PURPOSE

Prevention with PURPOSE

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Experiences With Twice-Yearly Lenacapavir for PrEP in the PURPOSE 1 Open-Label Extension Phase

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Acknowledgments and Presenter Disclosures

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Disclosures

- Thandeka Nkosi has no relevant financial relationships to disclose
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PI, principal investigator.

Summary

What is your main question?

- What were the experiences of using SC LEN during daily life among adolescent girls and young women in the PURPOSE 1 open-label extension phase?

What did you find?

- Twice-yearly LEN injections were the preferred PrEP option versus daily oral PrEP due to SC LEN's demonstrated high efficacy, convenience, and alignment with the active lifestyles of adolescent girls and young women

Why is it important?

- The attitudes and experiences described by participants during this study may be informative for future LEN implementation efforts

LEN, lenacapavir; PrEP, pre-exposure prophylaxis; SC subcutaneous.

Approximately 95% of PURPOSE 1 Participants Chose to Continue or Switch to LEN in the Open-Label Extension (OLE) Phase[1]

After PURPOSE 1 demonstrated robust efficacy of twice-yearly SC LEN in preventing HIV-1 infection among adolescent girls and young women,[2] they could choose to continue or switch to LEN in the OLE

In-depth interviews conducted during the randomized blinded phase of PURPOSE 1 showed that most participants preferred the convenience and lifestyle fit of twice-yearly SC LEN versus daily oral PrEP[3]

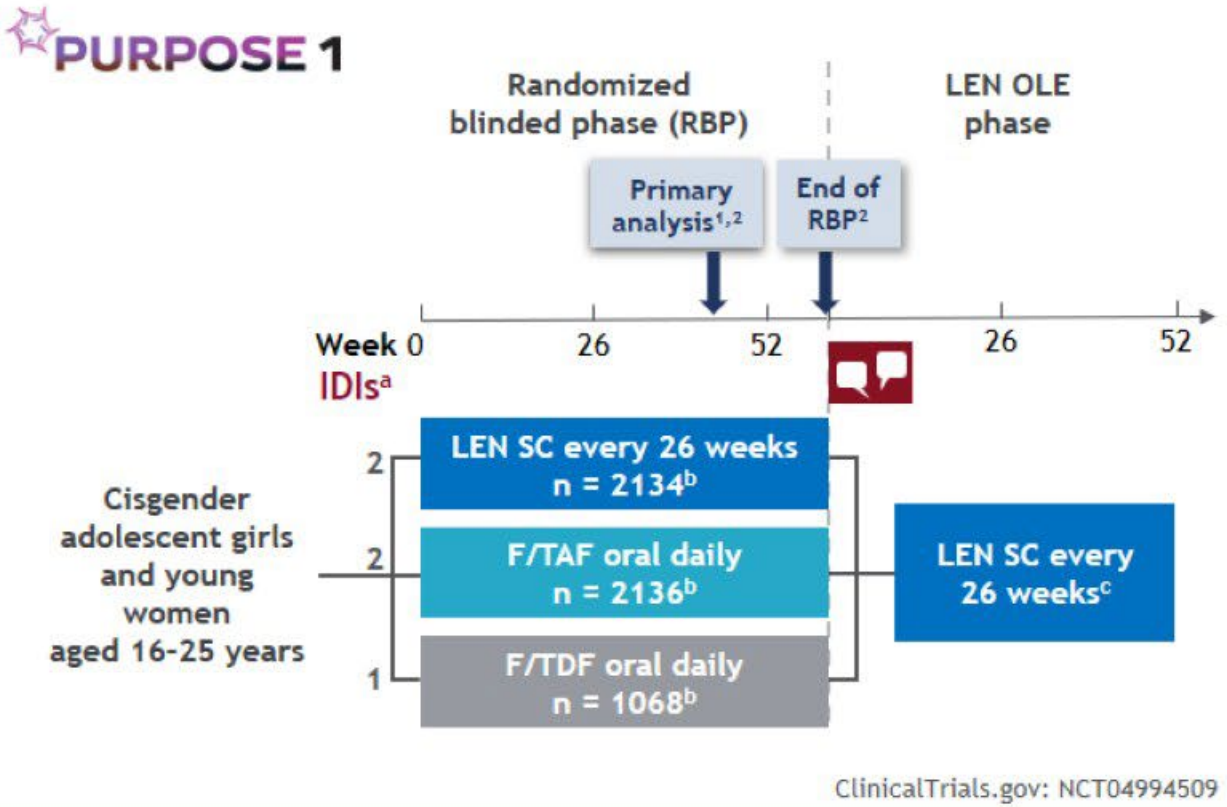
Building on the randomized blinded phase findings, this study is the first to explore participant-reported reasons behind their choice for LEN during the OLE

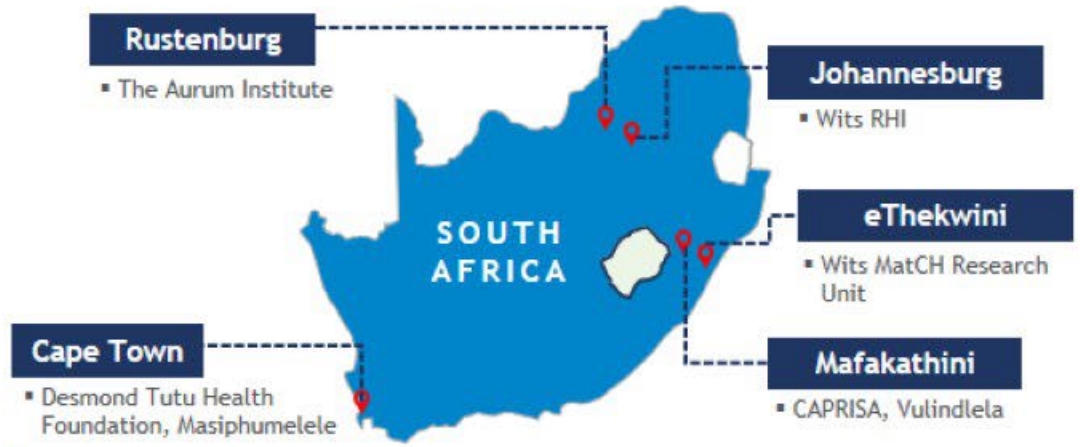
In this analysis, we captured the participant voice on the reasons underlying their PrEP administration choice, attitudes, and experiences during the PURPOSE 1 OLE phase

LEN, lenacapavir; OLE, open-label extension; PrEP, pre-exposure prophylaxis; SC, subcutaneous.

1. Aidsmap. https://www.aidsmap.com/news/jul-2025/lenacapavir-prep-special-cases-young-people-missed-doses-and-drug-interactions (accessed July 2, 2026); 2. Bekker LG, et al. *N Engl J Med.* 2024;391:1179-92;
3. Montgomery ET, et al. Poster 1234 presented at: CROI; March 9-12, 2025; San Francisco, CA, USA.

Qualitative Sub-Study in OLE Participants





Sample In-Depth Interview (IDI) Topics

- Personal life and context
- Developmental changes in adolescent participants' lives over the past 6 months
- PURPOSE 1 RBP results, transition to the OLE phase, and decision to join the OLE phase
- Comprehension of randomized assignment in the RBP
- Disclosure of PrEP use to others
- Attitudes to study PrEP and PrEP use experiences
- Peer and community views of injectable PrEP
- Overall satisfaction with study PrEP
- Willingness to use PrEP in the future

IDIs[a] were conducted at OLE Day 1 (n = 35) or by OLE Month 3 (n = 50)[d] with randomly[e] or purposively[f] selected participants from five South African PURPOSE 1 study sites

[a]IDIs were conducted after participant unblinding at the start of the OLE phase or within ~1-3 months of OLE initiation. Interviews were translated, transcribed, coded, and analyzed thematically. [b]Efficacy population.[1] [c]Participants who declined open-label LEN were offered up to 78 weeks of open-label F/TDF if they were on blinded LEN in the RBP. [d]One participant was interviewed twice (once while pregnant and again while breastfeeding), hence the total number of participants interviewed was 84. [e]Aged 18-25 years. [f]If they were aged 16-17 years, acquired HIV, became pregnant, started breastfeeding, or prematurely discontinued the study or study drug. F/TAF, emtricitabine/tenofovir alafenamide; F/TDF, emtricitabine/tenofovir disoproxil fumarate; IDI, in-depth interview; LEN, lenacapavir; OLE, open-label extension; PrEP, pre-exposure prophylaxis; RBP, randomized blinded phase; SC, subcutaneous. 1. Bekker LG, et al. *N Engl J Med*. 2024;391:1179-92, 2. Montgomery ET, et al. Poster 1234 presented at: CROI; March 9-12, 2025; San Francisco, CA, USA.

Participants in this Sample Were Representative of the Broader PURPOSE 1 South Africa Cohort

	Participants who were interviewed at five South African sites (n = 84)	Participants at the five South African sites who were not interviewed (n = 855)	PURPOSE 1 participants in South Africa who were not interviewed (n = 3569)
Age, years, median (range)	20 (16-25)	21 (16-26)	21 (16-25)
Highest education level, n (%)			
Did not attend primary school	0 (0)	0 (0)	6 (0.2)
Primary school	3 (3.6)[a]	21 (2.5)[a]	73 (2.0)[a]
Secondary school	73 (86.9)[a]	736 (86.1)[a]	3103 (86.9)[a]
Some college or university degree	8 (9.5)	98 (11.5)	381 (10.7)
Never married, n (%)	83 (98.8)	854 (99.9)	3557 (99.8)
Living with husband/partner, n (%)	1 (1.2)	45 (5.3)	202 (5.7)
Any STI, n (%)[b]	25 (29.8)	303 (35.4)	1192 (33.4)
Any previous PrEP use, n (%)	11 (13.1)	106 (12.4)	202 (5.7)

Participants were young, mostly secondary-school educated, nearly all never married, and had high rates of STIs at baseline

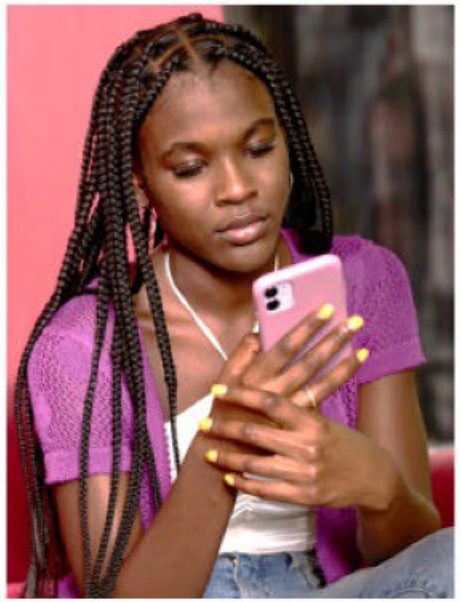
[a]Sum of "some primary (or secondary) school education" and "primary (or secondary) school complete" responses.
[b]Laboratory results based on central laboratory or local laboratories for gonorrhea, chlamydia, and trichomonas vaginalis, and local laboratories only for syphilis.
STI, sexually transmitted infection.

Twice-Yearly LEN Was Highly Favored for Convenience and Lifestyle Fit

> *The injection fits into my lifestyle because … I forget [to take the PrEP pills] a lot … [so] I think that the injection is the best way*

> *… if you are busy [or moving around], you won't have [to] stress that you need to go back home, or you must keep the pills here… So, you become stress free because you know you got the injection for 6 months. So, you're sorted*

> *It is very easy for me…. I am happy and relieved because… injection is my priority, and it is good*



> *…most people at my age are partying… [and] will forget [to take the PrEP pill] anyway [so] it is better with the injection*

- Participants highlighted the long-acting protection and practicality of LEN, noting that it integrated smoothly into their routines
- Participants described LEN as dependable, discreet, and trustworthy
- The high efficacy of LEN strengthened participants' confidence in its use

LEN offered discreet, continuous protection and aligned with participants' active lifestyles

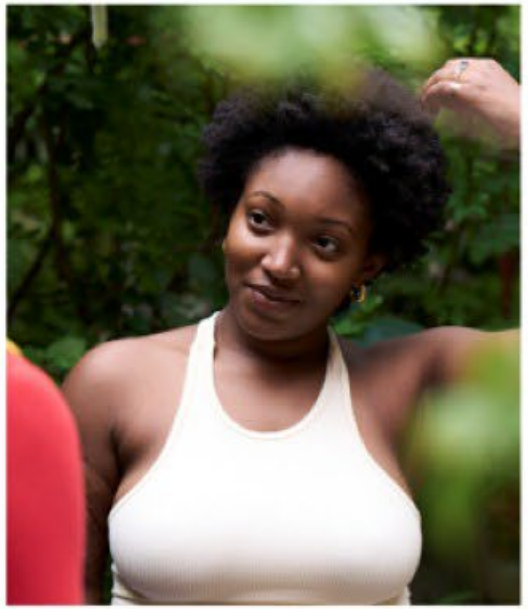
LEN, lenacapavir.

Protection Provided By Twice-Yearly LEN Injections Outweighed Concerns about Injections

> *I was in pain while I was receiving the injection but now it's better because they have introduced the ice pack*

> *At the beginning it was very painful, it was burning inside … now [getting the injection] is better, or we are used to it now. It is not the same as before*

> *[People] might be scared to get injected on the stomach. You can [avoid that] by injecting it on the bum or the [arm]*



> *The nurses always call us to check how we are doing … and [if] the side effects are affecting [us].*

- Injection-site reactions were **common but generally short-lived** and viewed as an **acceptable trade-off for long-acting protection**
- **Pain mitigation** measures like **ice packs** and **analgesics** helped to **alleviate** post-injection discomfort
- Some expressed a **preference for more familiar anatomic injection sites** (thigh, upper arm, or upper buttocks) offered during the OLE[1]
- **Clinic staff** provided **adherence support** such as follow-up calls and reassurance regarding side effects

Subsequent LEN injections were less painful and the use of pain-management measures improved the injection experience

LEN, lenacapavir; OLE, open-label extension; SC, subcutaneous. 1. Brites, C. Poster TUPEC184. Presented at: AIDS July 26-31, 2026; Rio de Janeiro, Brazil.

Participants Felt Empowered to Make Autonomous Decisions About Choosing LEN and Disclosing its Use

> *It was my decision to make alone, […] I told him […] I am now getting the PrEP injection from [site name] and he said "wow", and I said "yes"*

> *I didn't discuss with anyone, it was my choice because it is for my safety*

> *He [partner] doesn't have a problem. He supports me.*

> *Yes, I told my mom…She was fine as long I continue taking PrEP*

> *[Talking about partner's feelings regarding participant's decision to use LEN] Wow, I don't know, and I don't care. [laughs] I am doing it for myself*

Participants who chose LEN emphasized autonomy and personal choice

Participants received encouragement from partners and support from family members

Most participants made the choice to continue open-label LEN independently; others received and valued support from partners or family members

LEN, lenacapavir.

Participant Views on Future LEN Use Varied Based on Relationship Status and Life Circumstances

> *…when I am married, I will have less stress about getting HIV. At least it is a life partner. Maybe I might just [stop taking PrEP]*

> *Oh no, I would continue to take… the injection, because even when we are married, it's the same. … It doesn't mean that now that we will be married, my husband will only have eyes for me alone*

> *He [partner] … even asks me how the injection works, and I tell him. […] He says that if it can be available at the clinics he can take it too*

Participants shared varied attitudes about using LEN in the future, depending on their relationship status and life stage

Participants had differing attitudes toward LEN use after marriage due to differing perceptions of HIV risk during marriage

Interest in future LEN use varied by life stage, with most participants expecting consistent interest while dating

LEN, lenacapavir.

Conclusions

- In the context of known efficacy in the OLE phase of PURPOSE 1, twice-yearly SC LEN was widely appreciated for its **long-acting protection** and **convenience** compared with daily oral PrEP
- **Receiving protection** from twice-yearly LEN **outweighed concerns** about injections
- Participants who chose SC LEN described it as easy, long-acting, and practical, **fitting smoothly into daily life**

Twice-yearly SC LEN was the preferred PrEP option due to its demonstrated high efficacy, convenience, and alignment with the active lifestyles of adolescent girls and young women

LEN, lenacapavir; PrEP, pre-exposure prophylaxis; SC, subcutaneous.

A Growing PURPOSE Portfolio

#preventionwithpurpose ***#accesswithpurpose***

PURPOSE 1: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342; PURPOSE 5: NCT06513312; PURPOSE 365: NCT07047716.
LEN, lenacapavir; PrEP, pre-exposure prophylaxis.

PURPOSE studies. https://www.purposestudies.com (accessed July 24, 2026).

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