



HPTN

HIV Prevention
Trials Network

HPTN  **Q82**
HERS

**Evaluation of daily oral PrEP as a primary prevention strategy for
young African women**

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PrEP in Africa - key questions for implementation, esp for young women

- **How do you create demand?**
 - What information is needed?
 - How to communicate about a new prevention strategy (ie PrEP) in engaging, concise, non-technical ways to motivate young women in SA & Zim?
- **How do you support PrEP delivery?**
 - How do you identify those at highest risk without creating stigma?
 - What add'l services are needed & wanted?
 - How do we integrate with other interventions?
- **How do you support young women's effective use?**
 - What does adherence support look like?
 - Counselling, weekly SMS check-ins, clubs
 - Drug feedback levels
 - Targeted/intensification for those who need more support?

HPTN 082: Evaluation of daily oral PrEP as a primary prevention strategy for young African women



Study Population

Uninfected women
Ages 16-25 yrs

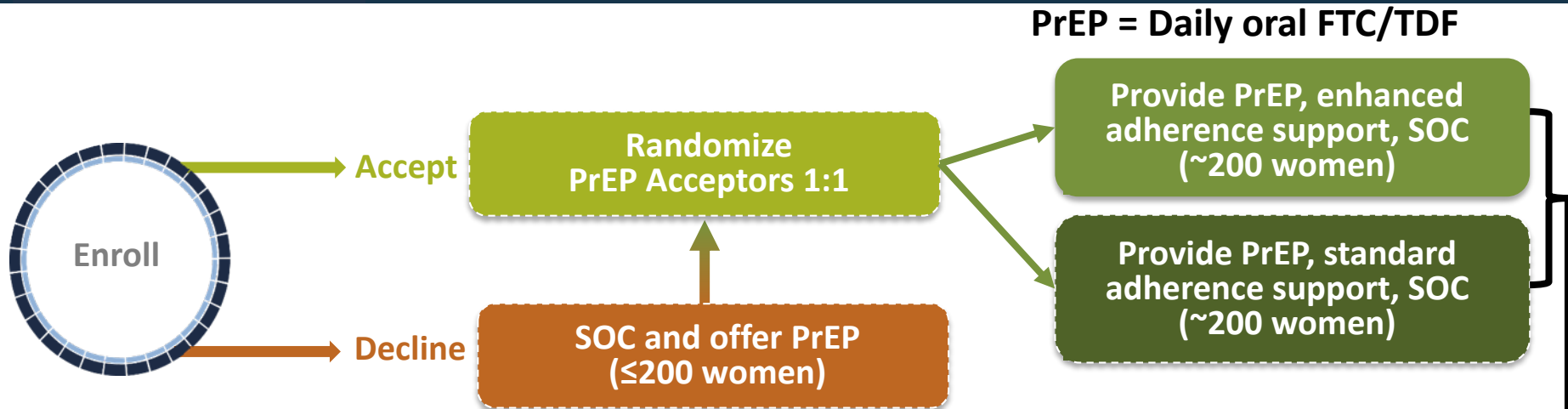
Johannesburg & Cape Town,
South Africa
Harare, Zimbabwe

Target Enrollment

- 400 women who accept PrEP at enrollment
- ≤ 200 women who decline PrEP at enrollment

Primary objectives:

Assess the proportion and characteristics of women who accept versus decline PrEP
Assess PrEP adherence using drug levels in young women



In-depth interviews about women's decisions to use PrEP, adhere to PrEP, and acceptability in the first 3 months after PrEP acceptance. (~75 total, including acceptors and decliners)

Standard Adherence Support

- CBT counseling
- SMS texting
- Adherence clubs

Enhanced Adherence Support

- CBT counseling
- SMS texting
- Adherence clubs
- **Drug level feedback counseling**

Primary Objectives of HPTN 082

- To assess the proportion and characteristics of young HIV-uninfected women who accept versus decline PrEP.
- To assess the difference in PrEP adherence in young women randomized to enhanced adherence support (using drug level feedback) versus standard of care adherence support.

Secondary Objectives

- Timing of PrEP acceptance among women who initially decline PrEP at enrollment but elect to accept PrEP during follow up.
- Correlates of early and delayed acceptance of PrEP.
- Correlates of PrEP adherence at Weeks 13, 26, and 52.
- Proportion who discontinue PrEP, timing, & factors associated with PrEP discontinuation.
- Specificity and predictive value of a PrEP readiness tool (based on the HIV Prevention Readiness Measure, HPRM) to predict uptake and adherence to oral PrEP.

Secondary objectives (continued)

- Qualitative factors that influence women's decisions to use PrEP, to adhere to PrEP, and acceptability of PrEP in the first 3 months after PrEP acceptance.
- Adverse events between women on PrEP and women not taking PrEP.
- HIV incidence in those who accept PrEP compared to those who do not.
 - And assess the association with detectable TFV in PrEP users who acquire HIV infection during the study.

Behavioral data collection (CASI)

- Partnership characteristics & partner's HIV status
- Sexual behaviors
- HIV risk perception
- HIV stigma
- PrEP readiness (HPRM)
- Future orientation and aspirations; self-efficacy



- Alcohol and drug use
- Gender-based violence
- Disclosure to peers, family members, teachers, and partner(s) about PrEP use and participation in the study

Qualitative interviews (25 per site, 75 total)

Sample of

- 1) Women who have high or low adherence based on drug levels at 1 & 2 months
- 2) Initial PrEP 'decliners' about:
 - Factors that influence women's uptake of PrEP
 - Factors that influence her adherence to PrEP (e.g., storage of product, disclosure, communication with partner, alcohol & drug use)
 - Among those randomized to get drug level feedback, their experience & how feedback influenced subsequent PrEP adherence

Get PrEPed! Recruitment Video

- Explains PrEP using youth-friendly graphics
- Filmed and edited by Umuzi (South Africa)
- Script, graphics and film developed in collaboration with and evaluated by youth in South Africa and Zimbabwe



Participants are presenting for screening having seen the video shared by peers on social media

Sites have reported that participants have less questions about how PrEP works after viewing the video in the waiting room

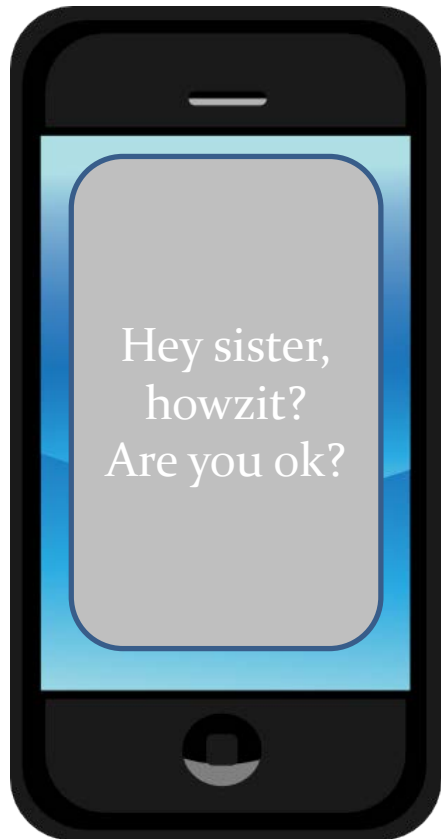
HPTN 082: Adherence Support

1. Counselling
2. Weekly SMS
3. Adherence clubs
4. Drug Level Feedback

Standard

Enhanced

Weekly SMS



- PrEP accepters will receive weekly SMS text messaging until Week 13, with the option to continue throughout follow up if desired

HPTN 082 Two-way SMS

- Friendly user interface to send weekly SMS check-ins
 - Modeled after WeTel program which increased ART adherence in Kenya (Lester, Lancet 2010)
 - Provides a “check-in” with participants during first 13 weeks on PrEP
- Transmission data will be collated to determine who & which women respond with concerns
 - Will evaluate outcomes of call-backs

HPTN 082 Adherence Clubs

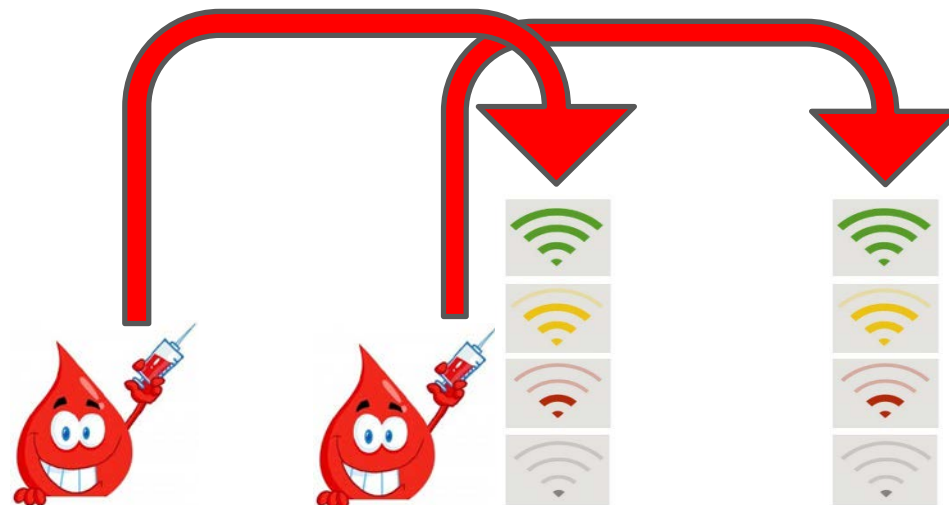
- Develop peer support
 - By sharing experiences and providing advice
 - Creates a cohort effect amongst ppts
- Address concerns about PrEP and adherence
 - Study staff and participants openly discuss issues
- Encourage uptake by non-users
- Problem-solve adherence challenges

Adherence Clubs: Format and Structure

- Formal and informal mix
 - Recreational and “Educational”:
 - Sports, movies, music, drama, income generation, tutoring
 - Motivational talks
 - Involving partners / parents? (open days?)

Drug level feedback

- Participants randomized to enhanced counseling will have DBS TFV-DP levels obtained at Weeks 4 & 8.
- Results given during counseling sessions at next visit (weeks 8 & 13)



ENR

Week 4

Week 8

Week 13



Key message: You are doing a great job! Keep taking one PrEP pill every day and you will have very strong protection against HIV.



Key message: You are doing a good job taking your PrEP pills. Keep working at it and remember that one pill every day is needed for strong HIV protection.



Key message: It looks like you have been trying to take the PrEP pills, but are having some difficulties. Remember that one pill each day is needed for strong HIV protection. How can we help you do better?



Key message: It looks like you haven't been able to take the PrEP medication. Is PrEP something that you are still interested in? If yes, how can we help you?

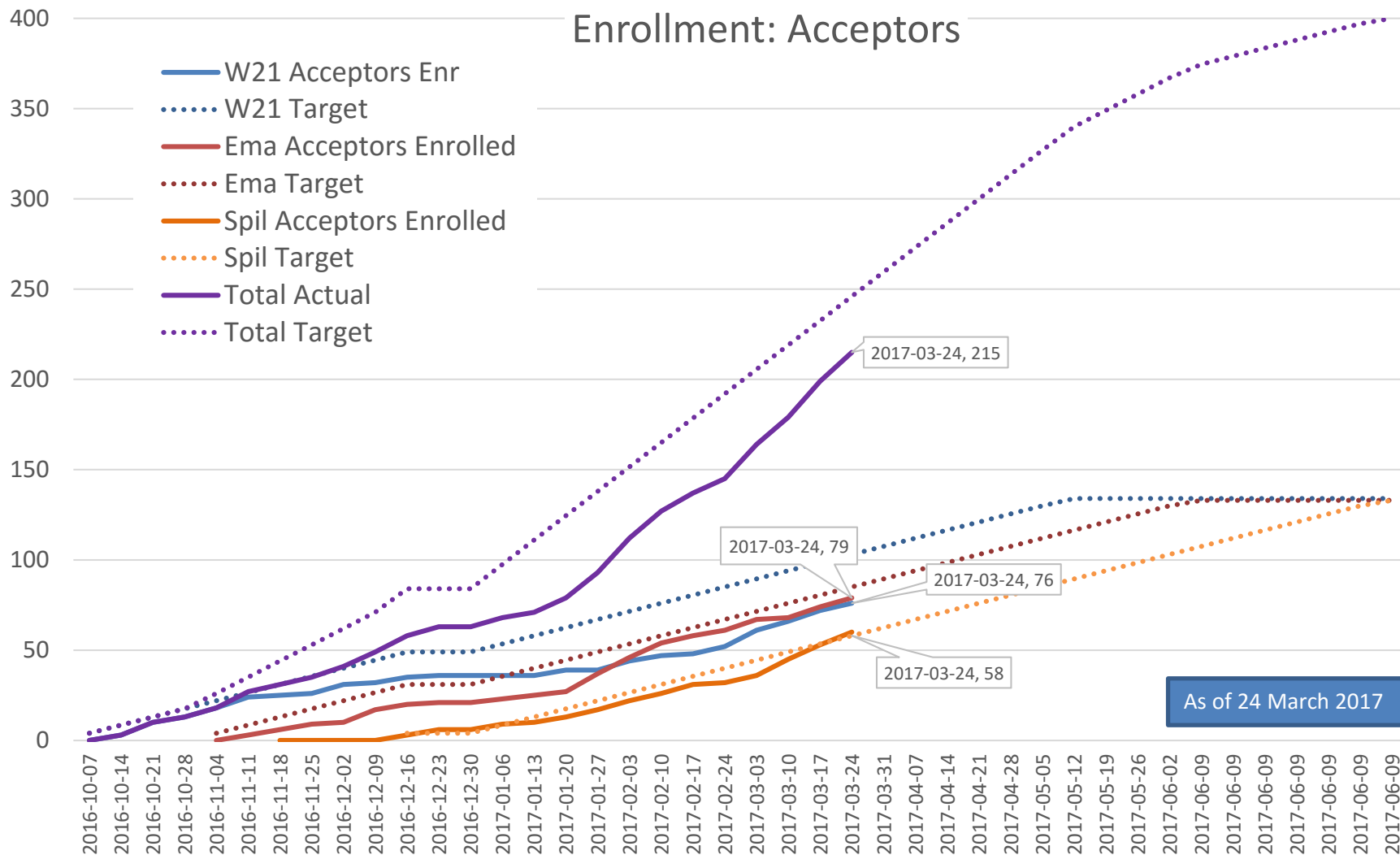
Clinical Research Sites

- Emmavulendeli, Cape Town
- Ward 21, Wits RHI, Johannesburg
- Spilhaus, Harare

Current Study Status

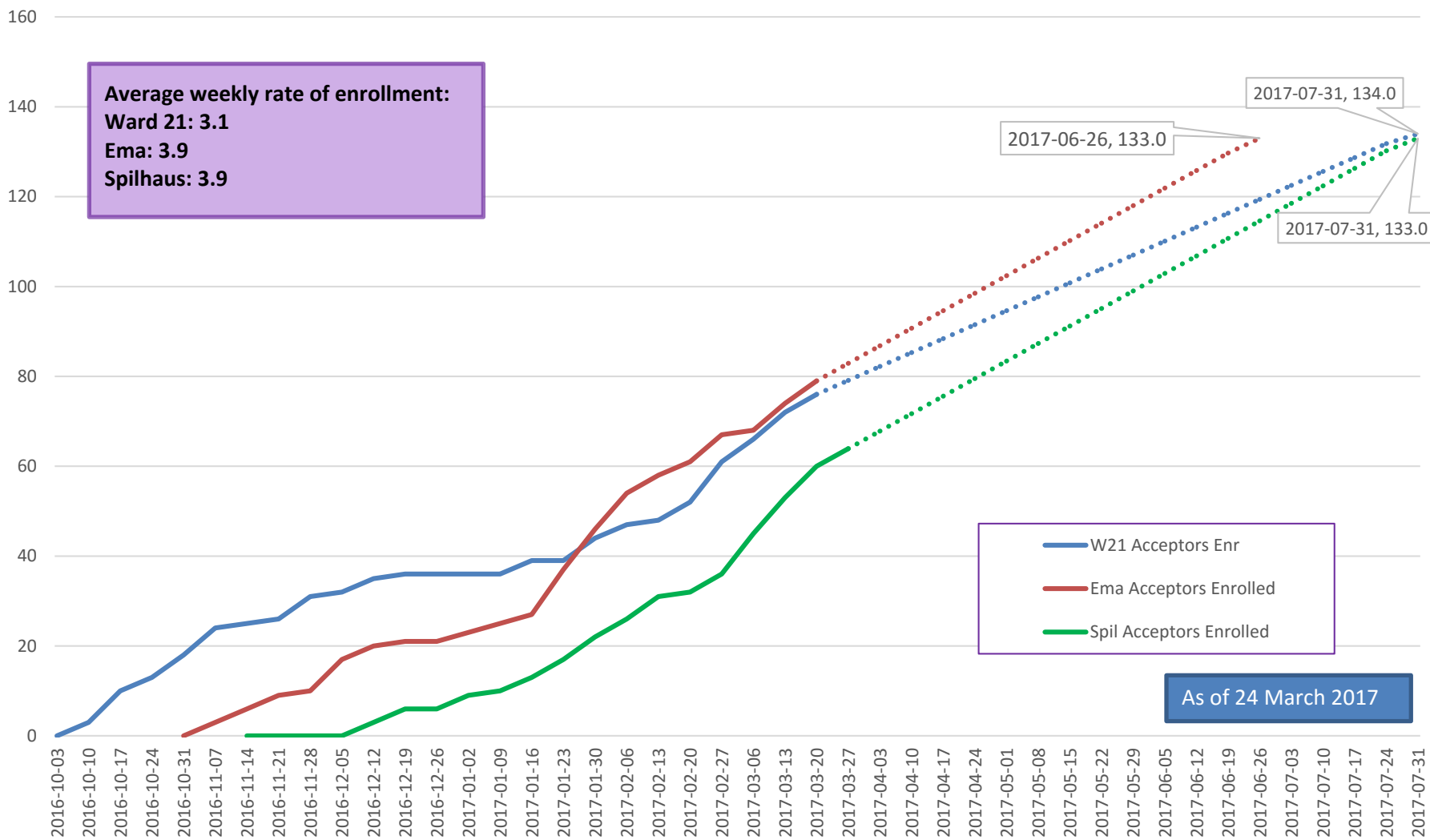
- We have passed the midway point for enrollment
 - 215/400 women who accept PrEP enrolled
- Only 12% (29/244) women enrolled declined PrEP at enrollment
 - Capped at 200
- Based on present rates of enrollment, all sites will be fully enrolled by August 2017

HPTN 082 Enrollment: Acceptors



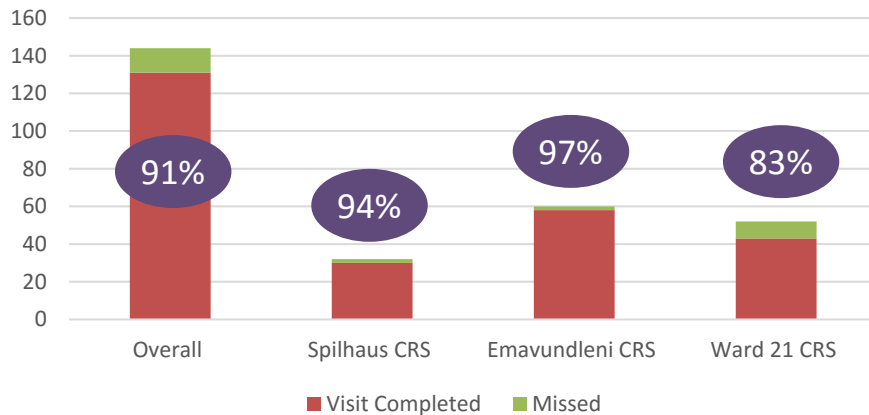
As of 24 March 2017

HPTN 082: Actual and projected enrollment

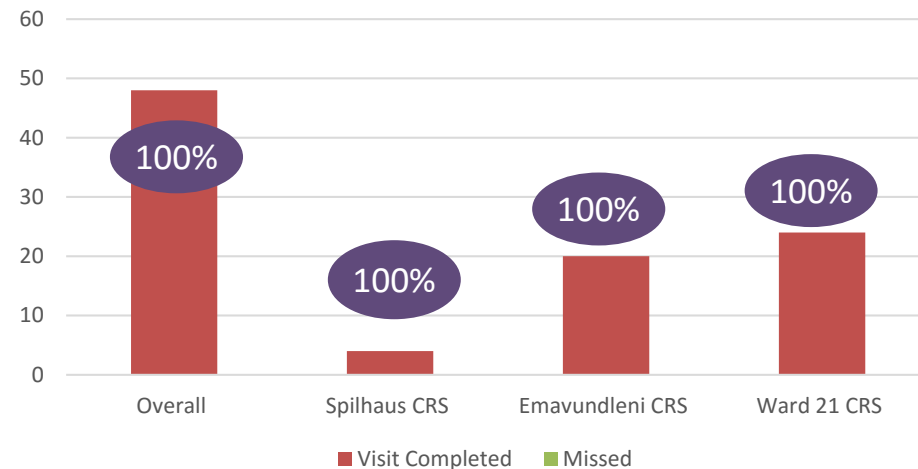


Retention at Weeks 4, 8 and 13 (PrEP acceptors)

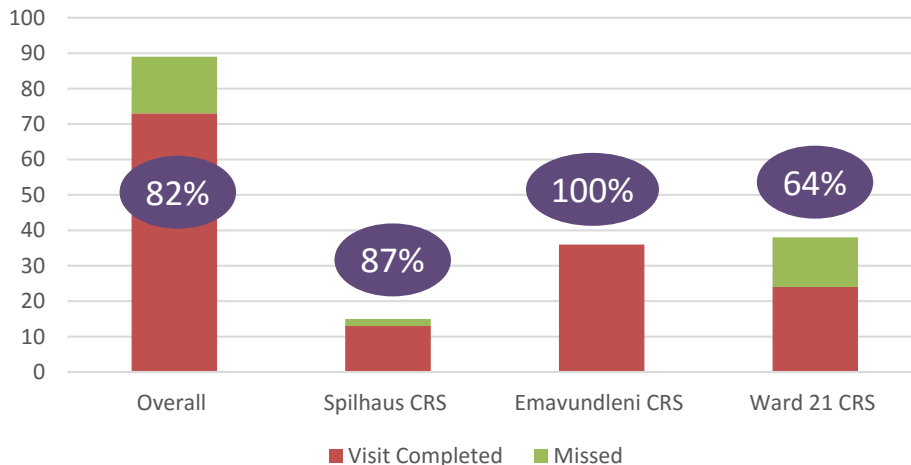
Week 4 Retention



Week 13 Retention



Week 8 Retention



Retention overall among acceptors is pretty high, some visits were impacted by the holidays.

HERS pill cases



Based on feedback from young women:

- Concerned about stigma from pill bottle that looks like ARVs
- Did not like the sound of tablets rattling
- Need to carry tablets when they are away from home
- Wanted discreet way to carry several tablets

Community Engagement

- Photo pending of WHRI youth CAB

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