

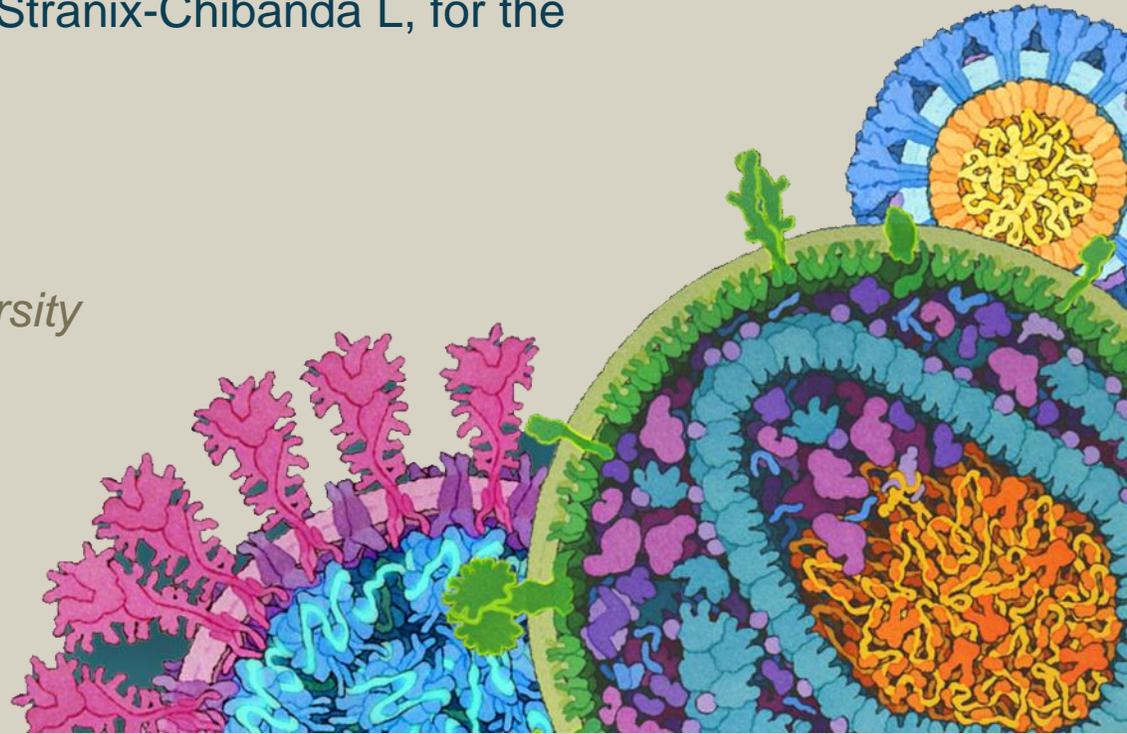
CAB LA FOR HIV PREVENTION IN AFRICAN CISGENDER FEMALE ADOLESCENTS (HPTN 084-01)

Hosek S, hamilton e, Ngo J, Jiao Y, Hanscom B, Delany-Moretlwe S, Mgodl N, Siziba B, Naidoo I, Mirembe Gati B, Kamira B, Marzinke M, McCoig C, Spiegel H, Stranix-Chibanda L, for the HPTN 084-01 Study Team

Sybil Hosek, PhD

*Stroger Hospital of Cook County/CORE Center & RUSH University
Chicago, IL, USA*

Disclosure: None



To the brave young participants, and their parents/guardians, who agreed to join this study and made it such a success...

THANK YOU!



- Preventing HIV among key populations, especially adolescent girls and young women (AGYW) in Africa and sexual and gender minority youth globally, is critical to controlling the HIV pandemic.
- Despite global guidelines recommending oral PrEP for key youth populations, profound inequalities in PrEP access as well as challenges with adherence and persistence.
- Long-acting cabotegravir (CAB LA) has been found to be highly effective for preventing HIV among cisgender sexual minority men and transgender women (HPTN 083) as well as cisgender women (HPTN 084).
- HPTN 084-01 was a single arm, open label, Phase 2b safety study of CAB LA among African cisgender adolescent females.

Primary

- To evaluate the safety, tolerability and acceptability of CAB LA in healthy, HIV uninfected female adolescents aged below 18 years

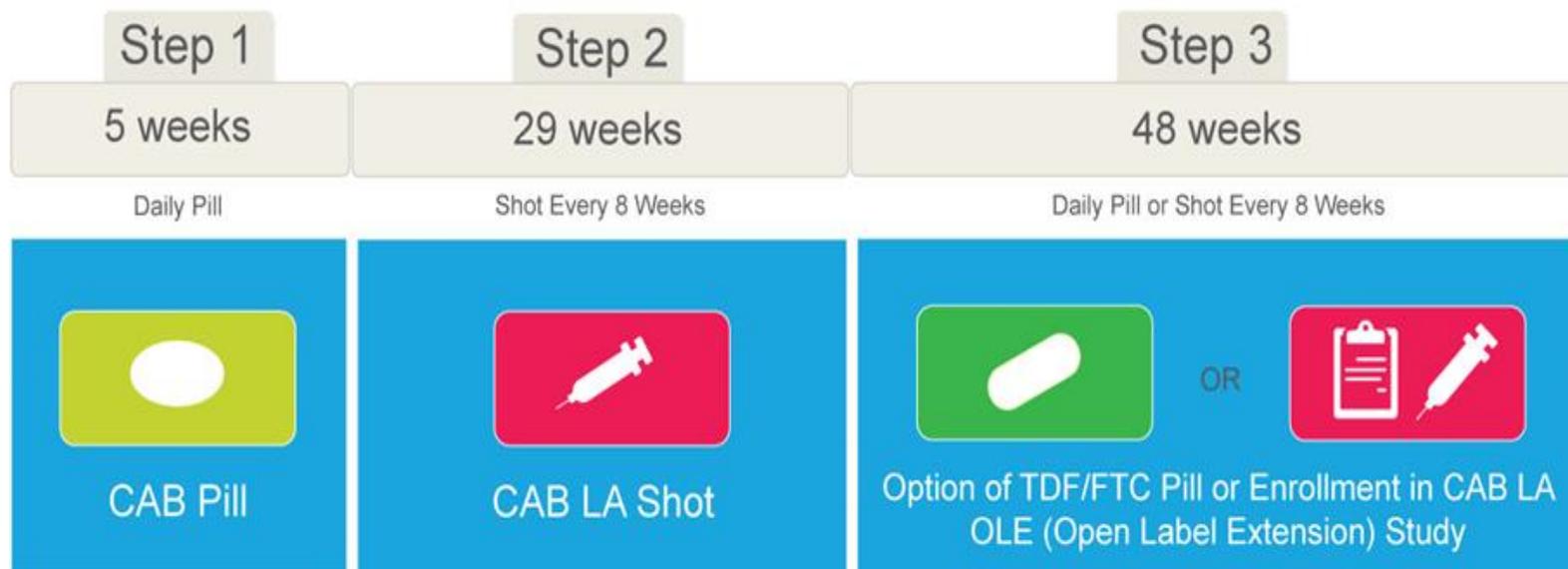
Secondary

- To examine adherence to, and timeliness of, injections over time among adolescent participants provided CAB LA and information regarding its safety and efficacy
- To examine patterns of sexual risk behavior over time among adolescent participants provided CAB LA and information regarding its safety and efficacy
- To characterize the pharmacokinetics of CAB LA in adolescents

Inclusion Criteria

- Assigned female at birth
- Below 18 years of age
- Body weight \geq 35 kg (72 lbs)
- Self-reported sexual activity with a male (oral, anal or vaginal) in the past 12 months
- Negative pregnancy test, not breastfeeding, and willing to use a reliable form of long-acting contraception
- In generally good health (including laboratory evidence)
- Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian informed consent

Study Flow



*In step 2, the first two shots are four weeks apart and 8 weeks apart after that

Graphics designed by Wits RHI and modified by FHI 360

084-01 Schema Infographic V3.0 | 3 September 2021

Study Product

- Step 1: Oral CAB 30 mg QD
- Step 2: IM injections of 3 mL (600mg) administered in the gluteal muscle
- Step 3: Oral TDF/FTC (300mg/200mg) QD or move to 084 OLE for CAB LA

* This presentation covers Steps 1 & 2

Study Sites

Uganda (Kampala;
MU-JHU Research
Collaboration CRS)

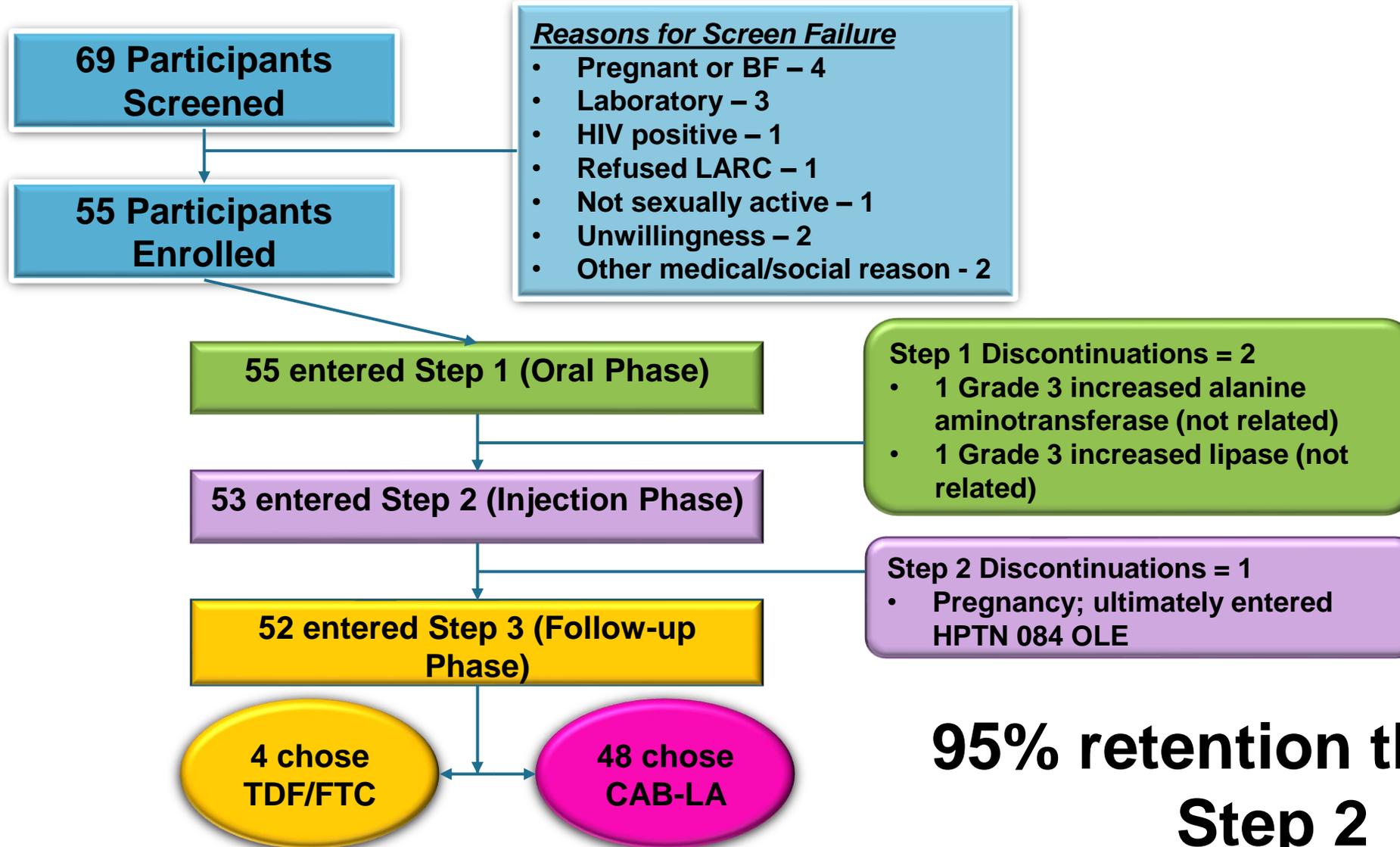
Zimbabwe (Harare;
Spilhaus CRS)

South Africa
(Johannesburg; Ward
21 CRS)

Accrual completed in 9 months
- - 3 months ahead of schedule!



Consort Diagram



Baseline Characteristics

Characteristic	Overall (n=55)
Mean Age (range)	16 (12-17) years
Black African race	100%
Weight	
35 to < 50 kg	27%
≥ 50 kg	73%
Sexually Transmitted Infections	
Gonorrhea	7%
Chlamydia	31%
At least one sex partner living with HIV	25%
Median episodes vaginal sex past month	2
Anal sex past month (yes)	5%
Transactional sex past month (yes)	22%
Significant depressive symptoms (CES-D-10)	36%

Safety

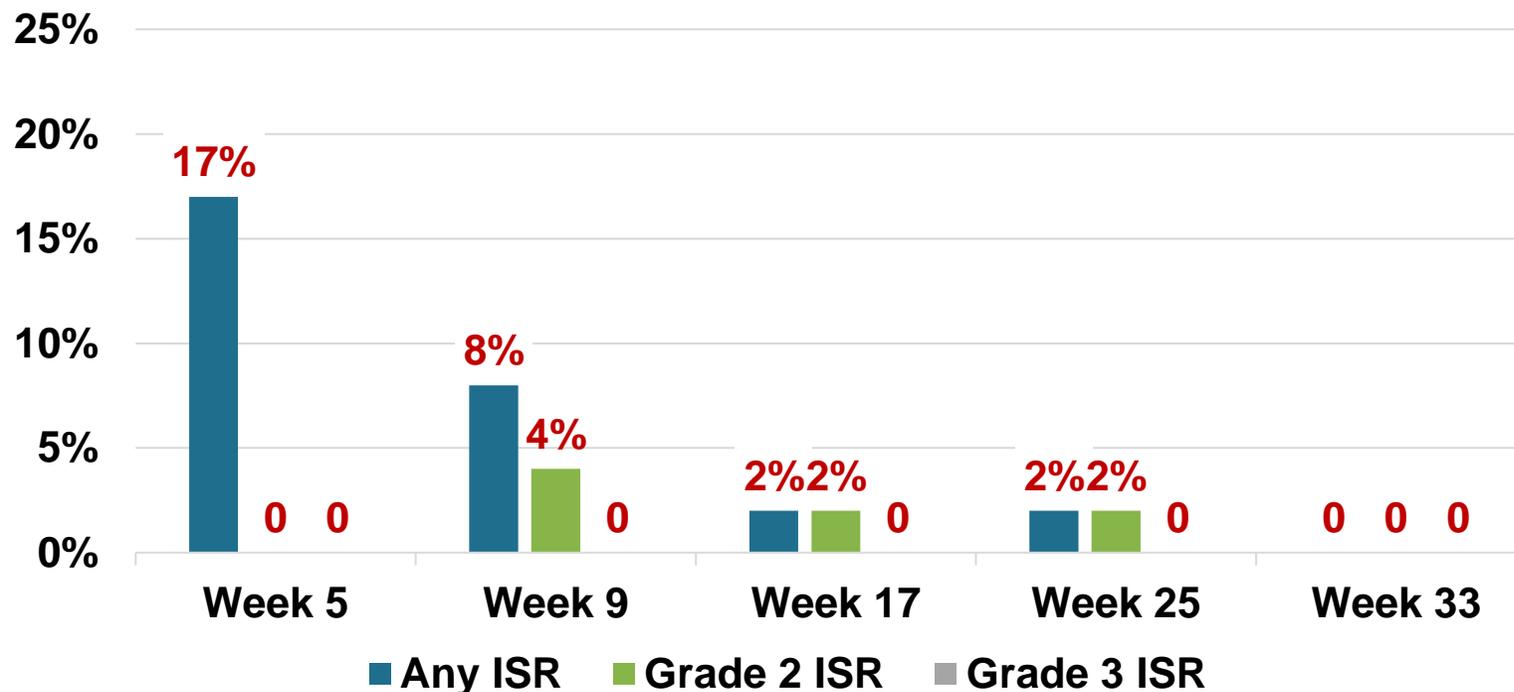
- No product related SAEs
- No product discontinuations due to AEs
- No incident HIV infections
- No events of weight gain, hepatotoxicity, hypersensitivity, rash, seizures or pancreatitis

AESI in Steps 1&2	# of pts	Severity (# of pts)	Detail
CrCl decreased	41	Grade 2 – 39 Grade 3 – 2	Resolved without intervention
Blood glucose increased	22	Grade 1 – 21 Grade 2 – 1	Resolved without intervention
Blood creatinine increased	9	Grade 1 – 1 Grade 2 – 6 Grade 3 – 2	Resolved without intervention
Neuropsychiatric events	3	Grade 1 – 1 Grade 2 – 1 Grade 4 – 1	Depressive symptoms Anxiety (stress) Suicidal behavior/attempt All resolved with counseling
Rhabdomyolysis	1	Grade 2	Myalgia resolved

Tolerability – Injection Site Reactions (ISR)

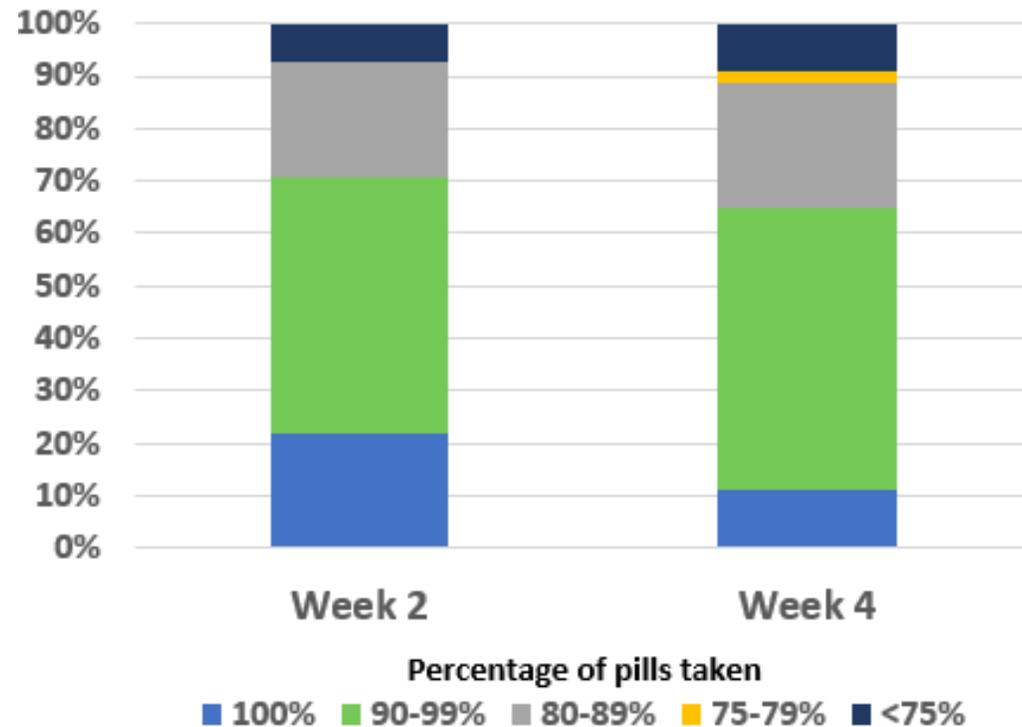
- No participants (n=53) discontinued early due to intolerability
- Most common ISR was injection site pain followed by induration and swelling

Percentage of Participants Reporting any ISR by Week and Grade

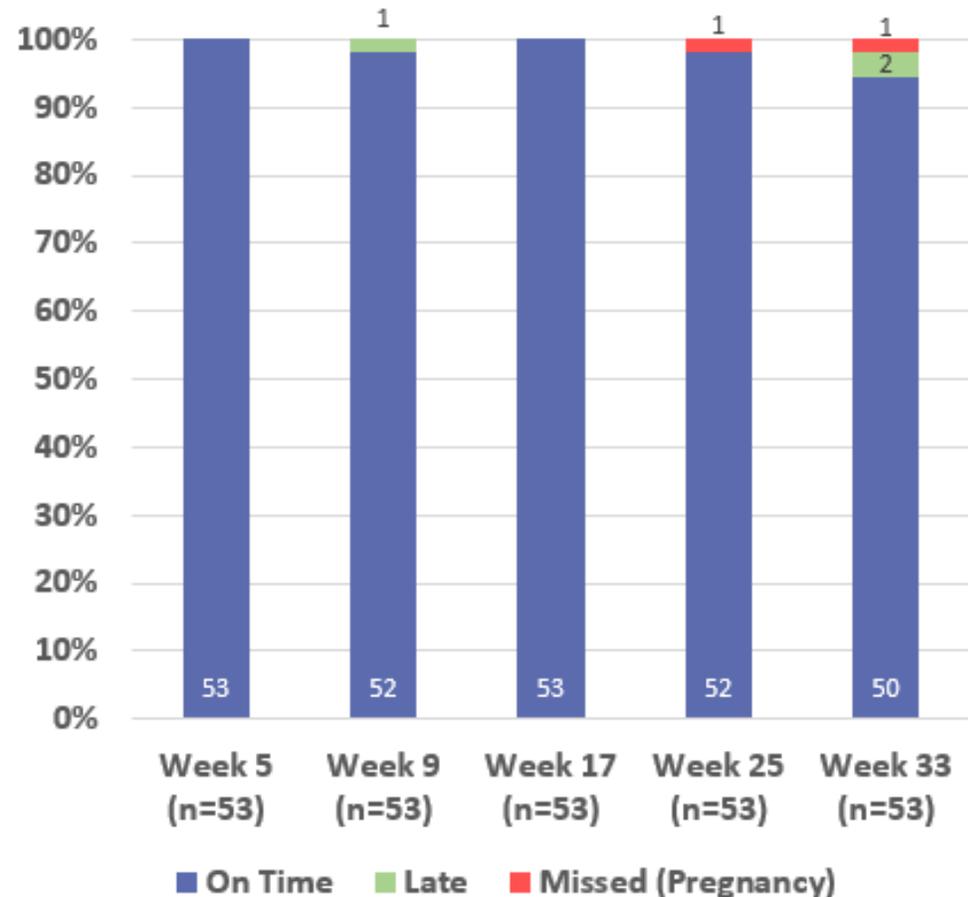


Adherence

Oral CAB Adherence (pill count)



Injection Adherence



Acceptability – Week 17 (after 3 injections)

What do you like about an injectable method?

Protects against HIV	54.7%
Easier to use than other methods	41.5%
Longer-term protection than other methods	22.6%
Can be used discreetly	18.9%
Administered by healthcare professional	9.4%
Doesn't interrupt sex	9.4%
Nothing	7.5%

What concerns do you have about an injectable method?

None	35.8%
May be painful	28.3%
May cause harmful side effects	18.9%
Once injected, it cannot be reversed	13.2%
May not protect against HIV	11.3%
Cannot be used discreetly	5.7%
May not be affordable	1.9%

Conclusions

- It is feasible to enroll sexually-active adolescents into biomedical HIV prevention trials, with parental/guardian consent
- Interest in a long-acting HIV prevention product was high among cisgender AGYW under the age of 18
- Adherence to the injection visits was exceptional
- CAB LA was found to be safe and tolerable, with no discontinuations of product due to adverse events
- Participants found CAB LA to be acceptable and expressed interest in future use
- Most participants (92%) chose to continue CAB LA over TDF/FTC when given a choice

Acknowledgments



A BIG THANK YOU to all of the HPTN 084-01 participants, their families, and the communities that support them for their commitment to the study and to the site staff for their dedication to study implementation!

Sponsor

- Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).
- HPTN 084-01 is also co-funded by the Bill & Melinda Gates Foundation (BMGF) and support is provided by ViiV Healthcare.
- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

DAIDS

- Adeola Adeyeye
- Hans Spiegel
- Carl Dieffenbach
- Sheryl Zwierski
- Melissa Kin
- Katie Shin
- Irene Rwakazina
- Usha Sharma
- Judi Miller
- Roberta Black

Pharmaceutical Support

- ViiV Healthcare

Additional Support

- Bill & Melinda Gates Foundation

HIV Prevention Trials Network (HPTN)

- Laboratory Center (Johns Hopkins University)
- Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Research Center
- Leadership and Operations Center, FHI 360
- HPTN Leadership

HPTN Leadership

- Myron Cohen
- Wafaa El-Sadr
- Deborah Donnell
- Sue Eshleman
- Nirupama Sista
- Kathy Hinson
- Beth Farrell

Acknowledgments

Leadership & Operations (LOC)

Study Team

- erica hamilton
- Scott Rose
- Amber Babinec
- Gabriela Salinas-Jimenez
- Tanette Headen

Community Team

- Marcus Bryan
- Rhonda White
- Molly Dyer

Communications Team

- Laura Long
- Sam Alvarado
- Eric Miller
- Kevin Bokoch

Finance Team

- Sarah Stone
- Gloria Pherribo
- Priti Patel

HPTN Lab Center (LC)

- Mark Marzinke
- Estelle Piwovar-Manning
- Yaw Agyei
- Ethel Weld

HPTN Statistical & Data Management Center (SDMC)

- Julie Ngo
- Lynda Emel
- James Hughes
- Sahar Zangeneh
- Brett Hanscom
- Jennifer Schille

Study Team Members

- Aida Asmelesh (Clinical Monitoring Committee)
- Kate MacQueen (HPTN Ethics Working Group)
- Linda-Gail Bekker (Protocol Team Member)
- Raphael J. Landovitz (Protocol Team Member)

Sites (Investigator of Record/PI, Sub-Investigators, Study Coordinators)

Ward 21 CRS (South Africa):

- Sinead Delaney-Moretlwe
- Carrie-Anne Mathew
- Elizabeth Helena Roos
- Ishana Naidoo

MU-JHU CRS (Uganda):

- Brenda Gati Mirembe
- Clemensia Nakabiito
- Betty Kamira

Spilhaus CRS (Zimbabwe):

- Nyaradzo Mgodzi
- Bekezela Siziba
- Eunice Tahuringana

Our Community Educators & Recruiters and CAB Members

ViiV Healthcare

- Cindy McCoig
- Alex Rinehart

Bill & Melinda Gates Foundation

- Lut Van Damme

