February 2022
8. FDA news release. FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention. Accessed February 2022
9. UNAIDS. 2025 AIDS targets. Available at: https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf. Accessed February 2022

Shift towards patient-centered care in HIV treatment



Person-Centred Care Advocacy Academy: HIV in the southern United States

The objectives are to:

- Provide training and skills building on current person-centred care approaches to service delivery and existing barriers to their implementation
- Disseminate information and tools related to person-centred care and highlight their importance to the wider community, including policy makers, the media and programme managers
- Create opportunities to interact with experienced researchers and advocates in the field
- Guide participants to identify service delivery gaps in their communities and develop action plans to overcome these challenges

What is a patient-reported outcome (PRO)?

A PRO is a health outcome **directly reported by the patient** who experienced it. It stands in contrast to an outcome reported by someone else, such as a physician-reported outcome, a nurse-reported outcome, and so on[1]

PRO tools, such as questionnaires, are used in clinical trials or other clinical settings to help better **understand a treatment's efficacy** or **effectiveness**[1]

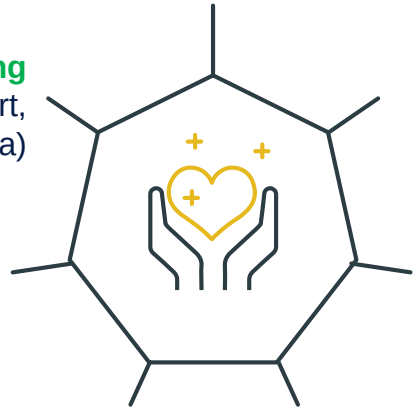
The use of **digitised** PROs, or **electronic patient-reported outcomes**, is on the rise in today's health research setting[2]

1. US FDA. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labelling Claims. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims. Accessed Jan 2022
2. Jensen RE, et al. Med Care 2015;53:153-9

PRO measures are tailored to specific assessments

PROs may include one or more dimensions[1–3]

HRQoL overall
Multidimensional: effect of an illness or treatment on physical, psychological and social aspects of life



Social wellbeing
(e.g. social support, HIV stigma)

Mental health
(e.g. depression, anxiety)

Physical symptoms
(e.g. pain, fatigue)

Health behaviours
(e.g. medication adherence, substance use including alcohol use, sexual risk behaviour)

Satisfaction with medication/treatment/care
…or other factors

Life circumstances
(e.g. housing, nutrition, family history of chronic illness, intimate partner violence)

PROs have an established role in the pharma industry as they provide additional evidence of treatment effectiveness and value:[4,5]

- Regulatory agencies want to see the impact of a drug on patient-relevant endpoints
- Pricing and reimbursement bodies are incorporating PROs into their reviews
- Clinicians and patients recognise the importance of a holistic assessment of a drug

Examples of PROMs used in HIV studies:[6–11]

- HIVTSQ (treatment satisfaction)
- HIV Symptom Index (symptom distress)
- PROQoL-HIV (QoL)

Qualitative interviews or focus groups[1,2,10,11]

- Can include about 20 participants and do not aim to be exhaustive or representative
- Allow capture of detailed subjective elements that cannot be captured with quantitative methods alone

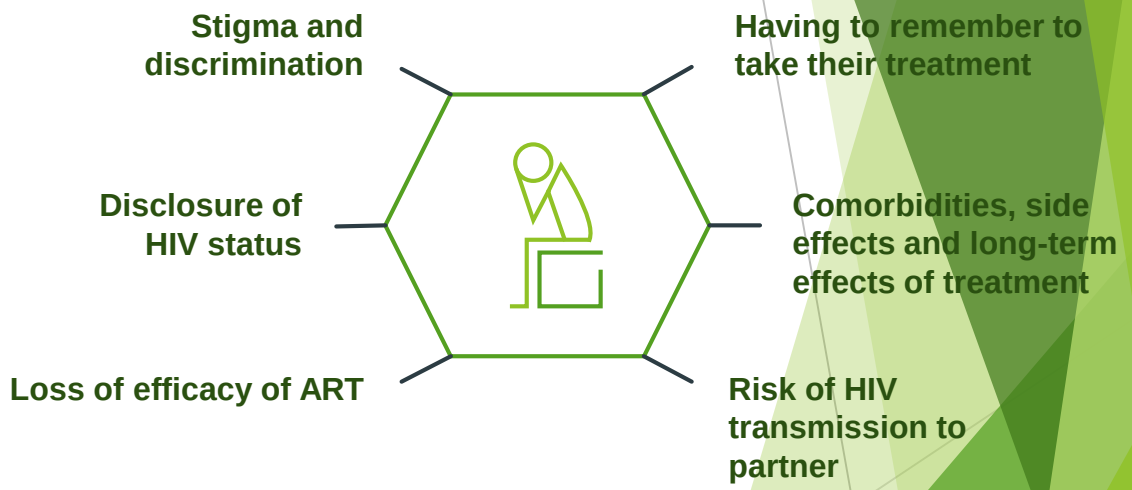
HIVTSQ, HIV Treatment Satisfaction Question; **PROQoL-HIV,** patient-reported outcome quality of life-HIV

1. Weldring T and Smith SMS. Health Serv Insights 2013;6:618; **2.** FDA. 2009. Patient-reported outcome measures: Use in medical product development to support labeling claims. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims. Accessed August 2023; **3.** Cella D, et al. Patient-Reported Outcomes in Performance Measurement. Research Triangle Park (NC): RTI Press; 2015; **4.** Medbery RL, et al. Semin Thorac Cardiovasc Surg 2019;31:856-60
5. Anker SD, et al. Eur Heart J 2014;35:2001-9; **6.** Herdman M, et al. Qual Life Res 2011;20:1727-36; **7.** Justice AC, et al. J Clin Epidemiol 2001;54:S77-90
8. Duracinsky M, et al. JAIDS 2012;59:498-505; **9.** Chassany O, et al. Drug Inf J 2002;36:209-38
10. Colafri KJ and Evans B. HERD 2016;9:16-25; **11.** Guidelines for Critical Review Form: Qualitative Studies Version 2.0, January 2007

PROs in HIV research…but also into routine!

- **Using PROs to capture the perspective of PLHIV is particularly important.** Due to the evolution of ART, many PLHIV can achieve viral suppression and have similar life expectancies as the general population; therefore, it is important to consider life beyond viral suppression[1,2]
- **With effective ART many PRO dimensions are still impacted:** physical health, body changes, sexual health, fatigue, sleep, cognitive function, mental health, social relationships[1,3]

The mental, emotional and social burden of living with HIV is prominent. **Patients worry about:**[1,3-6]



This burden may have an impact on **patient wellbeing, engagement in care** and **treatment adherence**[1]

1. Lazarus JV, et al. Nat Commun 2021;12:4450; **2.** Antiretroviral Therapy Cohort Collaboration. Lancet 2017;4:e349-56
3. Herrmann S, et al. Health Qual 2013;11:56; **4.** De los Rios JM, et al. Open Forum Infect Dis 2019;6:S481
5. Ramgopal MN, et al. Lancet HIV 2023;10:e566-77 (and suppl. appendix); **6.** Engelhard EAN, et al. AIDS 2018;32:103-112

Several PRO tools have been developed for PLHIV

PRO tools should assess the impact of long-term AEs (e.g. metabolic, renal, cardiovascular and skeletal effects)[1,2]

PROQoL-HIV[3]
- Uses multiple languages and accounts for HAART and AEs
- 37 items (8 dimensions including treatment impact)

King's College London's HIV-specific PRO tool 'Positive Outcomes'[4]
- Six domains of need: physical, cognitive, psychological, welfare, social and information

HIV Stigma Scale
- Stigma has been historically associated with depression and non-disclosure, contributing to higher morbidity and transmission of HIV[5]
- A more concise HIV Stigma Scale PRO tool may facilitate more widespread assessment of HIV stigma[6]

AE, adverse event; **QoL**, quality of life

1. Simpson N, et al. Health Qual Life Outcomes 2013;11:164; **2.** Gakhar H, et al. Drugs 2013;73:651-72
3. Duracinsky M, et al. JAIDS 2012;59:498-505; **4.** Bristowe K, et al. HIV Medicine 2019;20:542-54
5. Simbayi LC, et al. Soc Sci Med 2007;64:1823-31; **6.** Reinius M, et al. Health Qual Life Outcomes 2017;15:115

PROMs can be used to help address HRQoL and long-term wellbeing of PLHIV

UNAIDS targets for 2025:*[1]

- **95%** of PLHIV knowing their HIV status
- **95%** of PLHIV who know their status on treatment
- **95%** of PLHIV on treatment with suppressed VLs

Proposed additional target:[2,3]

90% of people with VL suppression have good HRQoL

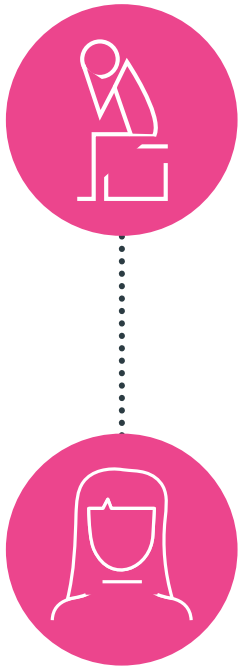
- Represents a limited effect of illness and treatment on physical, psychological and social aspects of life from the patient's perspective[4]
- Enabled by access to integrated or linked services for HIV treatment and cardiovascular diseases, cervical cancer, mental health, diabetes diagnosis and treatment, education on healthy lifestyle counselling, smoking cessation advice and physical exercise[3]

*Additional targets include 95% coverage of services for eliminating vertical transmission, 95% of women accessing HIV, sexual and reproductive health services and 95% use of combination prevention[1]

HRQoL, health-related quality of life; **PROM,** patient-reported outcome measure; **VL,** viral load

1. UNAIDS. 2025 AIDS Targets. Available at: https://aidstargets2025.unaids.org/. Accessed May 2023
2. Lazarus JV, et al. BMC Med 2016;14:94; **3.** Lazarus JV, et al. Nat Commun 2021;12:4450
4. FDA 2009. Patient-reported outcome measures: Use in medical product development to support labeling claims. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims. Accessed August 2023

A high proportion of PWH experience poor QoL



Despite the availability of highly effective, well-tolerated daily oral ART, **many people with HIV experience poorer QoL than the general population**[1,2]

Factors negatively affecting HRQoL of people with HIV include **stigma, difficulties disclosing HIV status and multimorbidity**[3]

In addition to the UNAIDS targets for people with HIV in 2025, there is a proposed "fourth 90":[3–5]

Ensure the long-term wellbeing of people living with HIV

by addressing multimorbidity, HRQoL, stigma, and discrimination

Addressing key unmet needs and improving HRQoL supports UNAIDS overall targets

An integrated, person-centred approach is likely to enhance the HRQoL of people with HIV, reinforcing the importance of involving them in treatment discussions and shared decision making[3,5,6]

HRQoL, health-related quality of life; **UNAIDS,** Joint United Nations Programme on HIV/AIDS

1. Miners A, et al. Lancet HIV 2014;1:e32-40; **2.** Engelhard EAN, et al. AIDS 2018;32:103-12; **3.** Lazarus JV, et al. Nat Commun 2021;12:4450
4. UNAIDS. 2025 AIDS targets. Available at: https://aidstargets2025.unaids.org/ (accessed Jan 2025)
5. Okoli C, et al. AIDS Behav 2021;25:1384-95; **6.** Kall M, et al. Lancet HIV 2020;7:e59-68

Why Focus on PROs?

- Capture patient's perspective on treatment impact.
- Assess satisfaction, convenience, stigma reduction, and quality of life.
- Identify barriers to adherence and treatment continuity.

The promise of LA ART

In recent years, **monthly and two-monthly LA injectable formulations** of CAB and RPV have been developed[1]

- The **LATTE-2 Phase IIb** study demonstrated that CAB + RPV LA was as effective as a daily oral 3DR (CAB + ABC/3TC) at maintaining viral suppression, and was well accepted and tolerated[1]
- Four Phase III studies (ATLAS, ATLAS-2M, FLAIR and SOLAR) have been completed to evaluate the efficacy, safety and acceptability of these treatments[2-5]
- The development of these therapies has the **potential to redefine HIV care of PLHIV** by addressing the psychosocial burdens (e.g. **fear of disclosure, adherence anxiety and daily reminder of HIV status**) of daily oral treatments[5,6]

Patient perspective on the **potential benefits of LA injectable ART** was compared with daily oral ART[2-5]

- The first Phase III studies of CAB + RPV LA (**ATLAS**, **ATLAS-2M** and **FLAIR**) used PROs to explore aspects of the patient experience, including **tolerability** and **acceptability** of IM injections, treatment **acceptance**, treatment **satisfaction** and **preference**, and **health status** and **QoL**[2-4]
- PROs were also used to assess **psychosocial challenges related to** daily oral ART at BL in the **SOLAR** study[2-5]

ABC, abacavir; **IM,** intramuscular

1. Margolis D, et al. Lancet 2017;390:1499–510; **2.** Swindells S, et al. N Engl J Med 2020;382:1112–23
3. Overton E, et al. Lancet 2021;396:1994–2005; **4.** Orkin C, et al. N Engl J Med 2020;382:1124–35
5. Ramgopal MN, et al. Lancet HIV 2023;10:e566–77 (and suppl. appendix); **6.** Thornhill J & Orkin C. Curr Opin Infect Dis 2021;34:8–15

CAB + RPV LA is recommended by guidelines as a strategy to improve quality of life for some PLWH

DHHS guidelines[1]

"[Consider] switch to a long-acting injectable regimen to **relieve pill fatigue** or to decrease potential **stigma** or **disclosure concerns** associated with taking daily oral medications"

IAS-USA guidelines[2]

"Those interested in non-oral options for ART because of **privacy**, **stigma** or **convenience** reasons will usually have **greater satisfaction with CAB and RPV** than continued oral ART"

ART, antiretroviral therapy; **CAB,** cabotegravir; **DHHS,** Department of Health and Human Services
IAS-USA, International Antiviral Society-USA; **LA,** long acting; **RPV,** rilpivirine

1. DHHS Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents living with HIV, Mar 2023
2. Gandhi RT, et al. JAMA 2022;329:63-84

Selection of PROs in Phase III studies

- Insights from qualitative interviews with patients in LATTE-2 and reviews of the literature were used to determine the PRO instruments included in Phase III studies[1–3]
- These insights led to the inclusion of three types of PRO instruments in Phase III studies as secondary and exploratory endpoints:

Treatment-related PROs (satisfaction and preference)

Pain and ISR-related PROs

General health and QoL-related PROs

ISR, injection-site reaction

1. Murray M, et al. AIDS Behav 2020;24:3533–44
2. Swindells S, et al. N Engl J Med 2020;382:1112–23 (and suppl. appendix)
3. Orkin C, et al. N Engl J Med 2020;382:1124–35 (and suppl. appendix)

PROs in Phase III trials: Subset measures

PRO dimensions	PRO instrument	Endpoint	Score range
Tolerability and acceptability of IM injections	Perception of Injection questionnaire (PIN)*	Tolerability and acceptability related to ISRs (21 questions)	1–5[1,2]
Treatment acceptance	Chronic Treatment Acceptance (ACCEPT®)*	Acceptance of treatment, defined as the balance between treatment advantages and disadvantages (only general treatment acceptance included – 3 questions)	0–100[1,2]
Acceptability and appropriateness	Acceptability of intervention measure (AIM) Intervention appropriateness measure (IAM)	AIM and IAM surveys have four items, rated on a scale of 1 (completely disagree) to 5 (completely agree)	1–5[3]
Treatment satisfaction and preference	HIV Treatment Satisfaction Questionnaire (HIVTSQ)*	Satisfaction with treatment (12 questions)	0–66 (HIVTSQs)[1,2]
	Preference for HIV Treatment†	ATLAS, FLAIR, CARISEL and CUSTOMIZE: Preference for CAB + RPV LA compared with CAR (1 question) ATLAS-2M: Preference for the Q4W vs Q8W regimen (3 questions)	N/A[1-4]
Health status and QoL	Short Form Health Survey (SF-12®)	Health status measure (12 questions)	0–100 (mental and physical scores) [1,2]

*These PRO instruments have been adapted for the programme
†These PRO instruments have been developed by ViiV Healthcare
AIM, acceptability of intervention measure; **CAR,** current antiretroviral regimen; **FAD,** fear of disclosure, adherence anxiety and daily reminder of HIV
HIVTSQs, HIV Treatment Satisfaction Questionnaire (status version); **IAM,** intervention appropriateness measure; **IM,** intramuscular
N/A, not applicable; **PIN,** Perception of Injection questionnaire; **Q4W,** every 4 weeks; **Q8W,** every 8 weeks

1. Murray M, et al. AIDS Behav 2020;24:3533–44; **2**. Chounta V, et al. Patient 2021;14:849–62
3. Garris CP, et al. J Int AIDS Soc 2022;25:e26006; **4.** Lutz T, et al. HIV Glasgow 2022. Poster P123

Clinical studies of LA injectable ART

Study	Overview	Treatment status	Primary endpoint timepoint	Sample size
ATLAS[1]	Phase III, open-label, randomised trial comparing **monthly** CAB + RPV LA to current daily oral ART	Virologically suppressed	48 weeks	618
ATLAS-2M[2]	Phase IIIb, open-label, randomised trial comparing **monthly** CAB + RPV LA to **two-monthly** CAB + RPV LA in subjects who completed the ATLAS study	Virologically suppressed	48 weeks	1,045
SOLAR[3]	Phase IIIb, open-label, randomised trial comparing switch to **two-monthly** CAB + RPV LA versus remaining on **daily BIC/FTC/TAF**	Virologically suppressed	11/12 months	687
FLAIR[4]	Phase III, open-label, randomised trial comparing **monthly CAB + RPV LA** to **DTG/ABC/3TC single-tablet oral regimen**	ART-naïve	48 weeks	566

1. Swindells S, et al. N Engl J Med 2020;382:1112–23; 2. Overton E, et al. Lancet 2021;396:1994–2005
3. Ramgopal MN, et al. Lancet HIV 2023;10:e566-77 (and suppl. appendix); 4. Orkin C, et al. N Engl J Med 2020;382:1124–35

Generation of PRO data for CAB + RPV LA in the real-world setting is ongoing

Study	Study design	Country	Aim
ILANA[1,2]	Multicentre, Phase IV	United Kingdom	Evaluate **feasibility and acceptability** of CAB + RPV LA administration at NHS HIV clinics and community settings in PLHIV receiving the regimen as part of their routine clinical care, with a particular focus on women, racially minoritised people and older PLHIV
CARLOS[3,4]	Multicentre, prospective cohort	Germany	Describe effectiveness, treatment **adherence and patient experience** of participants choosing CAB + RPV LA in routine clinical care
Grady Healthcare System[5]	Single centre, prospective cohort	United States	Evaluate real-world settings for **implementation** of LA injectables
IMSUT cohort[6]	Single centre, cross-sectional prospective cohort	Japan	Investigate **background factors** of PLHIV in Japan who chose CAB + RPV LA
Prisma Health cohort[7]	Single centre, retrospective cohort	United States	Assess clinical **implementation process** of CAB + RPV LA at a large HIV clinic

NHS, National Health Service

1. Farooq HZ, et al. BMJ Open 2023;13:e070666
2. Hayes R, et al. Spring BHIVA 2023. Poster P017; **3.** Borch J, et al. HIV Glasgow 2022. Oral O43
4. Scherzer J, et al. IAS 2023. Poster EPE0863; **5.** Collins LF, et al. Open Forum Infect Dis 2022;9:ofac455
6. Adachi E, et al. J Infect Chemother 2023;29:109-11; **7.** Taylor K, et al. ACCP 2022. Poster 61138

LATTE-2 , ATLAS, FLAIR and ATLAS-2M: Qualitative interviews Highlighting experiences with LA therapy (1 of 2)

- Semi-structured interviews exploring patient experiences with LA ART were conducted in:
  - 80 participants in LATTE-2, ATLAS, ATLAS-2M and FLAIR[1]
  - 53 participants in ATLAS, ATLAS-2M and FLAIR[2]

Logistical and psychological freedom

"Less tied to a packet of pills" "more control"

"…So, I wanted to get rid of the minor inconvenience of it, like having to fill the prescription, having to make sure I picked up the prescription in time and all that. So, I have to… I just go to my next appointment. It's all taken care of, and it's a one-stop shop"[2]

Male ATLAS/ATLAS-2M participant, U.S., age 29

"Just to know that I wasn't going to have to take a pill every day, it just meant freedom for me. It feels like come in, get it done. I'm out the door and just got to maintain my health and that's it. Gives me a lot of flexibility…"[1]

Female ATLAS participant, U.S., age 30

Dosing frequency and saving time

"The less I need to come to a hospital the better"

"The comfort that instead of you taking a pill every day at night… it is once every eight weeks… I lose a few hours but I face that for eight weeks, I don't take a pill at night"[1]

Female ATLAS-2M participant, Spain, age 29

"…I mean, if it's the same thing and you just… you can cut your visits by half. So you don't have to do the visit, and also don't have six more times of walking around with a limp. Even if it's just for a day, that's six days out of the year less that you have that"[2]

Male ATLAS/ATLAS-2M participant, U.S., age 49

1. Mantsios A, et al. IDWeek 2019. Poster 2497
2. Mantsios A, et al. AIDS Behav 2020;24:3473-81

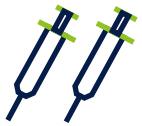
LATTE-2 , ATLAS, FLAIR and ATLAS-2M: Qualitative interviews Highlighting experiences with LA therapy (2 of 2)

- Semi-structured interviews exploring patient experiences with LA ART were conducted in:
  - 80 participants in LATTE-2, ATLAS, ATLAS-2M and FLAIR[1]
  - 53 participants in ATLAS, ATLAS-2M and FLAIR[2]

Less stress and anxiety with LA ART compared with oral ART[1]

"When I was taking Truvada and the pills once a day, I'd still get anxiety over whether I'd taken it or not, and once or twice I double-dosed, just because I couldn't remember, but then I'd go count and… it's just a lot of anxiety… only having to have something done once every other month is just awesome…"

Female ATLAS-2M participant, USA, age 35



Injection site reactions[2]

"It got better over time"

"The first time I ever got the injection, the soreness lasted a couple days but I knew about it ahead of time so I wasn't scared. I just expected it. But after that… after the next month I didn't feel anything to the point that I called and I asked them, 'I don't feel anything. Is that normal?' "

Female ATLAS participant, USA, age 30

The importance of clinical efficacy of LA ART[2]

"Are my numbers going down?"

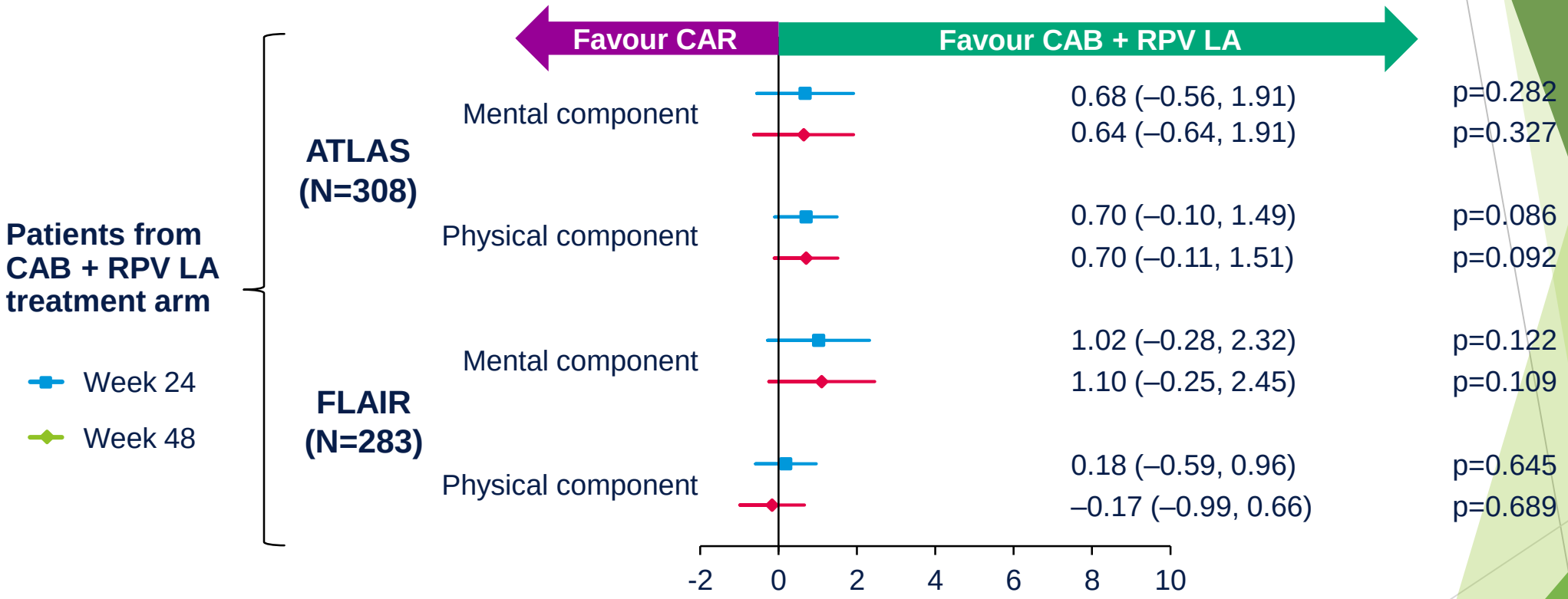
"The only concern I have had… was how could it last a month… Since the pill was daily, I was certain that it was having an effect each day. But with the injection, I won't necessary receive it today, so what will happen tomorrow?"

Male FLAIR trial participant, Spain, age 22

1. Mantsios A, et al. IDWeek 2019. Poster 2497
2. Mantsios A, et al. AIDS Behav 2020;24:3473–81

ATLAS and FLAIR pooled data: QoL SF-12:* Change from baseline score[1]

Adjusted† SF-12 mean difference (95% CI)

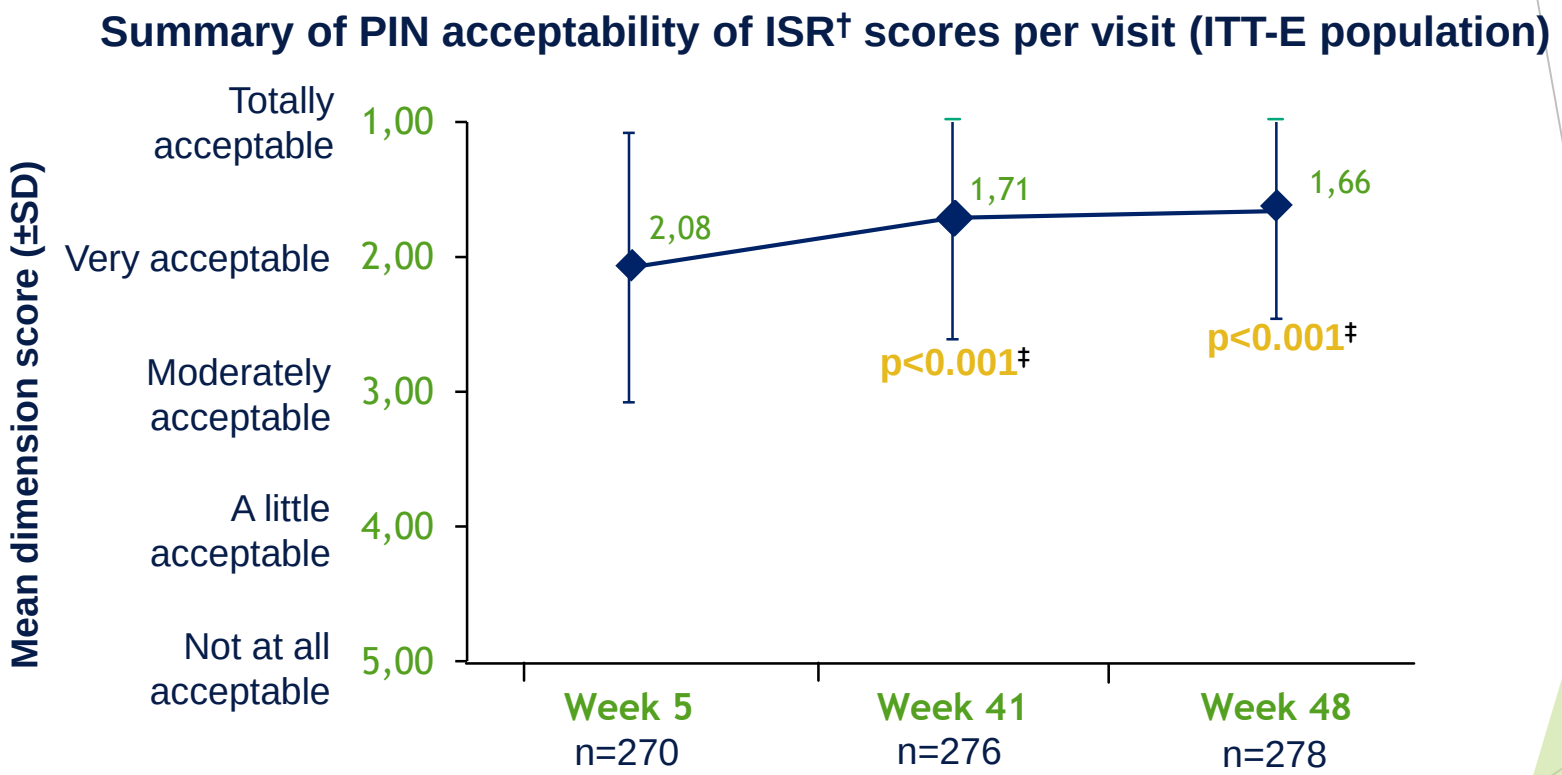


Generic QoL instruments may not be sufficiently sensitive to provide meaningful information in the study of HIV treatment

*SF-12: 12-item Short-form Health Survey; physical and mental components; range of component score 0–100[2]; scores >50 indicate above-average health status compared to the general population/positive changes indicate improvement[1]; †Adjusted mean is the estimated mean change from maintenance BL score (95% CI) by visit in each treatment calculated from an ANCOVA model. On top of sex at birth, age (<50 versus ≥50 years) and race (white versus non-white) were covariates for both analyses; ATLAS also included BL score and third agent class (INI, PI, NNRTI) and FLAIR included maintenance BL (day 1) score and induction BL (Week -20) HIV-1 RNA (<100,000 versus 100,000 c/mL). Maintenance BL scores were above the US national average of 50

1. Murray M, et al. AIDS Behav 2020;24:3533–44
2. Ware J, et al. Med Care. 1996;34:220–33

PIN questionnaire:* Change from Week 5 in dimension score[1]



ISRs were considered acceptable in participants using CAB + RPV LA.
Significant improvements in acceptability at Weeks 41 and 48 versus Week 5 were observed

Purple text indicates significance; *PIN: Perception of Injection questionnaire; 21 items and 4 dimensions; range of item and dimension scores 1–5 (mean of all items within a dimension is taken to give the dimension score); lower scores indicate greater acceptability/negative changes indicate improvement[2]
†The acceptability of ISRs dimension consists of two items: acceptance of local reactions and acceptance of pain[1,2]
‡p value from Wilcoxon signed-rank test for change from value at Week 5 for acceptability of ISRs dimension

1. Murray M, et al. IAS 2019. MOPEB258
2. Chounta V, et al. Patient 2021;14:849–62

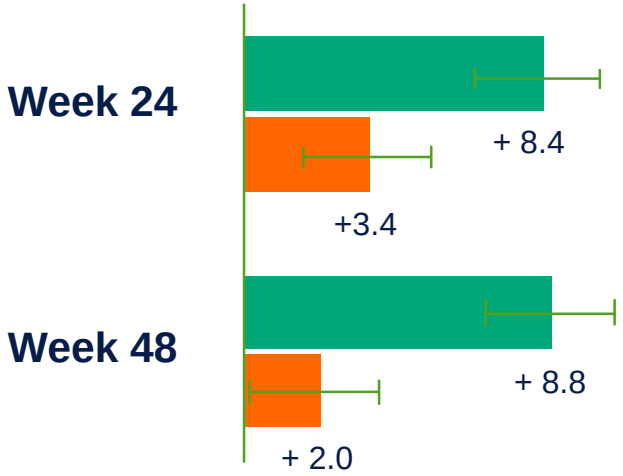
ATLAS and FLAIR pooled data: General acceptability ACCEPT®:* Change from baseline in domain score[1]

- Pooled mean (SD) BL scores: **CAB + RPV LA:** 80.5 (24.8); **CAR:** 78.8 (25.3)

ACCEPT® general acceptance domain score† → Improvement

CAB + RPV LA (N=591)

Current oral ART (N=591)



Adjusted treatment difference versus CAR (95% CI)

5.0 (2.4, 7.5), **p<0.001**

6.8 (4.2, 9.4), **p<0.001**

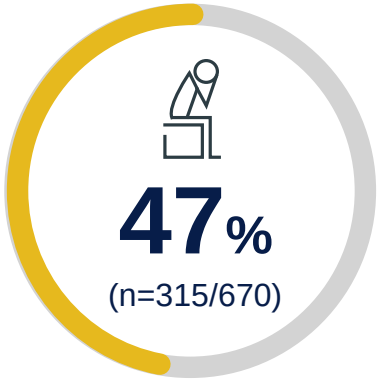
Acceptability of LA treatment increases over time. At study end, a significantly greater improvement in acceptance was observed for CAB + RPV LA versus current oral ART

Purple text indicates significance; *ACCEPT®: Chronic Treatment Acceptance questionnaire; 3 items in general acceptance domain; range of total score 1-100; higher scores indicate greater acceptability/positive changes indicate improvement[1,2]; †Adjusted mean change from maintenance BL is estimated from an ANCOVA model. Covariates are: maintenance BL score, sex at birth, age (<50 versus ≥50 years) and race

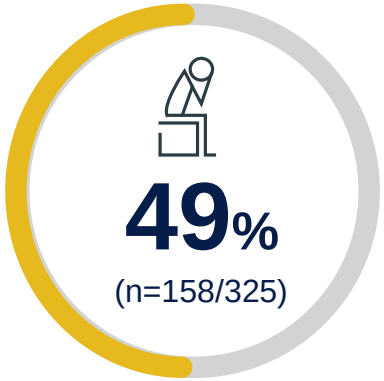
1. Murray M, et al. AIDS Behav 2020;24:3533-44
2. Marant C, et al. Patient 2012;5:239-49

Participants receiving daily oral ART reported psychosocial challenges at baseline

SOLAR[1]
(Phase IIIb)



CARLOS[2]
(real-world cohort)



... of participants reported always/often experiencing one or more of the following challenges at BL:

Fear of disclosure

Worried about people unintentionally discovering their HIV status

Adherence anxiety

Worried about forgetting to take their HIV medication

Daily reminder of HIV

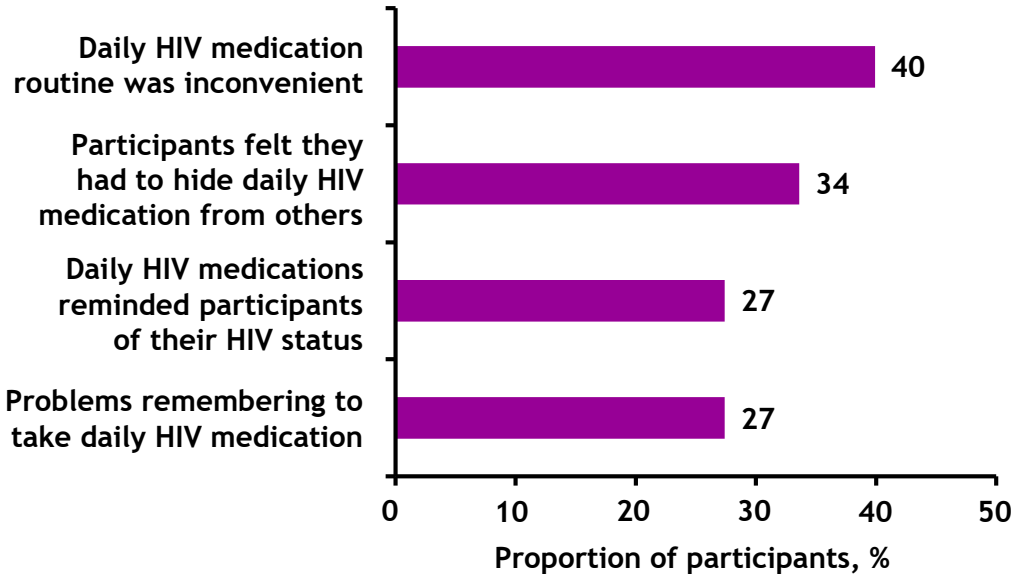
Felt that their HIV medication was a reminder of their HIV status

BL, baseline

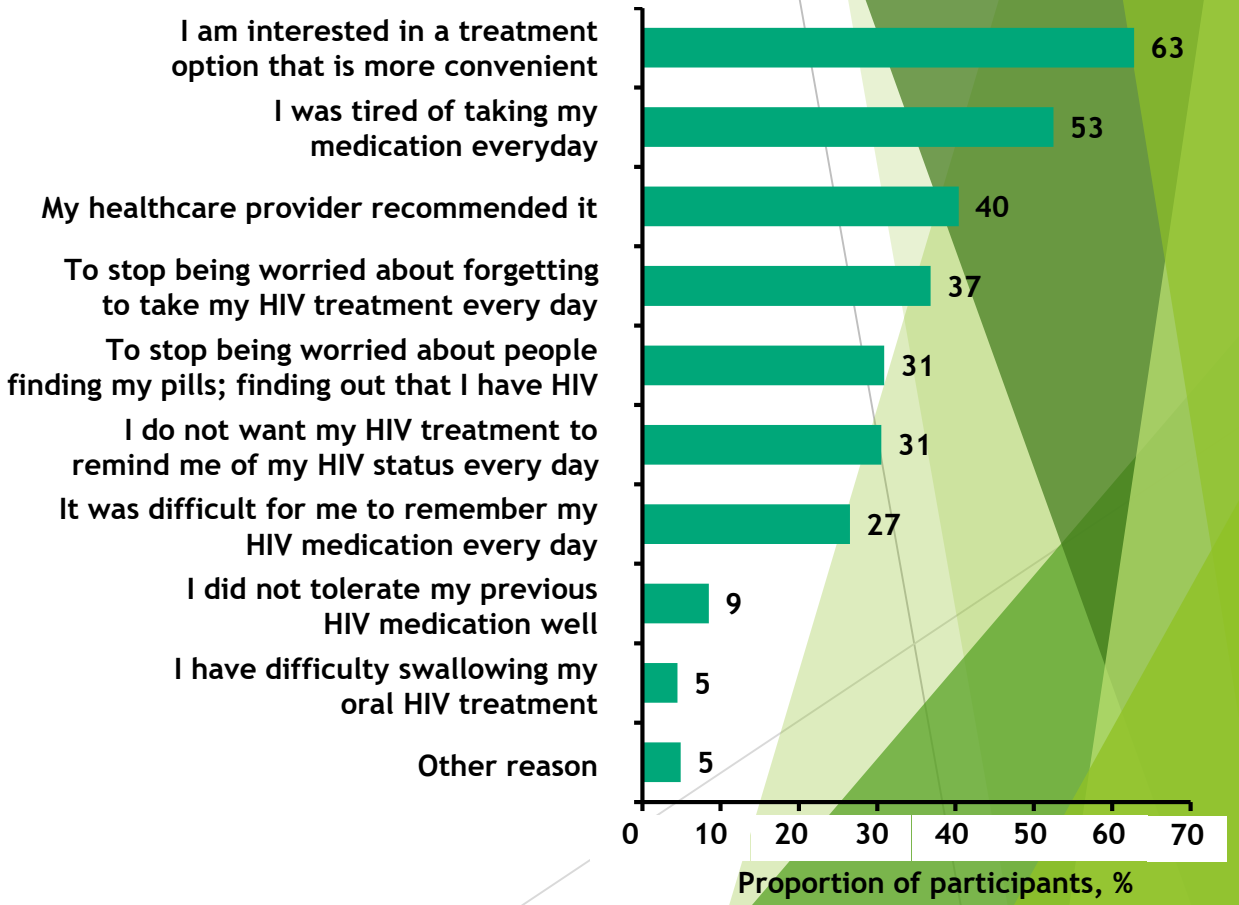
1. Ramgopal MN, et al. Lancet HIV 2023 (online ahead of print)
2. Scherzer J, et al. IAS 2023. Poster EPE0863

CARLOS: PLWH in real-world clinics in Germany reported multiple challenges with daily oral ART*

Most common challenges PLWH have with daily HIV medication (n=223)†‡



Reasons PLWH chose to switch to CAB + RPV LA (n=223)‡



*Experiences reported with oral ART prior to switching to CAB + RPV LA in an ongoing non-interventional, 3-year, prospective, multicentre cohort study; †Reported by >20% of participants; ‡Multiple answers were possible

Wyen C, et al. AIDS 2022. Poster EPB179

challenges after switching to CAB + RPV LA from BIC/FTC/TAF

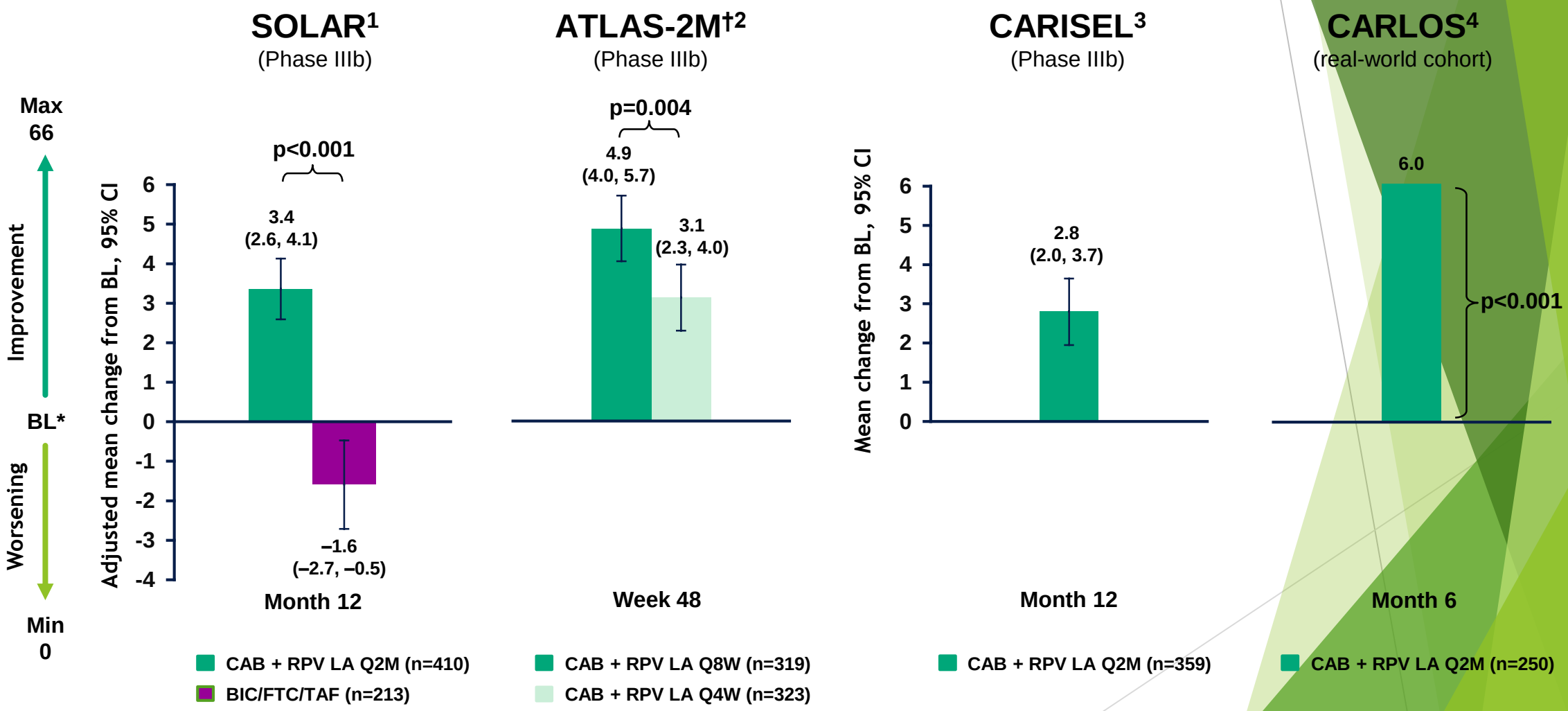
Participants that reported experiencing psychosocial challenges at BL and Month 12

Psychosocial challenges, n (%)*	CAB + RPV LA Q2M		BIC/FTC/TAF	
	BL (n=447)	Month 12 (n=409)	BL (n=223)	Month 12 (n=214)
Any one psychosocial challenge	**218 (49)**	**141 (34)**	**97 (43)**	**88 (41)**
Fear of HIV status disclosure	109 (24)	59 (14)	52 (23)	46 (21)
Adherence anxiety	119 (27)	70 (17)	53 (24)	52 (24)
Daily reminder of HIV status	111 (25)	91 (22)	49 (22)	53 (25)

*Participants reporting 'always' or 'often' to psychosocial questions

Chounta V, et al. IAS 2023. Poster TUPEB06

who switched to CAB + RPV LA from oral ART (HIVTSQs)

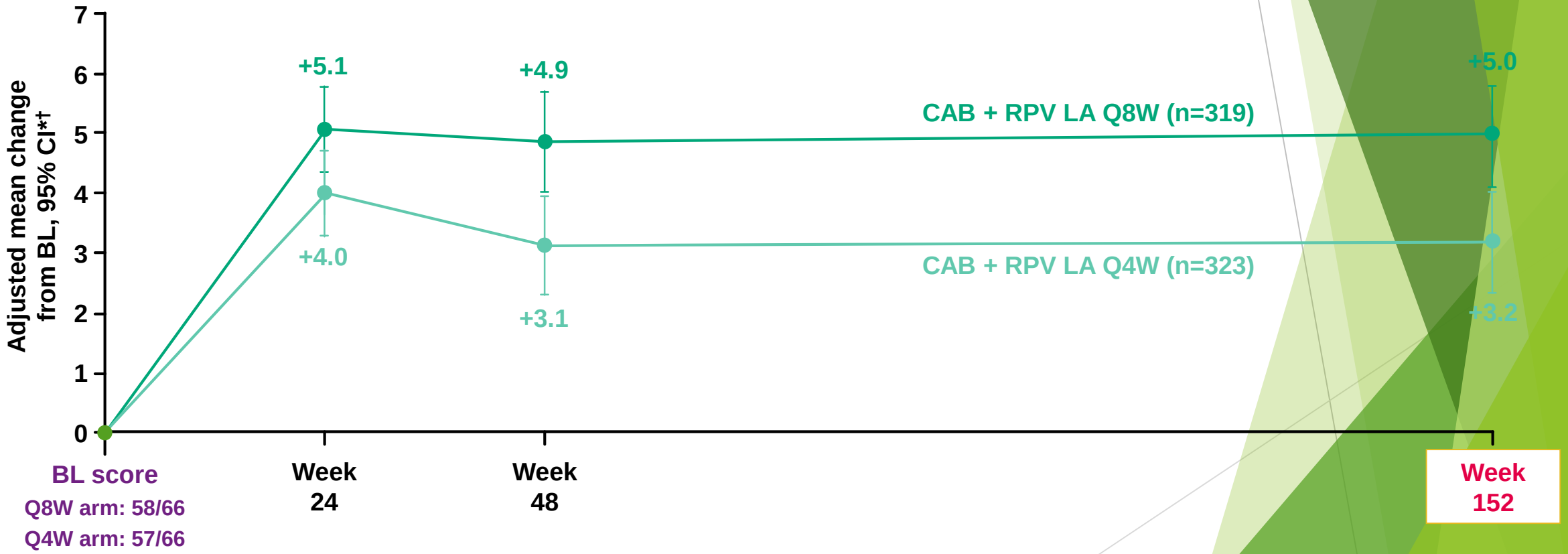


*BL HIVTSQs scores were: SOLAR 58 for both groups; ATLAS-2M 58 for Q8W, 57 for Q4W; CARISEL 59 (Day 1) and CARLOS 55
†Participants without prior CAB + RPV exposure
CI, confidence interval

1. Ramgopal MN, et al. Lancet HIV 2023 (online ahead of print) (and suppl. appendix)
2. Chounta V, et al. Patient 2021;14:849-62
3. Lutz T, et al. HIV Glasgow 2022. Poster P123
4. Scherzer J, et al. IAS 2023. Poster EPE0863

baseline were maintained for CAB + RPV LA through to Week 152

HIVTSQs total score in participants without prior CAB exposure[1–3]

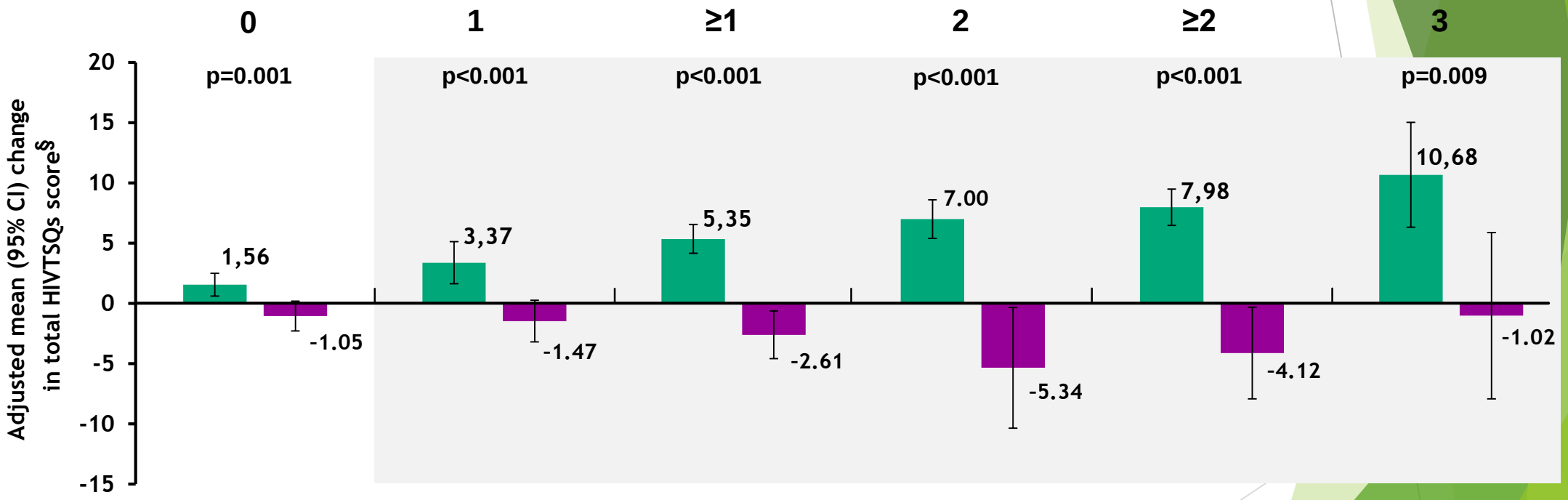


*Adjusted for BL score, sex at birth, age (<50, ≥50 years), race (White, non-White) and third-agent class (INI, PI, NNRTI)
†Difference between arms in adjusted mean HIVTSQs score change from BL: Week 24, 1.07 (p=0.036); Week 48, 1.73 (p=0.004); Week 152, 1.75 (p=0.004)
INI, integrase inhibitor; **NNRTI,** non-nucleoside reverse transcriptase inhibitor; **PI,** protease inhibitor

1. Overton ET, et al. Clin Infect Dis 2023;76:1646-54 (and suppl. appendix)
2. Chounta V, et al. HIV Glasgow 2022. Poster P070
3. Chounta V, et al. Patient 2021;14:849-62

clinically
significant improvement in treatment satisfaction in PLWH
who had experienced challenges with daily oral BIC/FTC/TAF

HIVTSQs* at Month 12 according to number of psychosocial challenges reported at BL†‡
(fear of disclosure, adherence anxiety and/or daily reminder of HIV status)

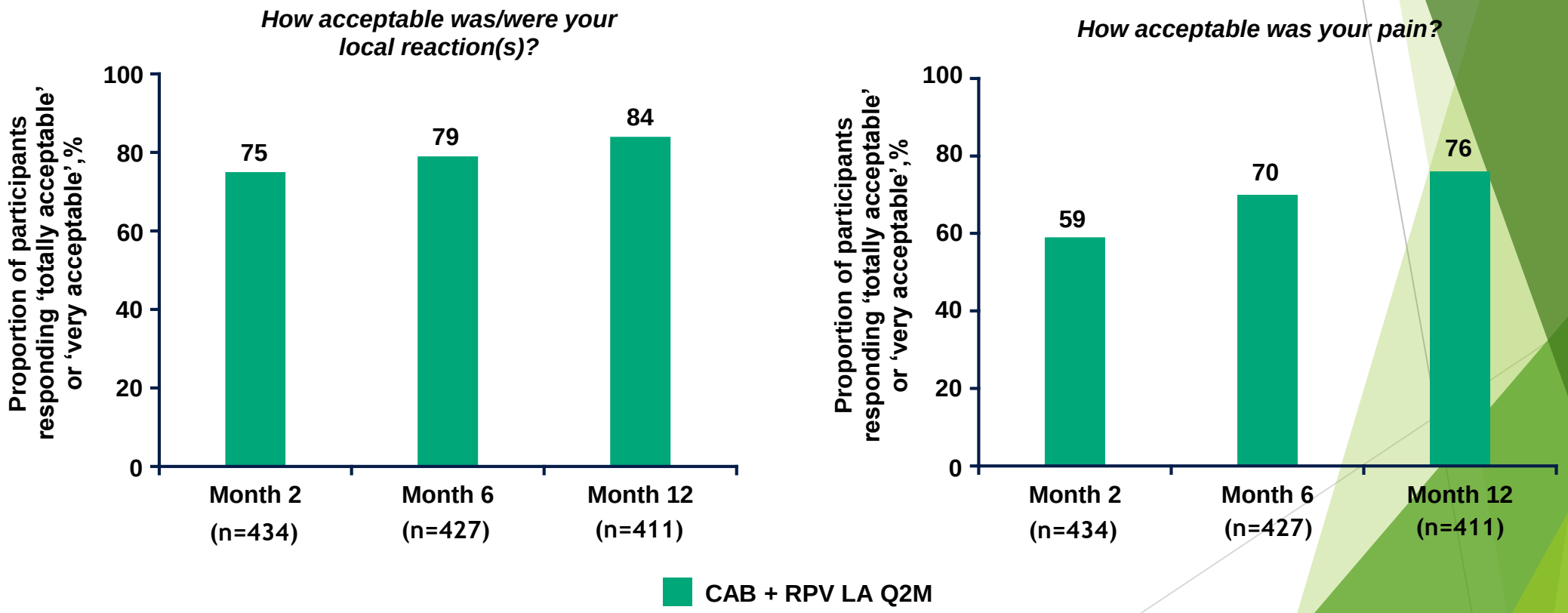


*HIVTSQs: 12-item status version; 7 range per item is 0-6, where 0 = 'very dissatisfied' and 6 = 'very satisfied.' Total score = sum of items 1-11
†Participants who scored 'always' or 'often' at BL to psychosocial challenge questionnaires; ‡Clinical significance determined using a distribution-based approach: mean difference between arms >½ SD at BL; §Mean (SD) HIVTSQs at BL by number of psychosocial challenges: 0 at BL: CAB + RPV LA, 60.1 (6.0; n=228), BIC/FTC/TAF, 60.1 (7.2; n=126); 1 at BL: CAB + RPV LA, 57.5 (7.7; n=122), BIC/FTC/TAF, 57.8 (7.6; n=52); ≥1 at BL: CAB + RPV LA, 55.5 (8.9; n=218), BIC/FTC/TAF, 56.1 (9.0; n=96); 2 at BL: CAB + RPV LA, 54.6 (8.9; n=71), BIC/FTC/TAF, 53.3 (10.8; n=31); ≥2 at BL: CAB + RPV LA, 53.0 (9.8; n=96), BIC/FTC/TAF, 54.1 (10.0; n=44); 3 at BL: LA, 48.6 (10.9; n=25), BIC/FTC/TAF, 56.0 (7.8; n=13)
SD, standard deviation

Chounta V, et al. IAS 2023. Poster TUPEB06

SOLAR: Acceptability of ISRs on CAB + RPV LA was high and increased over time

Acceptability of ISRs through to Month 12 (individual acceptability domain items of the PIN questionnaire)



ISR, injection-site reaction

Chounta V, et al. IAS 2023. Poster TUPEB06

acceptability of clinic visits

reported that coming into the clinic Q2M was **‘very’** or **‘extremely’** acceptable (n=220/255)

reported that the time spent in clinic per injection visit was **‘very’** or **‘extremely’** acceptable (n=234/255)

Scherzer J, et al. IAS 2023. Poster EPE0863

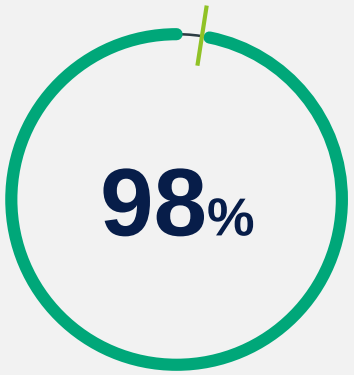
PLWH preferred CAB + RPV LA to daily oral therapy in Phase IIIb and real-world studies

Participant preference for CAB + RPV LA Q2M versus previous daily oral ART:

SOLAR*[1]
(Phase IIIb)

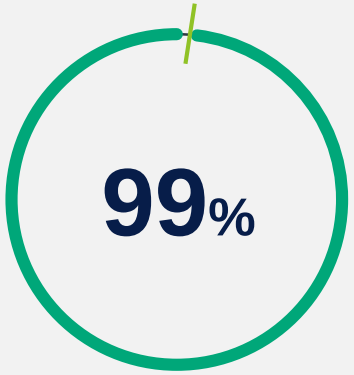
Month 12 (n=425)

ATLAS-2M†[2]
(Phase IIIb)



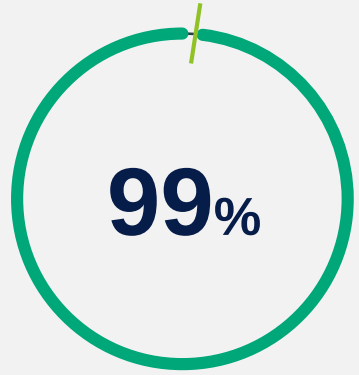
Week 48 (n=306)

CARISEL‡[3]
(Phase IIIb)



Month 12 (n=277)

CARLOS§[4]
(real-world cohort)



Month 6 (n=255)

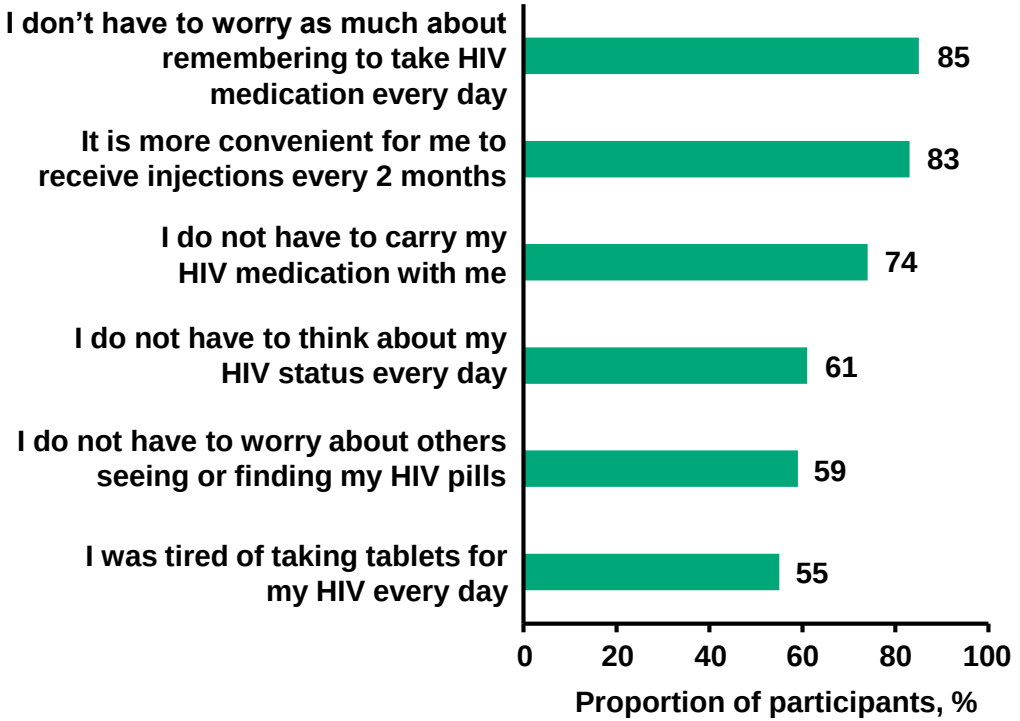
Permitted previous ART on entry into each study
*A single prior INI regimen was allowed if BIC/FTC/TAF was a second-line regimen 6 months prior to screening
†Participants not transitioning from the ATLAS trial were on PI, NNRTI or INI-based regimen with 2 NRTI backbone, uninterrupted for 6 months prior to screening; ‡Highly active daily oral ART for ≥6 months prior to screening[5]
§PLWH switched from suppressive daily oral ART to CAB + RPV LA Q2M in accordance with the label[6]
NRTI, nucleoside reverse transcriptase inhibitor

1. Ramgopal MN, et al. Lancet HIV 2023 (online ahead of print); **2.** Overton ET, et al. Lancet 2021;396:1994-2005
3. Lutz T, et al. HIV Glasgow 2022. Poster P123; **4.** Scherzer J, et al. IAS 2023. Poster EPE0863
5. Jonsson-Oldenbüttel C, et al. AIDS 2022. Poster EPLBB05; **6.** Borch J, et al. HIV Glasgow 2022. Oral O43

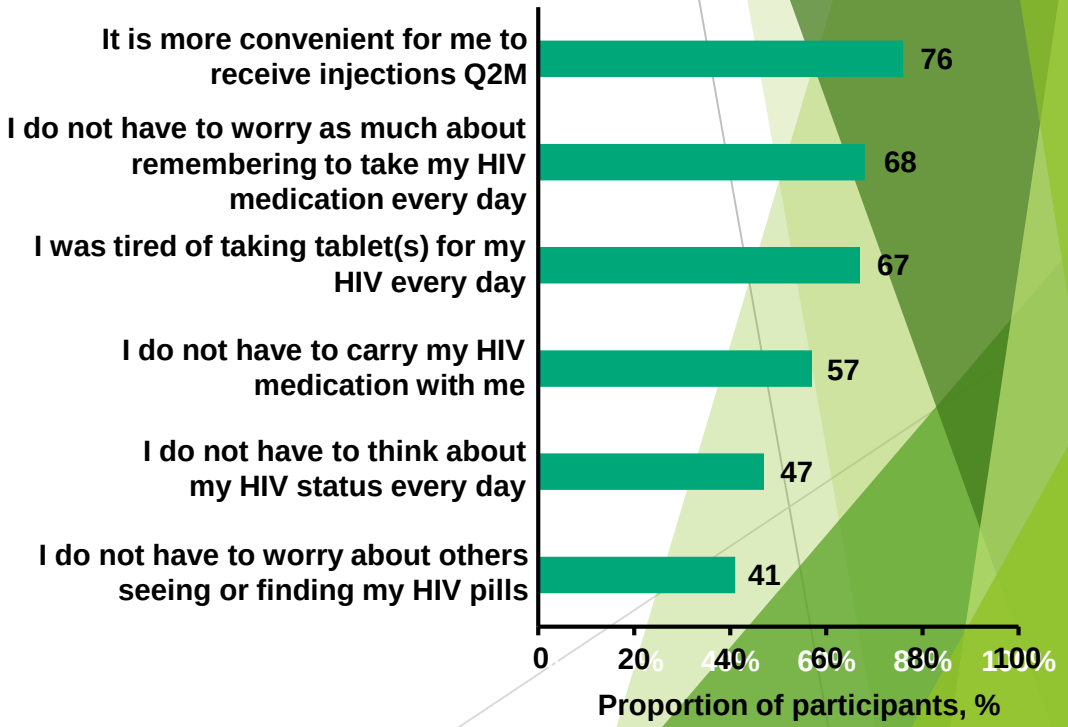
CAB + RPV LA was preferred in studies over oral ART for reasons including convenience and challenges with daily pills

Top reasons given for preferring CAB + RPV LA to daily oral ART

SOLAR (Month 12, n=382)*[1]



CARLOS (Month 6, n=253)†[2]



*Other reasons given were 'I feel more in control of managing my HIV condition' (47%), 'I like more frequent interaction with my HIV provider' (34%), 'Injections are more reliable than oral medication to keep viral load undetectable' (33%), 'I have difficulty swallowing oral HIV medication' (7%) and 'Other' (4%)

†Other reasons given were 'I feel more in control of managing my HIV condition' (17%), 'I like more frequent interaction with my HIV provider' (15%), 'I believe injections are more reliable than daily oral medication to keep my viral load undetectable' (12%), 'I experienced side effects with my previous oral therapy' (8%), 'I have difficulty swallowing oral HIV medication' (6%) and 'Other' (4%). Multiple answers were possible

1. Ramgopal MN, et al. Lancet HIV 2023 (online ahead of print) (and suppl. appendix)
2. Scherzer J, et al. IAS 2023. Poster EPE0863

CARISEL: Participants perceive CAB + RPV LA to be less stigmatising than daily oral BIC/FTC/TAF

'agreed' or 'completely agreed' that CAB + RPV LA is **less stigmatising** than oral medication*

'agreed' or 'completely agreed' that they would **recommend** CAB + RPV LA to other PLWH†

*Proportion of participant responses are as follows (n=379): Completely agree, 56.5%; agree, 24.5%; neutral, 15.6%; disagree, 1.1%; completely disagree, 1.3%; missing, 1.1%
†Proportion of participant responses are as follows (n=375): Completely agree, 74.7%; agree, 19.8%; neutral, 4.0%; disagree, 0.3%;completely disagree, 0.3%; missing, 1.1%

Lutz T, et al. HIV Glasgow 2022. Poster P123

ILANA:
Enrolment targets

- The protocol for enrolment required at least:

Women

Minority racial background

Aged ≥50 years

Hayes R, et al. Spring BHIVA 2023. Poster P017

Preliminary qualitative data
Influencing factors for acceptability of LA injectable ART

- Semi-structured qualitative interviews (August–November 2022) with 14 patients and 13 HCPs; thematic analysis was performed on interview data[1,2]
- Most BL interviews took place prior to first injection; follow-up interviews were conducted during 2023[1,2]
- At BL, CAB + RPV LA was **highly acceptable** to patients and HCPs; themes that emerged as facilitators and barriers to acceptability from the patient's perspective included[1,2]

Barriers

- Potential side effects and pain
- Potential for drug resistance

Facilitators

- Relief from pill fatigue and daily reminder of HIV
- Convenience of injection schedule
- Discrete nature of injections
- Confidence in effectiveness of CAB + RPV LA
- Benefits outweigh discomfort

Despite initial patient concerns about receiving injectable ART, **acceptability increased** once they had started OLI or injections due to:[2]

- Lack of side effects
- Relief from pill fatigue
- Minimal pain
- Maintenance of viral suppression

OLI, oral lead-in

1. Hayes R, et al. Spring BHIVA 2023. Poster P017
2. Hayes R, et al. IAS 2023. Poster MOPEE25

Perceived benefits of long-acting injectable antiretroviral treatment go beyond pill-burden relief: A qualitative study (1 of 2)

Results: Sociodemographic

- N=24 PLHIV with median age of 53 (range: 23–77), n=17 cisgender men & n=7 cisgender women, n=18 French-born, n=16 residing in the provinces, n=14 single, n=15 without children, n=15 employed
- Median time elapsed since HIV diagnosis: 13 years (range: 2–34)
- Median LAIT duration: 7 months (range: 2–24), 17 were continuing LAIT

PILL-BURDEN RELIEF

Psychological

"It's a big 'phew', it's a relief"
– 50-year-old female

"My mind calmed down a little"
– 45-year-old male

Organisational

"You now leave [home] without pills"
– 55-year-old female

"It liberates, it allows more spontaneity"
– 50-year-old male

From side-effects

"I don't have a stomach ache. I sleep really well too"
– 60-year-old female

"The plus was to have no more acidity problems"
– 35-year-old male

HIV-RELATED PERCEIVED IMPROVEMENTS

Better immunity

"I have the impression that my CD4 count is increasing more quickly"
– 60-year-old male

"[I feel] less sick than before"
– 50-year-old female

Less stigma exposition

"You no longer have to hide"
– 70-year-old female

"You can't see it and it can't be seen. There is no trace"
– 55-year-old male

COMMORBIDITIES-RELATED PERCEIVED IMPROVEMENTS

Opportunity to diagnose

"He had very sore legs [...] after the injections [...] he did extensive examinations and he has a degenerative disease"
– 70-year-old female

Opportunity to manage

"It helped me to recover from depression"
– 25-year-old female

LAIT, long-acting injectable treatment

Roucoux G, et al. EACS 2023. Poster eP.C3.029

Perceived benefits of long-acting injectable antiretroviral treatment go beyond pill-burden relief: A qualitative study (2 of 2)

Take-home messages

- LAIT perceived benefits go beyond pill-burden relief
- LAIT improved other dimensions of the participants QoL, such as stigma, and offered the opportunity to improve other clinical outcomes

Implication

- LAIT has benefits beyond the administration mode

BEYOND:
Perspectives of People Living With HIV 6 Months Following Switch to CAB + RPV LA in an Observational Real-world US Study

- **Study design:** Prospective, 2-year, observational, real-world study of utilization, outcomes, and experiences of people living with HIV initiating CAB + RPV LA across 27 US sites
- 308 participants ≥18 years of age were enrolled and completed baseline surveys about reasons for initiating CAB + RPV LA, challenges with daily oral ART, ART preference, and perceived benefits of more frequent clinic visits
- The most common HCP-reported relevant social determinants of health were comorbidities (23% [70/308]), adherence issues (19% [58/308]), and mental health issues (15% [47/308])
- At the time of data cut-off, 217 of 308 (70%) participants had reached Month 6 follow-up and completed surveys

Baseline Characteristics and Demographics of Participants Initiating CAB + RPV LA

Characteristic	Total participants (N=308)
Age, n (%)	
Median (range), years	45 (18, 80)
18 to <26	13 (4)
26 to <50	174 (57)
≥50	121 (39)
Gender identity, n (%)	
Male	256 (83)
Female	40 (13)
Transgender woman	5 (2)
Transgender man	1 (<1)
Non-binary	6 (2)
Race, n (%)[a]	
White or Caucasian	147 (48)
Black or African American	119 (39)
Native American, American Indian, or Alaska Native	19 (6)
Other race[b]	40 (13)
Prefer not to answer	14 (5)
Ethnicity, n (%)	
Hispanic/Latinx	68 (22)
Non-Hispanic/Latinx	220 (71)
Prefer not to answer	20 (7)
Time since initiation of first ART[c]	
Median (range), years	9.9 (0.1, 35.7)

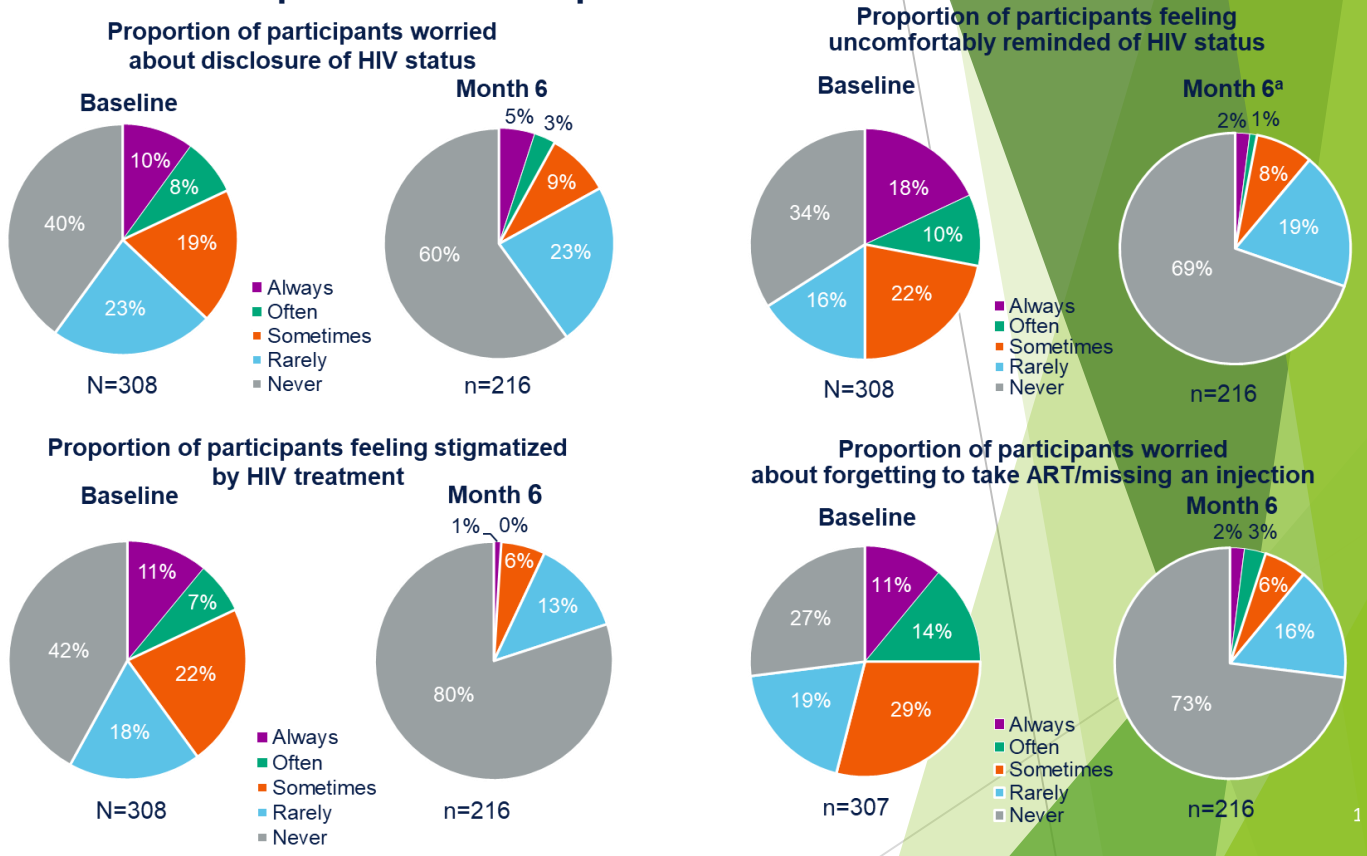
ART, antiretroviral therapy; CAB, cabotegravir; HCP, healthcare provider; LA, long-acting; RPV, rilpivirine.
[a]Not mutually exclusive. [b]Asian (n=8), Native Hawaiian or Other Pacific Islander (n=3), and race(s) not listed (n=29). [c]n=302, missing data for 6 participants.

Dandachi et al. IDWeek 2023; Boston, MA. Poster 1567.

BEYOND:
Perspectives of People Living With HIV 6 Months Following Switch to CAB + RPV LA in an Observational Real-world US Study

- The proportion of participants receiving CAB + RPV LA reporting fear of HIV status disclosure, anxiety around adherence to treatment, feeling reminded about HIV, and feeling stigmatized by HIV treatment decreased from baseline to Month 6
- Treatment satisfaction, as measured by HIVTSQ scores, improved from baseline to Month 6
- At Month 6, 95% (207/217) of participants who initiated CAB + RPV LA strongly preferred CAB + RPV LA over oral therapy, and participants reported multiple benefits with more frequent clinic visits

Proportion of Participants at Baseline and Month 6



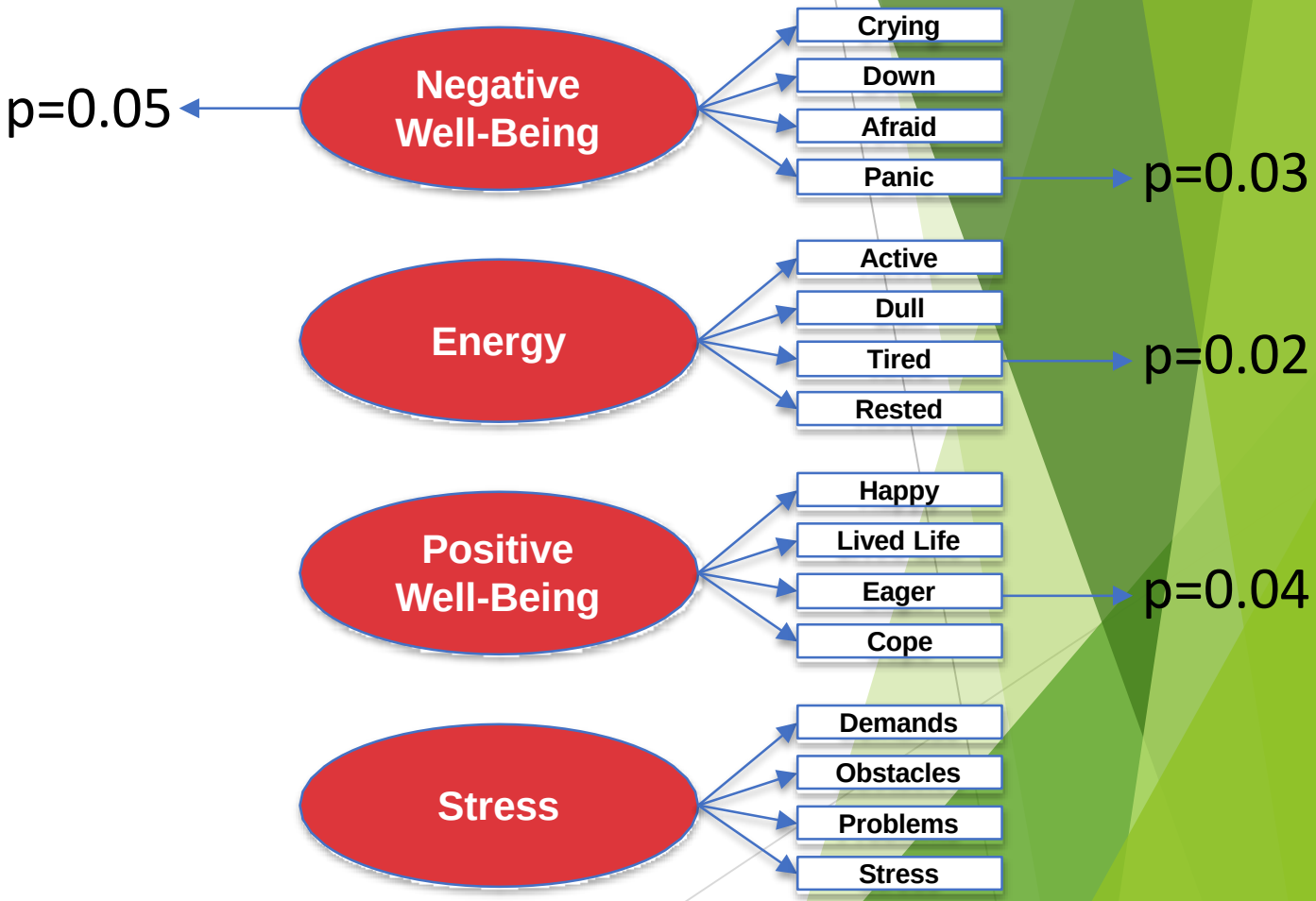
CAB, cabotegravir; HIVTSQ, HIV Treatment Satisfaction Questionnaire; LA, long-acting; RPV, rilpivirine.
[a]After rounding to whole numbers, Month 6 proportions add to 99%.

95% of participants who initiated CAB + RPV LA strongly preferred it over oral therapy and felt more engaged in their HIV care

Dandachi et al. IDWeek 2023; Boston, MA. Poster 1567.

SCohoLART:
Well-being in people with HIV after one year of long-acting CAB+RPV

- **Study design:** SCohoLART is a single-center, prospective, cohort study of PWH on virological suppression who switched to long- acting CAB/RPV.
- The 16-item Generic Well-Being (W-B) Questionnaire (W-BQ16) was administered at CAB/RPV start (baseline, BL; Q1) and after one year of treatment (Q2).
- The General Well-Being score was calculated by adding the Energy and Positive Well-Being subscale scores and the inverse of the Negative Well-Being and Stress subscale scores. People answered on a 4-point scale (ranging 0,1,2,3).
- 391 participants completed at least the baseline questionnaire and 234 at both timepoints.
- At baseline, 357 (91.3%) male, median age years 48.8 (40.1-56.1) and 43 (11%) discontinued CAB+RPV during FU
- No significant differences were observed in the General W-B score between BL and one year after the switch to CAB/RPV.
- The subscale Negative W-B (frequent crying, feeling down, anxious and/or upset) improved throughout the study.



Alberton et al. ICAR 2024 Oral OC 37.

Key Domains to Measure

- Treatment satisfaction
- Health-related quality of life (HRQoL)
- Injection site reactions
- Emotional well-being
- Stigma and social functioning

CLINICAL SCIENCE

Sleep disturbances and their correlation with cardiovascular risk, obesity, and mood disorders in people with HIV

Mazzitelli, Maria[a,*]; Trunfio, Mattia[b,c,*]; Milinkovic, Ana[d,e]; Castelli, Eleonora[a]; Sasset, Lolita[a]; Leoni, Davide[a]; Salvucci, Margherita[e]; Cazzaro, Riccardo[e]; Calcinoni, Ilaria[e]; Balducci, Pietro[e]; Ribeiro, Gustavo Coelho Quirino[e]; Filagrana, Giacomo[f]; Scaglione, Vincenzo[a]; Cattelan, Anna M.[a,g,h]

Author Information

AIDS 37(6):p 925-934, May 1, 2023. | ***DOI:*** 10.1097/QAD.0000000000003493

Characteristics	Overall ($n = 46$)
Age, median (IQR)	46 (41–57)
Gender, male, n (%)	35 (76.1)
Ethnicity, n (%)	
Caucasian	36 (78.3)
Latin	5 (10.8)
Asian	3 (6.5)
Black-African	2 (4.4)
Level of education, n (%)	
Low	35 (76.1)
High	9 (23.9)
Smoking status, n (%)	
Never	32 (69.6)
Current smoker	12 (26)
Ex-smoker	2 (4.4)
Regular physical exercise, n (%)	17 (36.9)
Alcohol consumption, n (%)	3 (6.3)
Risk factor for HIV acquisition, n (%)	
MSM	26 (56.5)
Heterosexuals	16 (34.7)
IVDU	10 (8.8)
Years living with HIV, median (IQR)	10 (5–19)
Previous AIDS events, n (%)	5 (10.8)
CD4+ at nadir, cell/mm^3, median (IQR)	360 (205–500)
CD4+ before switch, cell mm^3, median (IQR)	724 (524–894)
Antiretroviral regimen before switch, n (%)	
TAF/FTC/RPV	18 (39.1)
DTG/3TC	15 (32.6)
ABC/3TC + NVP	3 (6.5)
TAF/FTC/BIC	2 (4.4)
DTG/RPV	2 (4.4)
TDF/3TC/DOR	1 (2.16)
ABC/3TC + EFV	1 (2.16)
TAF/FTC + RAL	1 (2.16)
DOR + DTG	1 (2.16)
DTG + ATV/r	1 (2.16)
TDF/FTC/RPV	1 (2.16)
Hepatitis coinfections, n (%)	
HBV	0 (0)
HCV (eradicated)	3 (6.5)
Comorbidities, n (%)	
Malignancies	2 (4.4)
Dyslipidemia	14 (30.4)
Lipodystrophy	4 (8.8)
Hypertension	9 (19.5)
Obesity	4 (8.8)
Diabetes	1 (2.1)
Osteoporosis	5 (10.8)
COPD	2 (4.4)
Anxiety/depression	7 (15.2)
Autoimmune disorders	3 (6.5)
Neurological diseases	2 (4.4)
Other comorbidities	18 (39.1)
Multimorbidity, n (%)	23 (50)
Polypharmacy, n (%)	6 (13)

HIV RESEARCH & CLINICAL PRACTICE
2024, VOL. 25, NO. 1, 2351258
https://doi.org/10.1080/25787489.2024.2351258

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BRIEF REPORT

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Impact of switching to injectables cabotegravir and rilpivirine on sleep disturbances in a cohort of people living with HIV

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Item/parameter	Baseline, ($n = 46$)	Follow-up ($n = 46$)	P value
Sleep disorders*			
Overall, n (%)			
None	29 (63)	26 (56.5)	0.512
2 or more positive categories in BQ, n (%)	9 (19.5)	7 (15.2)	0.748
ISI >15, n (%)	6 (13)	4 (8.7)	0.739
ESS > 10, n (%)	7 (15.2)	2 (4.4)	0.157
PSQI> 5, n (%)	6 (13)	20 (43.5)	0.002
Parasomnia, n (%)	1 (2.2)	1 (2.2)	1
*Each patient may have more than one			
Scoring for each questionnaire, median (IQR)			
BQ score, median (IQR)	1 (0–2)	1 (1–2)	0.41
ISI score, median (IQR)	5 (3–7)	6 (3–7)	0.26
ESS score, median (IQR)	7 (5–8)	6 (5–8)	0.23
PSQI score, median (IQR)	4 (3–5)	7 (5–7)	0.001
Self-reported insomnia severity			
None, n (%)	21 (45.6)	24 (52.2)	0.676
Mild, n (%)	12 (26.1)	17 (36.9)	0.369
Moderate, n (%)	8 (17.4)	3 (6.5)	0.197
Severe/extremely severe, n (%)	5 (10.9)	2 (4.4)	0.434
Self-reported snoring, n (%)	19 (41.3)	18 (39.1)	1
Sleeping hours per night, hours, median (IQR)	7 (6–8)	7.0 (7–8)	0.214
Time to fall asleep > 30 min, n (%)	12 (26)	10 (8.8)	0.807
Early awakening, n (%)	18 (39.1)	12 (26)	0.260
Issues in sleep maintenance, n (%)	21 (45.6)	11 (23.9)	0.048
Issues in falling asleep, n (%)	19 (41.3)	12 (26)	0.185
Afternoon nap (yes), n (%)	34 (73.9)	28 (60.9)	0.266
Overall use of hypno-inducing drugs, n (%)	4 (8.7)	6 (13)	0.739
Self-reported wellness (0–10), median (IQR)	8 (7–9)	8 (7–9)	0.388
How would you rate the overall quality of your sleep?			
Improved	–	17 (37)	–
Unchanged	–	29 (63)	–
Worsened	–	0 (0)	–

Some Available PRO Tools

- HIV Treatment Satisfaction Questionnaire (HIVTSQ)
- EQ-5D (Generic Quality of Life)
- SF-36 (Short Form Health Survey)
- PROQOL-HIV (Quality of Life in HIV)
- Visual Analog Scales (for pain and discomfort)

HIV Treatment Satisfaction Questionnaire (HIVTSQ)

- Specifically developed for antiretroviral therapy.
- Measures satisfaction with convenience, efficacy, and tolerability.
- Validated in both oral and injectable regimens.

HIV Treatment Satisfaction Questionnaire: HIVTSQ (1 of 2)

- Versions include HIVTSQs ('status') and HIVTSQc ('change')[1,2]
- Measures overall satisfaction with HIV ART by assessing concepts, such as:[2,3]
  - Ease or difficulty of treatment
  - Demands of treatment
  - Convenience
  - Flexibility
  - Willingness to continue treatment
  - Treatment recommendation
  - Side effects
  - Treatment fit within patient's lifestyle

- The concept of satisfaction is a central precursor of patients' adherence to their treatment[4]
- Patient satisfaction with care affects both adherence to ART ($p<0.0001$) and retention in HIV care ($p<0.0001$), which impacts the overall HIV care cascade (95-95-95)[5,6]
- The original scale consisted of 10 items;[2,3] in 2016, an additional two items were added (validated in the LATTE-2 study)[7] to account for LA treatment dosing in the ATLAS and FLAIR studies[8]

1. Health Psychology Research. HIV-TSQ Summary 2015. Available at: https://www.healthpsychologyresearch.com/guidelines/hivtsq-hiv-treatment-satisfaction-questionnaire. Accessed May 2023; **2.** Woodcock A and Bradley C. Value Health 2006;9:320–33
3. Woodcock A and Bradley C. Qual Life Res 2001;10:517–31; **4.**Barbosa CD, et al. Patient Prefer Adherence 2012;6:39–48
5. Dang BN, et al. PLoS One;2013;8;e54729; **6.** UNAIDS. Fast-track - ending the AIDS epidemic by 2030. Available at: https://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf. Accessed May 2023
7. Romaine J, et al. Value Health 2016;19:A420; **8.** Murray M, et al. AIDS Behav 2020;24:3533–44

HIV Treatment Satisfaction Questionnaire: HIVTSQ (2 of 2)

Item number	Item label	Item wording	HIVTSQs response options, 0-6
1	Current treatment	How satisfied are you with your current treatment?	Very dissatisfied 0 to very satisfied 6
2	Control	How well controlled do you feel your HIV has been recently?	Very poorly controlled 0 to very well controlled 6
3	Side effects	How satisfied are you with any side effects of your present treatment?	Very dissatisfied 0 to very satisfied 6
4	Demands	How satisfied are you with the demands made by your current treatment?	Very dissatisfied 0 to very satisfied 6
5	Convenience	How convenient have you been finding your treatment to be recently?	Very inconvenient 0 to very convenient 6
6	Flexibility	How flexible have you been finding your treatment to be recently?	Very inflexible 0 to very flexible 6
7	Understanding	How satisfied are you with your understanding of your HIV?	Very dissatisfied 0 to very satisfied 6
8	Lifestyle	How satisfied are you with the extent to which the treatment fits in with your lifestyle?	Very dissatisfied 0 to very satisfied 6
9	Recommend to others	Would you recommend your present treatment to someone else with HIV?	No, I would definitely not recommend the treatment 0 to Yes, I would definitely recommend the treatment 6
10	Continue	How satisfied would you be to continue with your present form of treatment?	Very dissatisfied 0 to very satisfied 6
11	Easy/difficult	How easy or difficult have you been finding your treatment to be recently?	Very difficult 0 to very easy 6
12	Pain/discomfort	How satisfied are you with the amount of discomfort or pain involved with your present form of treatment?	Very dissatisfied 0 to very satisfied 6

Items in 10-item HIVTSQ (total score range: 0–60)[1]

Items in 12-item HIVTSQ (total score range from items 1–11: 0–66; item 12 treated as a standalone item)[1–3]

1. Woodcock A and Bradley C. Value Health 2006;9:320-33
2. Murray M, et al. AIDS Behav 2020;24:3533-44
3. Romaine J, et al. Value Health 2016;19:A420

Generic QoL Instruments (EQ-5D, SF-36)

- Broadly assess physical, emotional, and social health.
- Useful for comparisons across conditions and populations.
- May lack sensitivity to HIV-specific issues.

European Quality of Life 5-Dimension 5-Level: EQ-5D-5L (1 of 2)

- EQ-5D descriptive system is a standardised global health state questionnaire that assesses five dimensions:[1,2]

Mobility | Self-care | Usual activities | Pain/discomfort | Anxiety/depression

  - The 5L version has five levels of severity to select from for each dimension: no problems, slight problems, moderate problems, severe problems, extreme problems[1,2]
  - Answers selected for each dimension generate one of 3,125 different health state profiles[1,2,3]
  - Results are translated into a utility score with a range of <0 (worse than dead) to 1 (full health) and can be compared with the general population (bottom end of range differs between countries/regions, as scores are assigned based on societal preference weights for the health state, which often represent national or regional values)[3,4]

- EQ-VAS allows the patient to self-rate health on a vertical scale from 'the worst' to 'the best' health that they can imagine[1,2]
  - Corresponds to endpoints on a scale of 0 to 100[1,2]

EQ-VAS, European Quality of Life visual analogue scale

1. Herdman M, et al. Qual Life Res 2011;20:1727-36; **2.** EQ-5D. Available at: https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/. Accessed May 2023
3. EuroQol Research Foundation. EQ-5D-5L User Guide v3.0, 2019. Available at: https://euroqol.org/publications/user-guides. Accessed July 2023
4. Obradovic M, et al. Health and Quality of Life Outcomes 2013;11:110

European Quality of Life 5-Dimension 5-Level: EQ-5D-5L (2 of 2)

EQ-5D-5L

Under each heading, please tick the ONE box that best described your health TODAY

MOBILITY
- ❑ I have no problems in walking about
- ❑ I have slight problems in walking about
- ❑ I have moderate problems in walking about
- ❑ I have severe problems in walking about
- ❑ I am unable to walk about

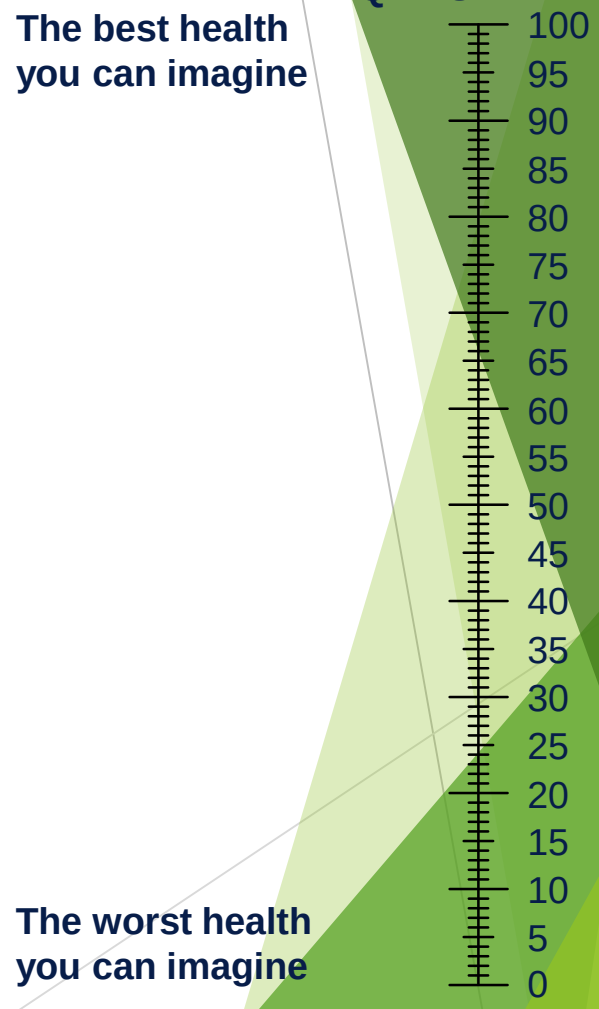
SELF-CARE
- ❑ I have no problems washing or dressing myself
- ❑ I have slight problems washing or dressing myself
- ❑ I have moderate problems washing or dressing myself
- ❑ I have severe problems washing or dressing myself
- ❑ I am unable to wash or dress myself

USUAL ACTIVITIES*
- ❑ I have no problems doing my usual activities
- ❑ I have slight problems doing my usual activities
- ❑ I have moderate problems doing my usual activities
- ❑ I have severe problems doing my usual activities
- ❑ I am unable to do my usual activities

PAIN / DISCOMFORT
- ❑ I have no pain or discomfort
- ❑ I have slight pain or discomfort
- ❑ I have moderate pain or discomfort
- ❑ I have severe pain or discomfort
- ❑ I have extreme pain or discomfort

ANXIETY / DEPRESSION
- ❑ I am not anxious or depressed
- ❑ I am slightly anxious or depressed
- ❑ I am moderately anxious or depressed
- ❑ I am severely anxious or depressed
- ❑ I am extremely anxious or depressed

EQ-VAS



*E.g. work, study, housework, family or leisure activities

EuroQol Research Foundation. EQ-5D-5L User Guide v3.0, 2019. Available at: https://euroqol.org/publications/user-guides. Accessed July 2023

PROQOL-HIV

- HIV-specific instrument.
- Addresses stigma, body image, sexual function.
- Suitable for detailed quality-of-life profiling.

HIV Symptom Index SDM[1]

- SDM: 0–80 bother score
- Likert five-point scale for each item: 0–4; the lower the score, the less bothersome the symptoms

Characteristics

Concept of interest
Signs and symptoms

Number of items
20

Population for intended use
Adult

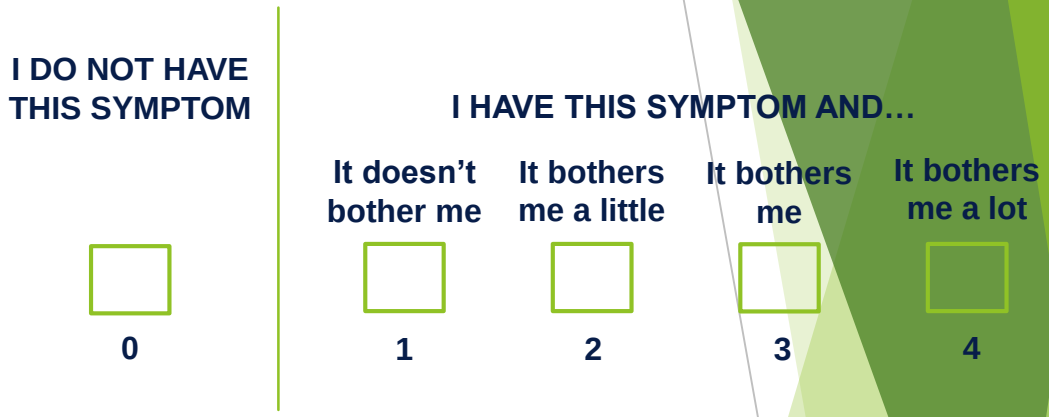
Population age range
≥18 years

Administration mode
Self-administered

Data collection mode
E-version[2]
Paper and pen

Recall/observation period
The past four weeks

Time for completion
5 minutes



1. Justice AC, et al. J Clin Epidemiol 2001;54:S77-90

Perception of injection: PIN

- Explores the acceptance of pain and ISRs following injections[1]
  - Adapted from the Vaccines Perception of Injection Questionnaire by Sanofi Pasteur, initially used for evaluating influenza vaccinations[2]
- Contains 21 items:[1,2]
  - Four dimensions:
    - Bother of ISRs (6 items)
    - Sleep (4 items)
    - Leg movement (4 items)
    - **Acceptability of ISRs** (2 items: acceptance of local reactions and acceptance of pain)
  - Five individual items:
    - Pain during injection
    - Anxiety before injection
    - Anxiety after injection
    - Willingness for future injection
    - Overall satisfaction with injection system over time
- Scores range from 1 (most positive) to 5 (least positive)[2]

Significance testing pre-planned only for this dimension to avoid multiplicity

1. Chounta V, et al. Patient 2021;14:849–62
2. Chevat C, et al. Health Qual Life Outcomes 2009;7:21

Chronic treatment acceptance: ACCEPT®

- ACCEPT® is a 32-item, self-administered questionnaire, validated to measure patient acceptance of treatment[1]
  - Acceptance is defined as the balance between treatment advantages and disadvantages as rated by the patient, and may help predict adherence[1]
  - In the ATLAS and FLAIR studies, only the three items that cover the General Acceptance score were used[2]

ACCEPT® items used in ATLAS and FLAIR:[2]

1. Do you agree with the following statement: "My medication has more advantages than disadvantages"?

Totally disagree	Somewhat disagree	Somewhat agree	Totally agree	I don't know
☐1	☐2	☐3	☐4	☐5

2. Given the advantages and disadvantages of your medication, do you consider it to be an acceptable solution?

Not at all acceptable	Not very acceptable	Somewhat acceptable	Totally acceptable	I don't know
☐1	☐2	☐3	☐4	☐5

3. Are you convinced that in the long term, it is worth taking your medication?

Not at all convinced	Not really convinced	Fairly convinced	Totally convinced	I don't know
☐1	☐2	☐3	☐4	☐5

1. Marant C, et al. Patient 2012;5:239-49
2. Murray M, et al. AIDS Behav 2020;24:3533-44

Practical Implementation

- Select 1-2 instruments to minimize patient burden.
- Integrate PRO assessments into routine visits.
- Use electronic formats where possible.
- Interpret results to guide shared decision-making.

Challenges

- Time constraints in busy clinics.
- Literacy and language barriers.
- Ensuring confidentiality.
- Need for clinician training in PRO interpretation.

Conclusions

- PROs are essential to fully understand patient experience with long-acting cabotegravir and rilpivirine.
- Several validated tools are available; HIVTSQ and PROQOL-HIV are particularly suitable.
- Systematic implementation can improve patient outcomes and satisfaction.


Danke
Gracias
Merci
Thanks!
Grazie
THANK
YOU!