



2nd Long-Acting Treatment and Prevention Conference

29 October 2024 | Johannesburg



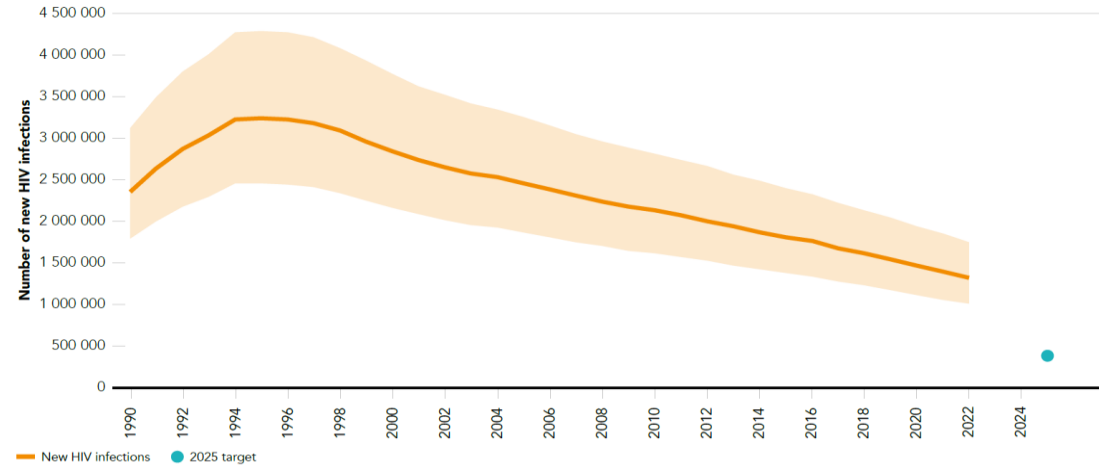
Differentiated antiretroviral based HIV prevention for rural youth: Long-acting PrEP integrated with sexual health (LAPIS)

Professor Maryam Shahmanesh (PhD, FRCP)
Director of Implementation Science Africa Health Research Institute

Problem statement

- 39.0 million people living with HIV
- 1.3 million new HIV infections

Figure 12.1 Number of new HIV infections, global, 1990–2022, and 2025 target



Source: UNAIDS epidemiological estimates, 2023 (<https://aidsinfo.unaids.org/>).



- Effective biomedical tools to prevent HIV transmission (ART) or acquisition (PrEP and PEP)
- Individual-level effectiveness has failed to translate into population effect

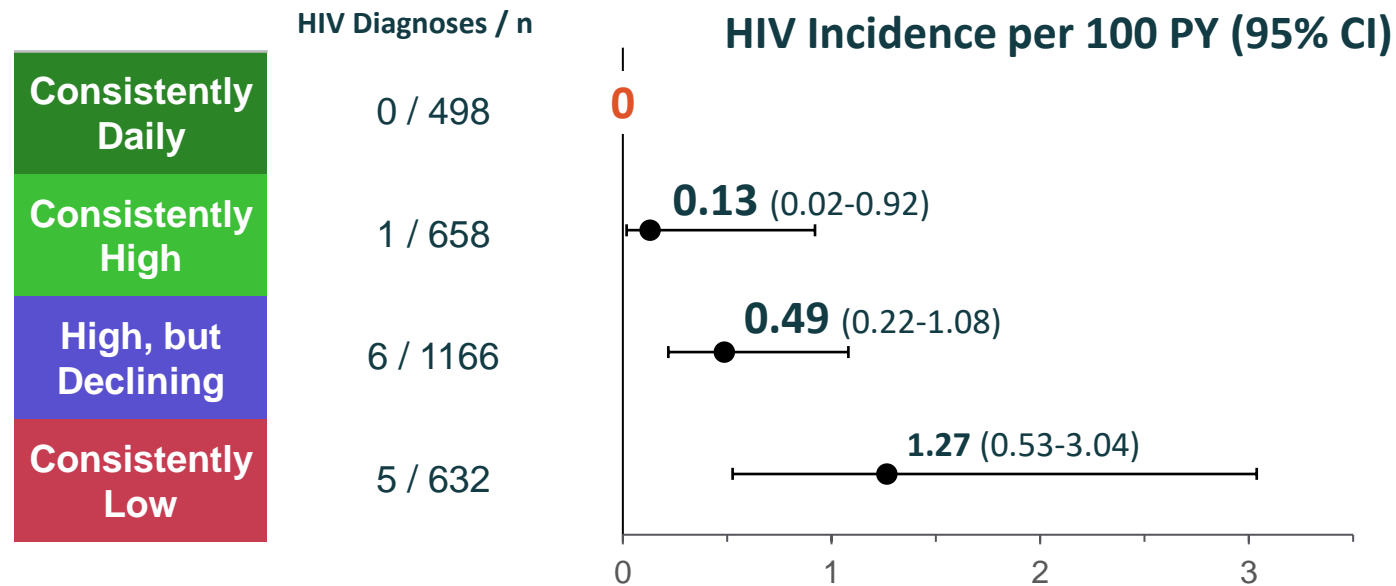
Challenge



- Offering PrEP to those who need PrEP
- Those who need PrEP take PrEP
- Those who take PrEP continue PrEP
- Those who continue PrEP adhere to PrEP

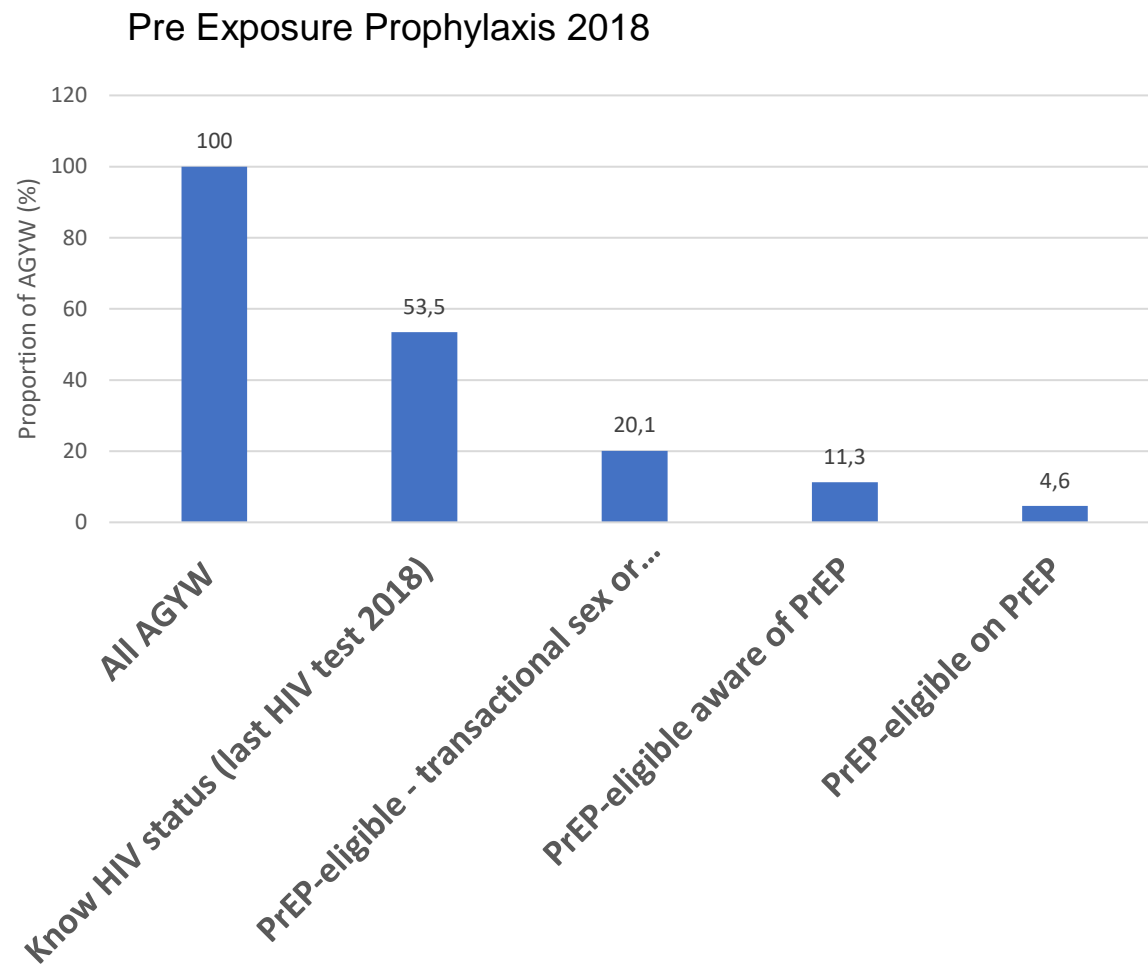
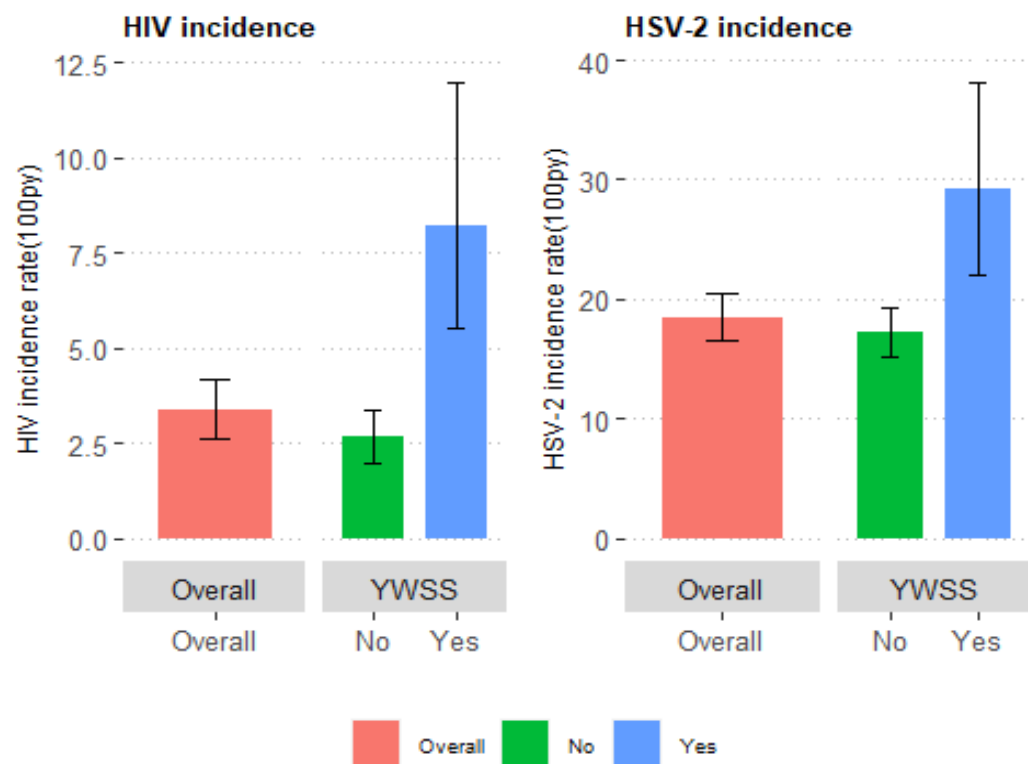


HIV Incidence Rates Among Women (2955)



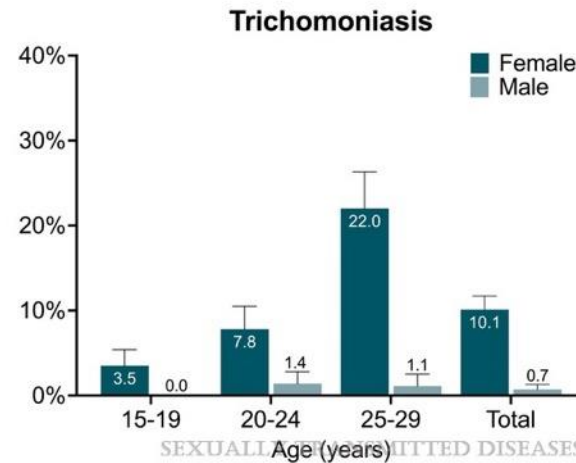
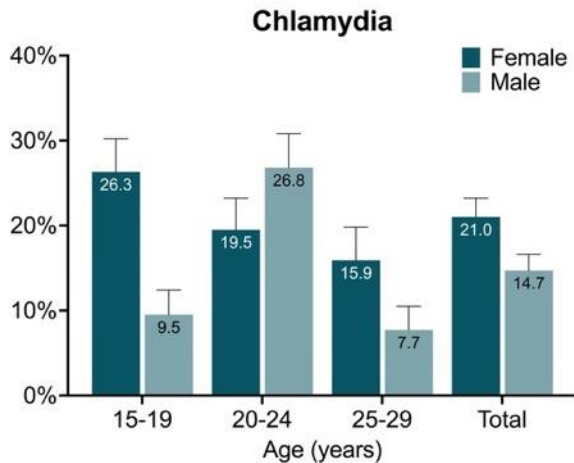
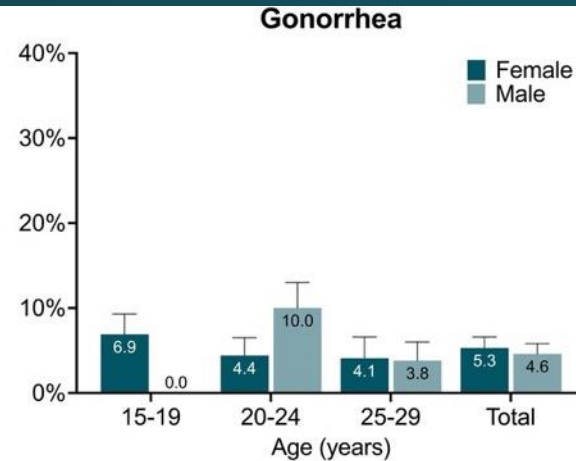
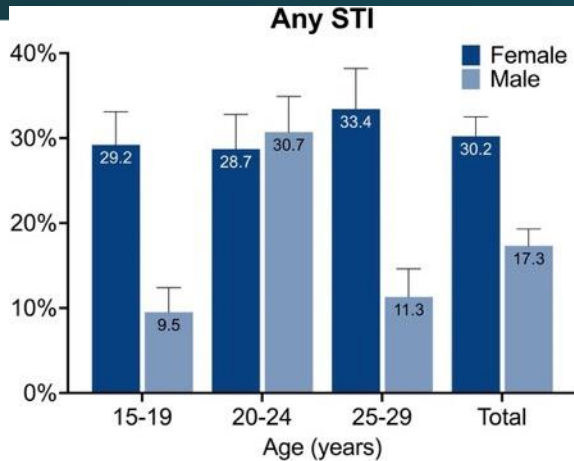
- 1 in 3 consistent or high adherence (~4-7 tablets a week)
- Higher patterns of adherence were directly associated with lower risk of HIV acquisition

Challenge reaching those at greatest risk



1. Mthiyane, et al AIDS 2022
2. Magu et al ICASA 2023
3. Chimbindi, et al AIDS Care 2021

Unmet sexual health need



Population-weighted prevalence estimates for any STI and each individual STI, by sex and age group (with 95% CI).

SEXUALLY TRANSMITTED DISEASES

Journal of the American Sexually Transmitted Diseases Association (ASTDA)
www.stdjournals.com

[Articles & Issues](#) ▾ [Collections](#) [Real World](#) [GC Surveillance](#) [For Authors](#) ▾ [Journal Info](#) ▾

ORIGINAL STUDIES

Prevalence of Curable Sexually Transmitted Infections in a Population-Representative Sample of Young Adults in a High HIV Incidence Area in South Africa

Jarolimova, Jana MD, MPH¹; Chidumwa, Glory PhD^{1,2}; Chimbindi, Natsayi PhD^{1,5,6,7}; Okesola, Nonhlanhla BSN¹; Dreyer, Jaco NDipIT¹; Smit, Theresa PhD¹; Seeley, Janet PhD^{1,11,12}; Harling, Guy ScD^{1,5,11,12}; Copas, Andrew PhD⁵; Baisley, Kathy MSc^{1,11}; Shahmanesh, Maryam PhD^{1,5,6,7}; the Isisekelo Research Group; Herbst, (Carina MSc¹; McGrath, Nuala ScD^{1,11,12}; Zuma, Thembelihle PhD^{1,5,6,7}; Khoza, Thandeka MBChB¹; Behuhuma, Ngundu MBChB¹; Bassett, Ingrid V. MD, MPH^{1,7}; Sherr, Lorraine PhD⁹

[Author Information](#) ☺

Sexually Transmitted Diseases 50(12):p 796-803, December 2023. | DOI: 10.1097/OLQ.0000000000001871 ©

OPEN

SDC

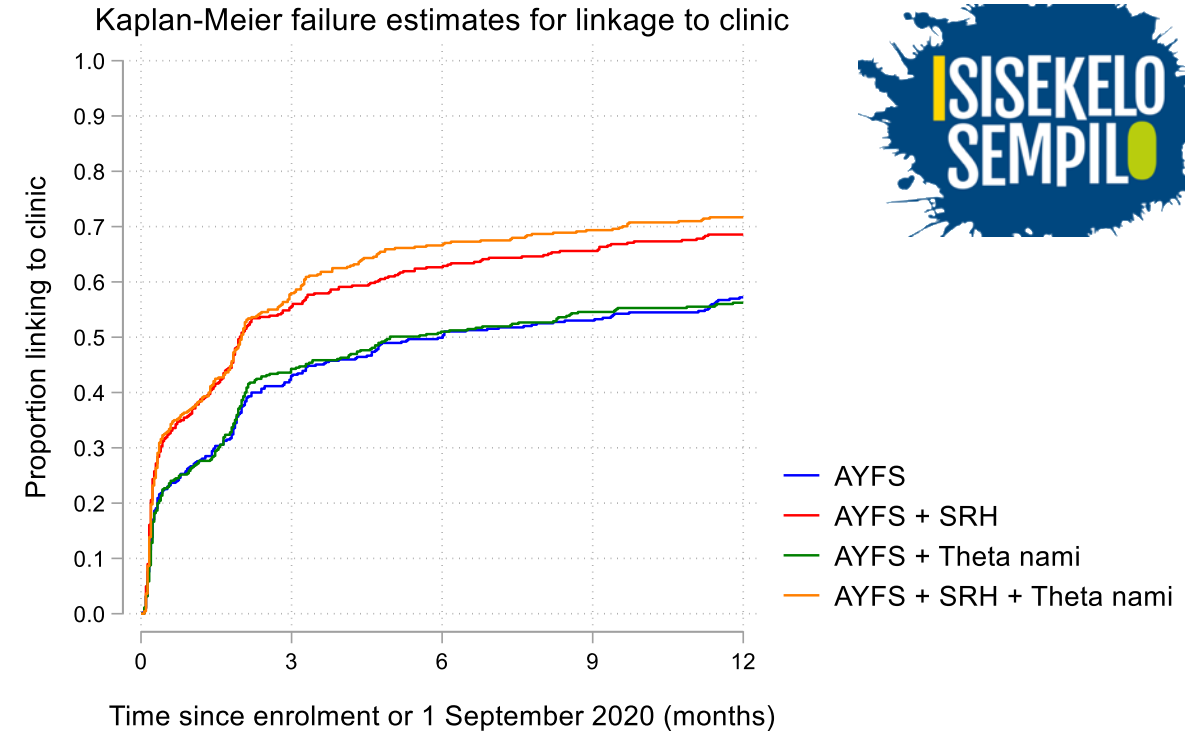
Metrics

Incidence of pregnancy aged 18-19 is 20%

Sexual health reaches those with need



- Community-based care effective and safe¹⁻³
- Home-based STI self-sampling and SRH had 60% higher odds of linking to HIV prevention⁴



Log rank p-value <0.0001.

1. *Shahmanesh, et al BMC Public Health 2021*
2. *Barnabas, et al Lancet Global Health 2020*
3. *Schaefer, et al Lancet HIV 2022*
4. *Shahmanesh et al Lancet HIV in press*

Thetha nami ngithethe nawe (let's talk)



Peer navigators



Mobile sexual health services



Peer Navigators



Nurse, social worker, admin
(Theta Nami review committee)

1) Mobilise youth in area:

- Harness social capital
 - Safe spaces
 - Youth groups

2) Tailored support:

- Needs assessment on mobile phones
 - Action plans

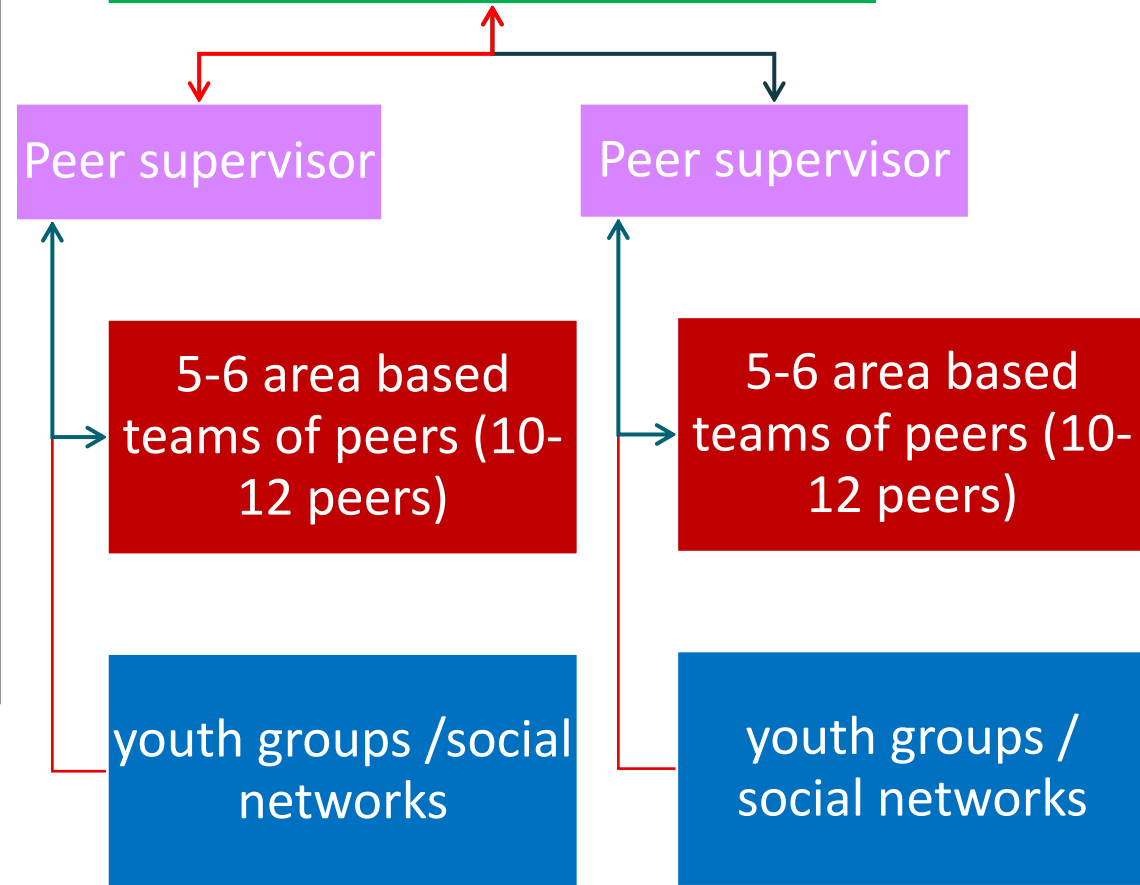
3) Peer mentorship

- Differentiated follow-up
- Case based management supported by electronic clinical management tool

High need: Escalate to review committee & FU

Medium need: Referral & FU

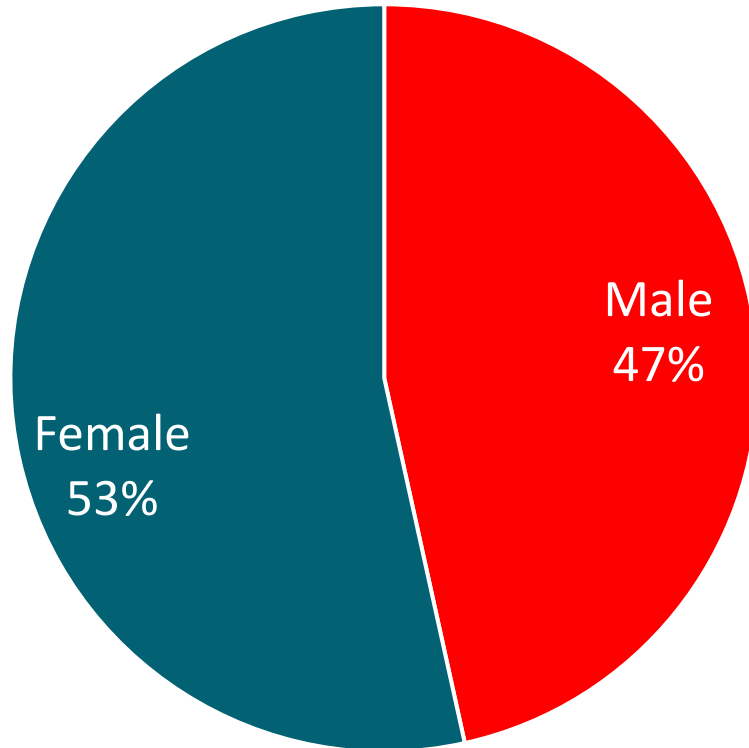
Low need: Touch base 3 monthly



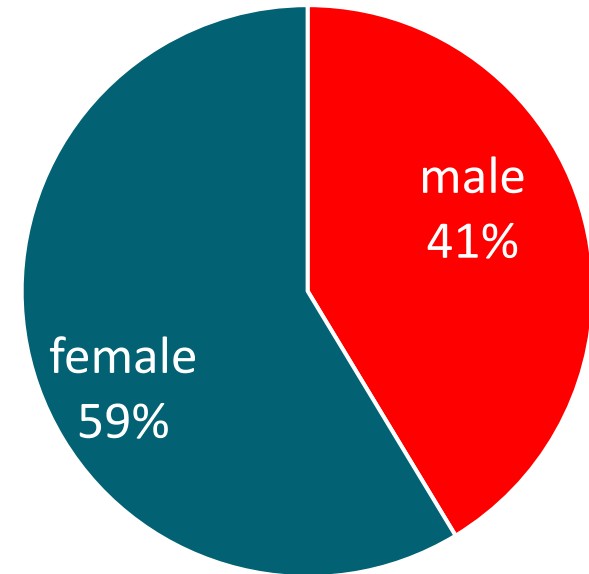
Peers reach 75% of adolescents and youth



n=12494 15-30 year-olds in clusters
undergone a peer-led needs
assessment



n= 3073 (25%) attended mobile
SRH clinic

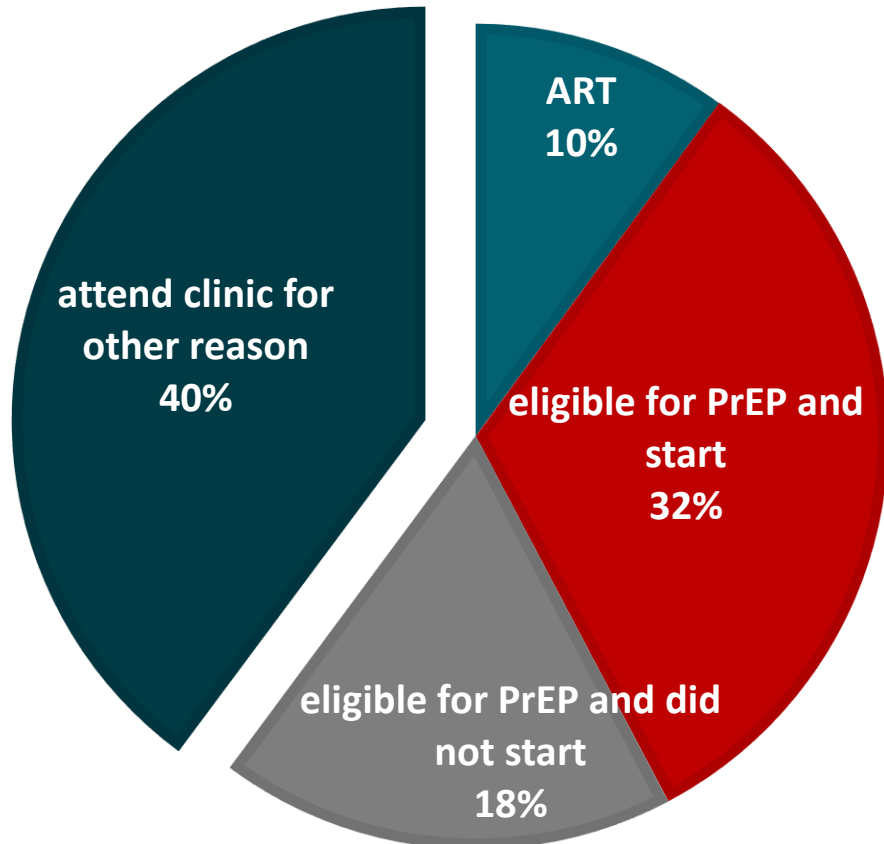




60% mobilised to SRH clinic need ART/PrEP

PREP ELIGIBILITY AND UPTAKE N=3073 15-30 YEAR OLDS SEEN BY PEER NAVIGATORS

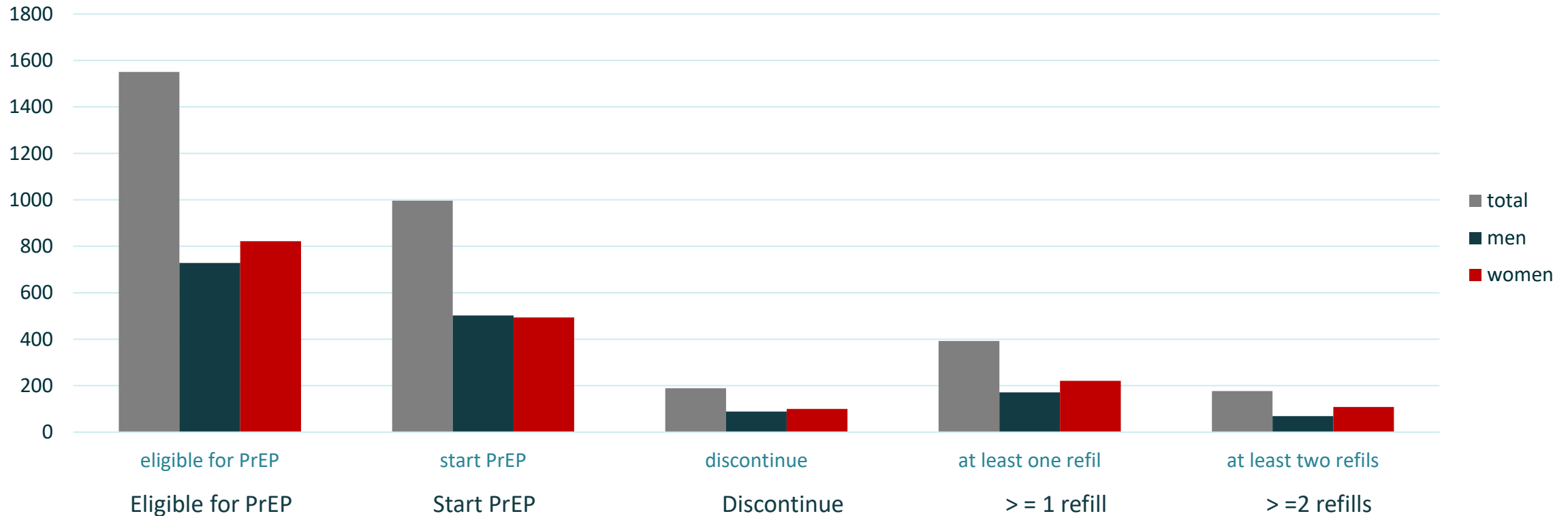
■ ART ■ eligible for PrEP and start ■ eligible for PrEP and did not start ■ attend clinic for other reason



64% of eligible for PrEP start PrEP & 20% continue



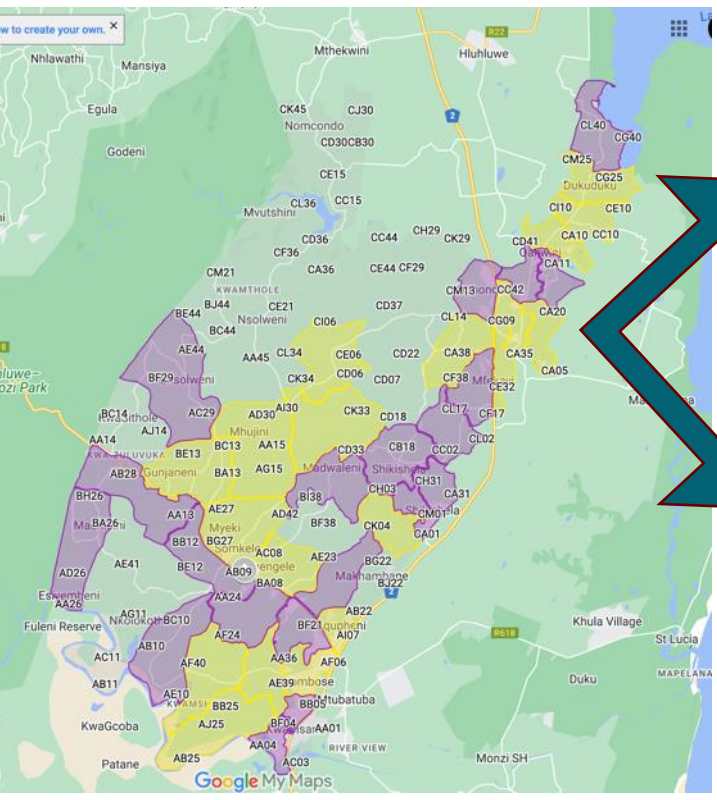
PrEP Cascade amongst 1550 AYA eligible for PrEP in mobile sexual health clinics



	Eligible for PrEP	Start PrEP	Discontinue	> = 1 refill	> =2 refills
Total	1550	996 (64%)	189 (19%)	392 (39%)	177 (18%)
Men	728	502 (70%)	89 (18%)	171 (34%)	69 (14%)
Women	822	494 (60%)	100 (20%)	221 (45%)	108 (22%)

LAPIS: cRCT Implementation trial of long-acting PrEP

40 clusters
26000 AYA aged 15-30



Intervention LAPIS:

- Peer navigators mobilise promote long-acting and oral PrEP
- Integrated HIV& sexual reproductive health (SRH) mobile clinics youth **offer choice of oral PrEP or injectable CAB LA or vaginal Ring or PEP packs**
- Peer navigators support refills and follow-up injection appointments

Standard of care: *Let's Talk*

- Peer navigators promote PrEP
- SRH mobile clinics youth will be **offered oral PrEP only**
- Peer navigators support refills



Outcome uptake and retention on PrEP in population surveys

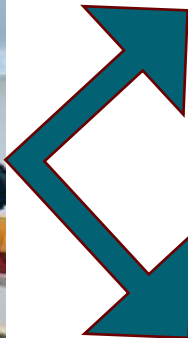


Procedures



AYA aged 16-30 @mobile clinic from 40 clusters

1. Check eligibility for LAPIS
2. Informed Consent
3. Point of Care HIV test negative



Intervention LAPIS:

- Choice counselling
- Same day start oral PrEP or injectable CAB LA or vaginal Ring or PEP packs
- Family planning, SRH and STI testing (*HIV Elisa, Hep B, Hep C, LFT and FBC sent to NHLS*)
- Peer navigators support refills and follow-up injection appointments

Standard of care: *Let's Talk*

- Same day start oral PrEP
- Family planning, SRH and STI testing (*HIV Elisa, Hep B, Hep C, LFT and FBC sent to NHLS*)
- Peer navigators support refills and follow-up appointments

Follow-up *Lapis*

- 7 day phone
- 1month
- 2 or 3 monthly (depend on choice)
- POCT for HIV & SRH
- Choice counselling
- Continue or switch (*DBS for HIV elisa*)

Follow-up SoC

- 7 day phone
- 1 month
- 3 monthly
- POCT for HIV & SRH (*DBS for HIV elisa*)



Exit appointment
Both arms
POCT HIV

(HIV Elisa, STI Testing, Hep B, Hep C, LFT)

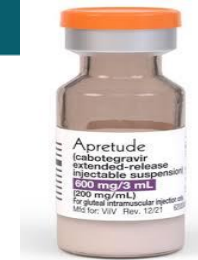
Characteristics of participants



	Total		Oral		CAB-LA		PEP pack or PEP	
	N=587		N=202		N=310		N=33	
Male	216	36.8%	87	43.1%	101	32.6%	19	57.6%
Female	371	63.2%	115	56.9%	209	67.4%	14	42.4%
Age								
15-19	102	17.4%	38	18.8%	51	16.5%	4	12.1%
20-24	274	46.7%	89	44.1%	154	49.7%	18	54.5%
25-30	211	35.9%	75	37.1%	105	33.9%	11	33.3%
Rural	425	72.4%	150	74.3%	222	71.6%	19	57.6%
No STI	418	73.2%	153	78.5%	202	66.7%	31	93.9%
Any STI	153	26.8%	42	21.5%	101	33.3%	2	6.1%
Chlamydia	122	21.4%	34	17.4%	81	26.7%	2	6.1%
Gonorrhoea	27	4.7%	5	2.6%	22	7.3%	0	0.0%
STI treated	142	92.8%	38	90.5%	94	93.1%	2	100.0%

Early Learnings from LAPIS

- Uptake higher when offered choice
 - 587 offered PrEP and 545 (93%) initiated PrEP or PEP, n=338 women.
- Choice arm (n=407) - Majority choose injectable PrEP
 - n=310 (76%) chose injectable cab, 209 (80%) of women
 - N=67 oral PrEP (15%) and 30 (7%) PEP
 - None chose the ring.



Early Learnings from LAPIS



- High STIs
 - One third had gonorrhoea or chlamydia at baseline
 - No Hep B, Hep C, eGFR <60 or ALT > 2ULN
 - One sero-converter who had 1st dose - switched to ART within 7 days
- Retentions with just phone and text reminders high but suboptimal
 - CABLA - 63% retained for one refill c.f. Oral PrEP 36%
- 9 pregnancies, 2 on cabla
- No HIV seroconversions to date



Early Learnings from LAPIS



- Cabotegravir easy to transport over distances & no temp excursion even > 48°C
- Cabotegravir injections feasible in mobile clinic & familiar to providers & users
- No HIV testing issues to date
 - point of care HIV test to start + confirmatory ELISAs sent

nature.com / s41591-...-02618-8

News & views

Infectious disease

<https://doi.org/10.1038/s41591-023-02618-8>

Person-centered HIV PrEP for cisgender women

Maryam Shahmanesh, Natsayi Chimbindi & Frances M. Cowan

Check for updates

Two modelling studies offer compelling evidence that less-than-perfect adherence to HIV pre-exposure prophylaxis can still provide reasonable protection for cisgender women – providing optimism for a more person-centered approach and lower discontinuation rates.



Despite 1.6 million people taking at least one dose of safe, effective and affordable antiretroviral-based HIV pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (TDF/FTC), there were 1.3 million new HIV infections in 2022, most in cisgender women'. In the context of receptive vaginal intercourse, the predicted efficacy in fully adherent women would be substantially lower than the actual

efficacy of TDF/FTC within sexual and reproductive health and antenatal services, or to decentralise care to community-based lay healthcare

nature medicine

Volume 29 | November 2023 | 2707–2708 | 2707

Conclusions



- Integrating PrEP choice with community-based peer support and sexual health services is feasible
- Community based product choice that includes long-acting PrEP and PEP may improve uptake and retention
- The majority of women and those with STIs choose the injectable option
- One in four chose an oral option





Implementation Scientists and clinical trialists: Lucky Mtoli, Limakatso Lebina, Nkosinathi Ngcobo, Willem Hanekom, Maryam Shahmanesh

Social Scientists: Thembelihle Zuma, Janet Seeley.

Statistics and data management: Jacob Busang, Kathy Baisley, Andrew Copas, Kobus Herbst, Jaco Dreyer

Project Management, clinical and social work: Nonhlanhla Okesola, Carina Herbst, Sithembile Msane, Samke Ngubane, Thandeka Danisa, Theresa Smit.



BILL & MELINDA
GATES foundation



NIHR | National Institute
for Health Research



2nd LA ARVs Conference