

SEARCH study insights on Men and PrEP/PEP in rural East Africa

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On behalf of the SEARCH Collaboration

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Men and HIV
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- SEARCH: multi-disciplinary, international research collaboration examining population-level approaches to reduce HIV incidence and improve Community Health in rural east Africa
- We design and evaluate multi-disease interventions for persons of all ages and genders
 - Men's attitudes and perspectives on health require communication and implementation that meet their priorities
 - We used mixed methods approaches in our work to understand what is effective, what is not and why for men
 - **Our prior work in SEARCH on men informed our approach** for HIV prevention interventions for men

SEARCH 1.0 Study



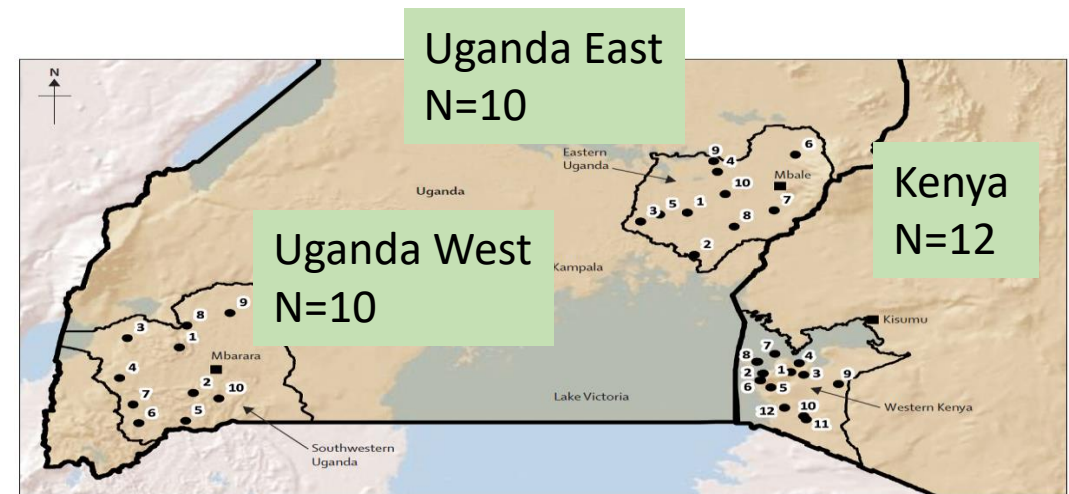
SEARCH Hypothesis: HIV “test and treat” with universal ART using a multi-disease, patient-centered care model would reduce new HIV infections and improve community health compared to a country guideline approach

Study Design: Pair-matched, community randomized study of 32 rural communities

Study Population: Age \geq 15 years

- Comprehensive baseline census with biometric identifier

32 communities, of 10,000 persons each
~320,00 person study



Men are “distinct”; HIV testing experience

Model- population based multi-disease testing using health fairs and homebased testing for health fair non-attendeess.

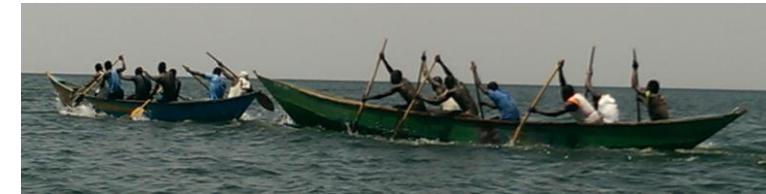


Proactively identified barriers faced by men in accessing testing¹

- Labor opportunities often require extended absences from households
- Men often tested "by proxy", believing their wives' results to be their status
- Masculine gender norms/stigma and fears of accessing HIV services

Testing – Mobilizing & Reaching Men

1. Community engagement with male-centered mobilization activities
 - Moonlight/Beach outreach & health campaigns (with HIV testing)
 - Non-health-related attractions: Football matches, Boat rowing competitions, Bands and theater groups, Higher value, but fewer, lottery prizes²
2. Embed HIV testing within health fairs with services to address men's needs
 - Men's Health Tent (Sexual health, STIs, partner concerns)
 - Non-communicable disease screening (diabetes and hypertension)
3. SEARCH approach (above) achieved high adult men testing coverage & status awareness
 - 95% of men living with HIV aware of status by SEARCH test & treatment endpoint³



1. Camlin et al, "Men 'missing' from population-based HIV testing: insights from qualitative research," AIDS Care, 2016

2. Chamie et al, "Comparative effectiveness of novel nonmonetary incentives to promote HIV testing," AIDS, 2018

3. Havlir et al, "HIV testing and treatment with the use of a community health approach in rural Africa," NEJM, 2019

Added Oral PrEP (Truvada).....



Men viewed PrEP as a vehicle for reducing their risk of HIV while safely pursuing opportunities for sex.

“I have many girlfriends but I have not slept with any of them since I do not know their HIV status, which is why I decided to enroll on PrEP” Male adolescent

“If I have swallowed these drugs [PrEP], even when I forget to put on a condom I will already be protected from contracting HIV”
Male participant

Men are interested in PEP and will complete treatment

1

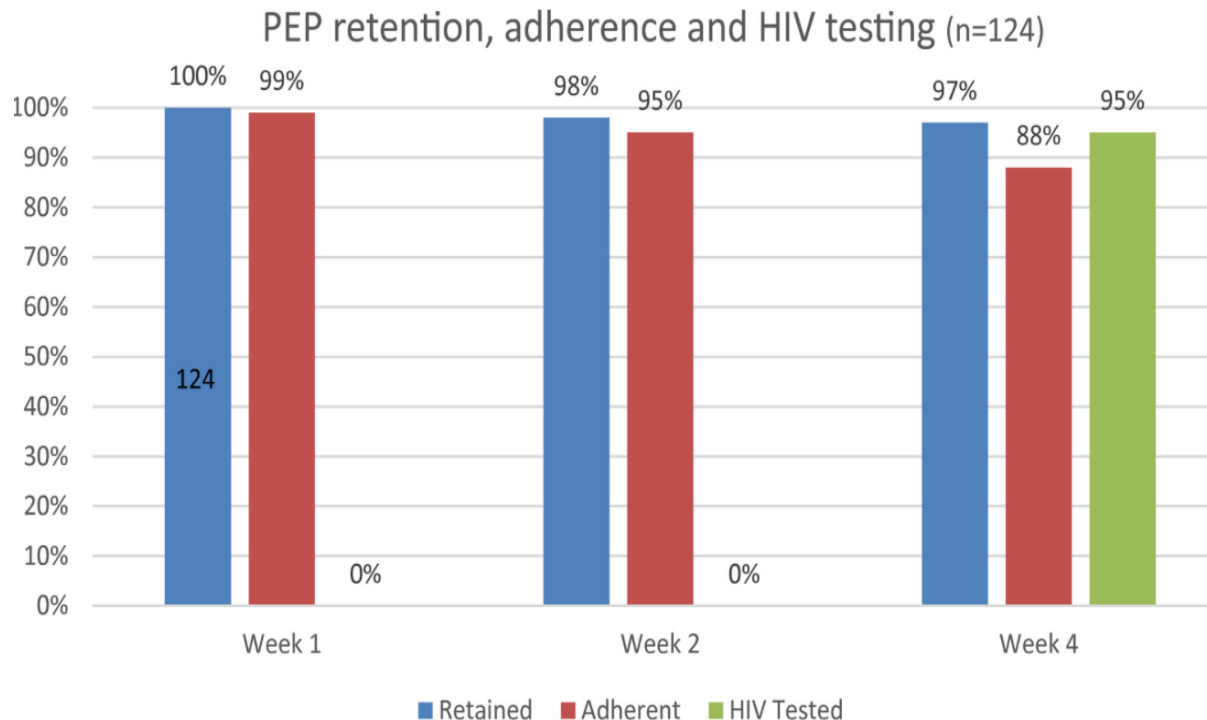
- 124 people sought PEP
- **1/3** were male
- **1/4** were <25 years
- **41%** were fisherfolk

2

PEP Delivery model Exposures

- **20%** reported exposure with a **sero-different** partner
- **72%** with a **new or existing relationship**
- **7%** from **transactional sex**
- 35% of participants had ≥ 1 out-of-facility visit.

3



4

88% completed 4 week course
No Seroconversions

Ayieko, JIAS, 2021

Highlights

- To reach men, understand their 'contexts' and adapt your intervention to navigate barriers
- Status neutral testing as entry point can be enhanced with multi-disease approach and being responsive to clients changing needs
- Men are as interested in health as anyone else
- There is high interest in PrEP in rural settings among men
- PEP has an important role in HIV prevention among men

SEARCH 2.0 Dynamic Choice prevention randomized studies

- **Hypothesis:** dynamic choice HIV prevention intervention comprising:
 - Flexibility to move between PrEP and PEP
 - Responsiveness to the needs of both men and womenwould increase HIV biomedical prevention coverage among persons at risk in rural Kenya and Uganda

Design: Randomize trials of intervention vs standard of care

- Community
- Out Patient department
- Antenatal Care

SEARCH 2.0: Dynamic Choice HIV Prevention

NCT04810650

- Using PRECEDE framework, we developed a “**Dynamic Choice HIV Prevention**” Model, including PrEP and PEP for men and women

PRODUCT CHOICE

(+ option to switch products)

- Oral PrEP (TDF/XTC)
- PEP (pill in pocket option)¹

SERVICE LOCATION CHOICE

- Clinic
- Home/Community site
- Phone/Virtual visit

HIV TESTING CHOICE

- Rapid test
- HIV self-test option

PATIENT-CENTRED CARE

- Structured assessment of barriers** to PrEP/PEP start/adherence, with **personalized plans** in response
- Longer PrEP supply for start/refills (up to 3 months)**
- Phone access to clinician** for PEP or PrEP starts, advice/questions (24hrs/7 days/week)
- Reproductive health and/or STI service integration at antenatal clinics & outpatient departments**
- Psychological support** – referrals to counseling for trauma/gender-based



1. Adopted from Tumarkin et al. JAIDS 2018

Presented at CROI 2023: Dynamic Prevention increased self-reported coverage

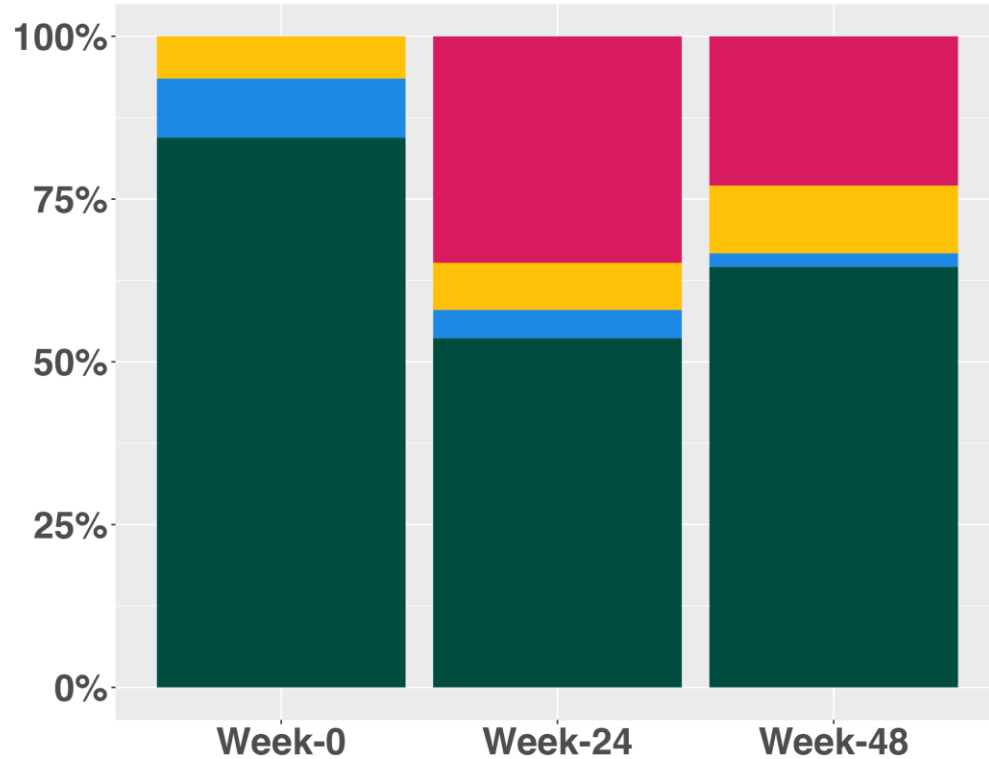
| Setting | N | Intervention coverage | Control coverage | Increase |
|-----------|-----|-----------------------|------------------|----------|
| Antenatal | 400 | 69.6% | 29.4% | 40.2% |
| OPD | 403 | 47.5% | 18.3% | 29.2% |
| Community | 429 | 28.0% | 0.5% | 27.5% |

Characteristics of male participants in OPD and community studies

| | OPD | Community | Overall |
|-------------------------------------------|-----------|-----------|-----------|
| N | N=158 | N=186 | N=344 |
| Age 15-24 | 65 (41%) | 71 (38%) | 136 (40%) |
| Country | | | |
| - Kenyan | 96 (61%) | 87 (47%) | 183 (53%) |
| -Ugandan | 62 (39%) | 99 (53%) | 161 (47%) |
| Marital status | | | |
| -Single (Unmarried) | 54 (35%) | 68 (37%) | 122 (36%) |
| -Married/Cohabiting | 100 (64%) | 110 (59%) | 210 (61%) |
| -Divorced/separated/widowed | 2 (1%) | 8 (4%) | 10 (3%) |
| Partner HIV+/unknown in past 6mo | 151 (96%) | 114 (61%) | 265 (77%) |
| Alcohol use (any, prior 3mo) | 25 (16%) | 23 (12%) | 48 (14%) |
| Highly mobile (at least 1 night away/3mo) | 63 (40%) | 90 (50%) | 153 (46%) |
| Any PrEP in past 6mo | 10 (6%) | 1 (1%) | 11 (3%) |
| Any PEP in past6mo | 7 (4%) | 1 (1%) | 8 (2%) |

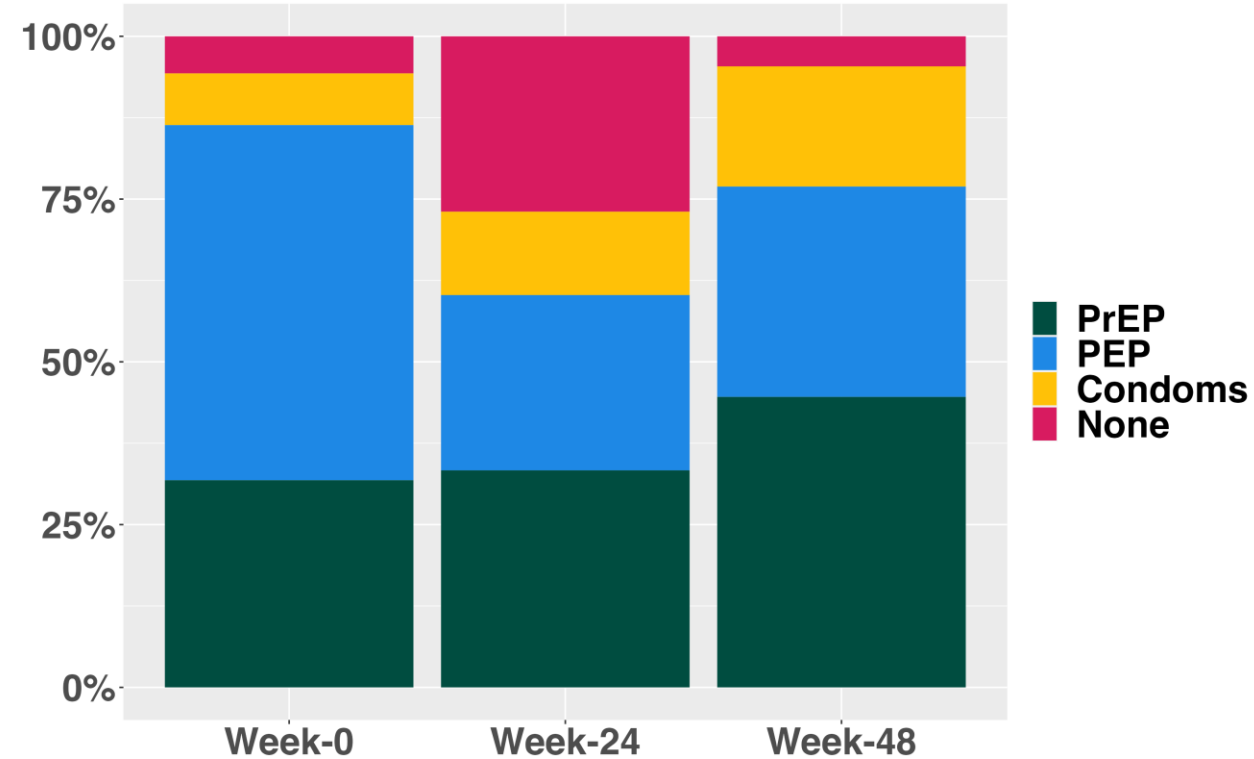
Product choice varied by time and setting

Outpatient Department



- 87% chose PrEP & 12% chose PEP at least once over 48 weeks
- Similar among women

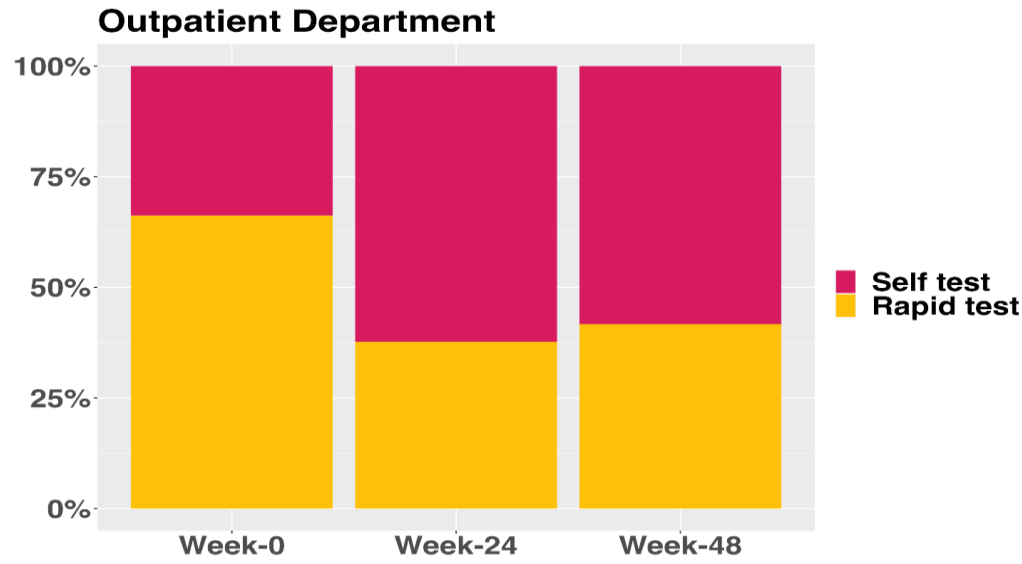
Community



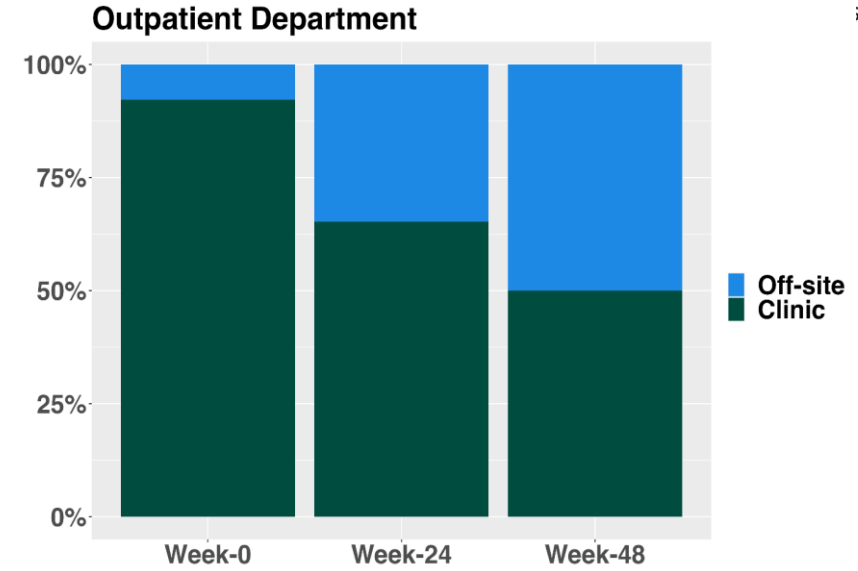
- 56% chose PrEP & 67% chose PEP at least once over 48 weeks
- More interest in PEP than women

Testing and location choice also varied

OPD

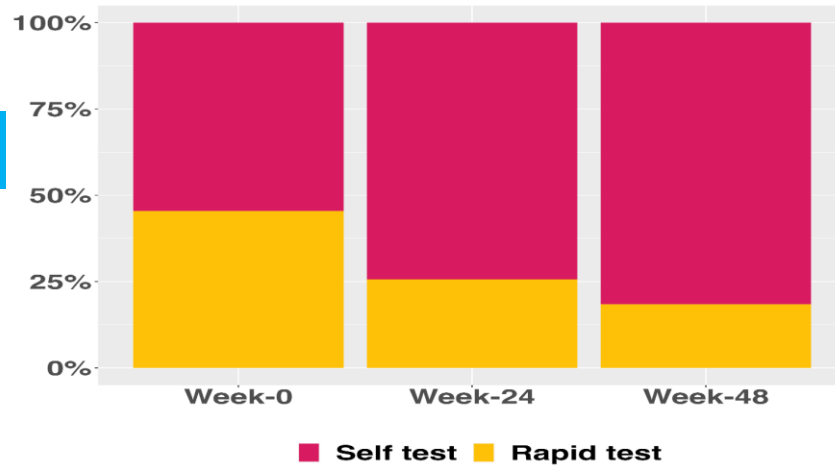


Choice in HIV self-testing increased from 34% to 58%

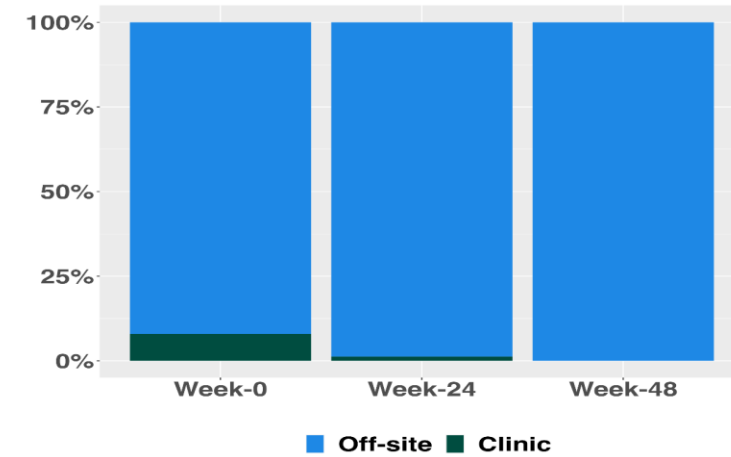


Choice of off-site visits increased from 8% to 50%

Community



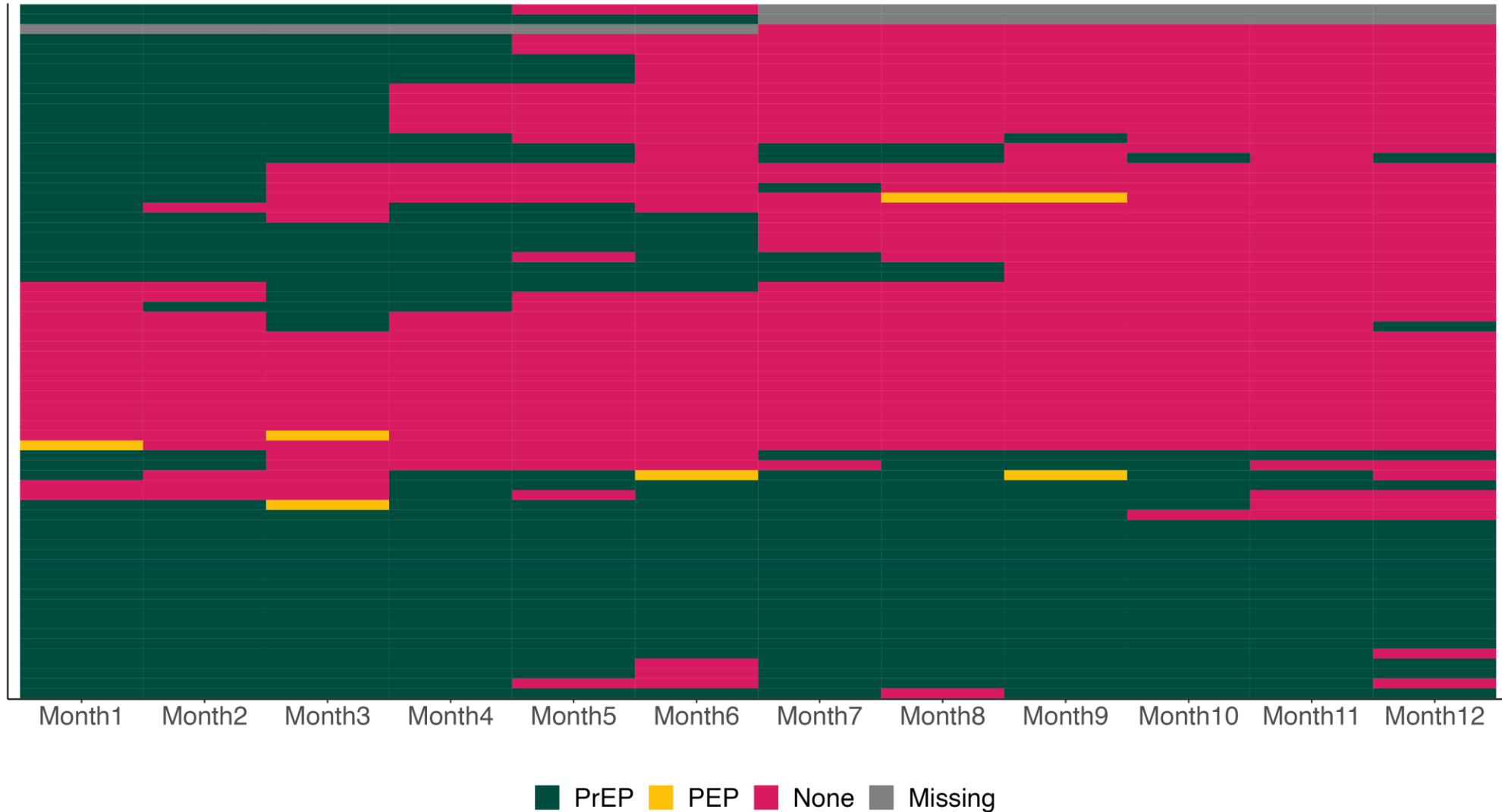
Self-testing was preferred to rapid testing



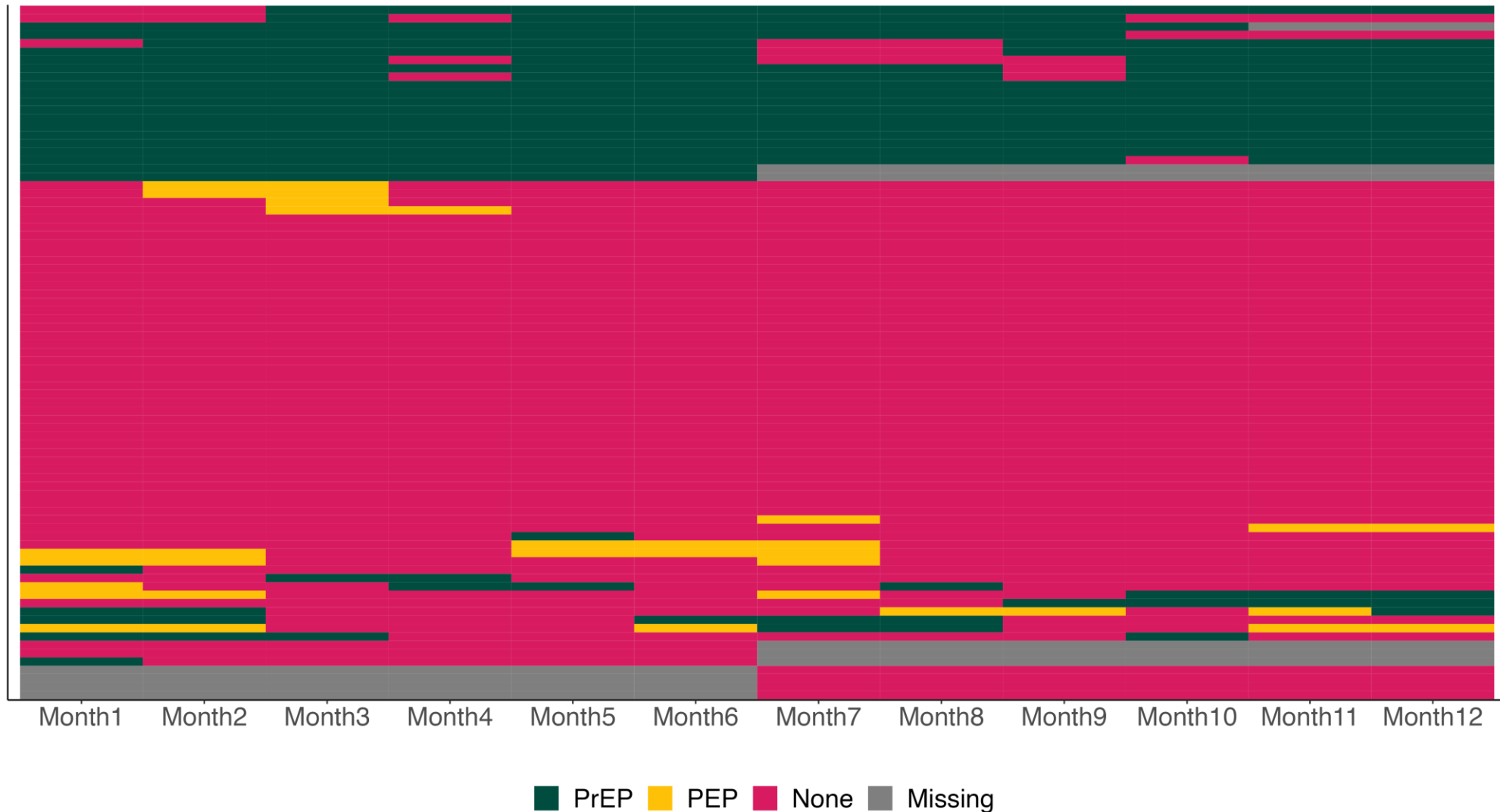
Nearly all men chose an **off-site location** at each visit

What biomedical prevention interventions did men actually use in the SEARCH study?

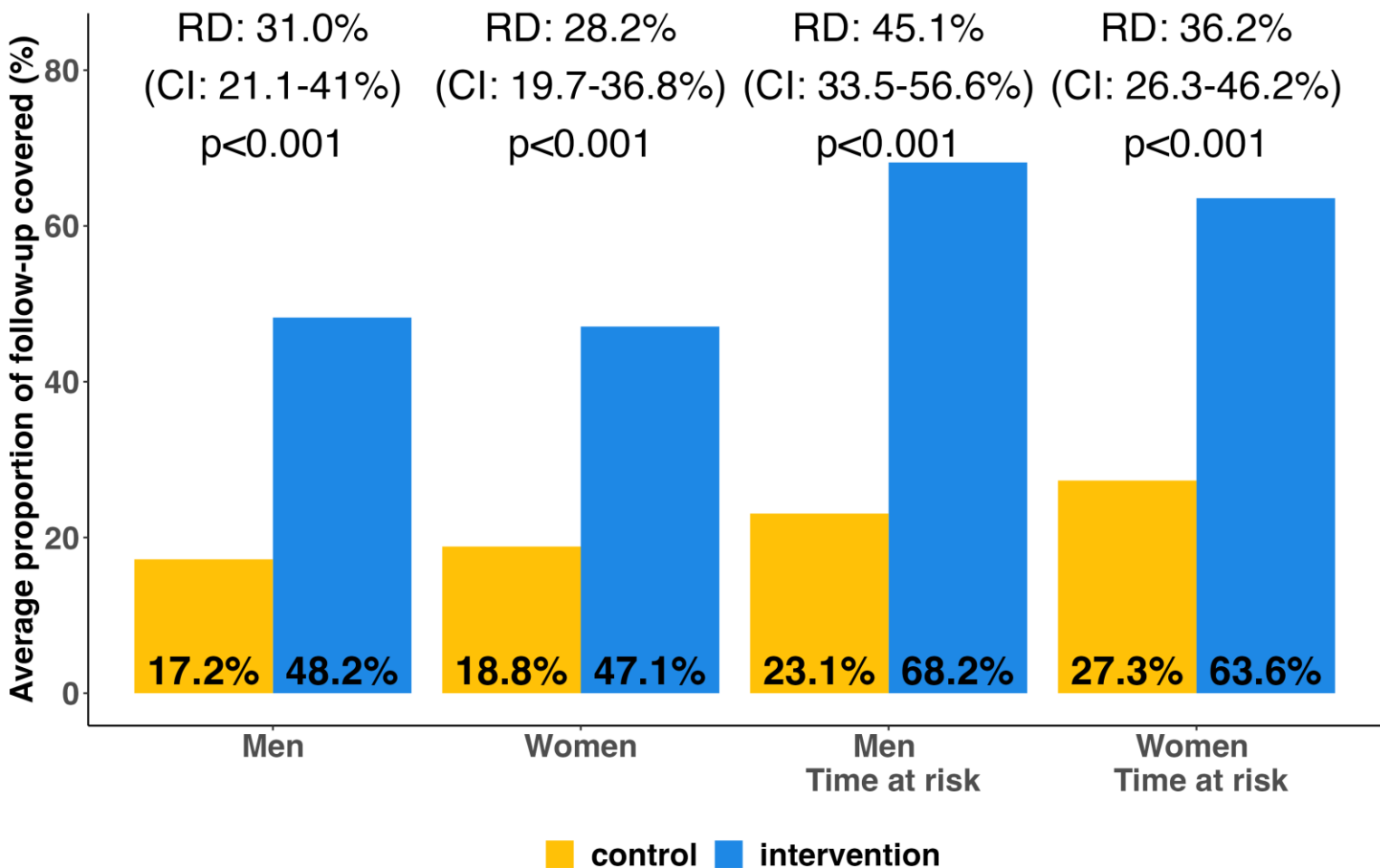
Biomedical coverage, showing PrEP and PEP use, among men in the Outpatient Department



Biomedical coverage, showing lower PrEP use and higher PEP use, in the community setting

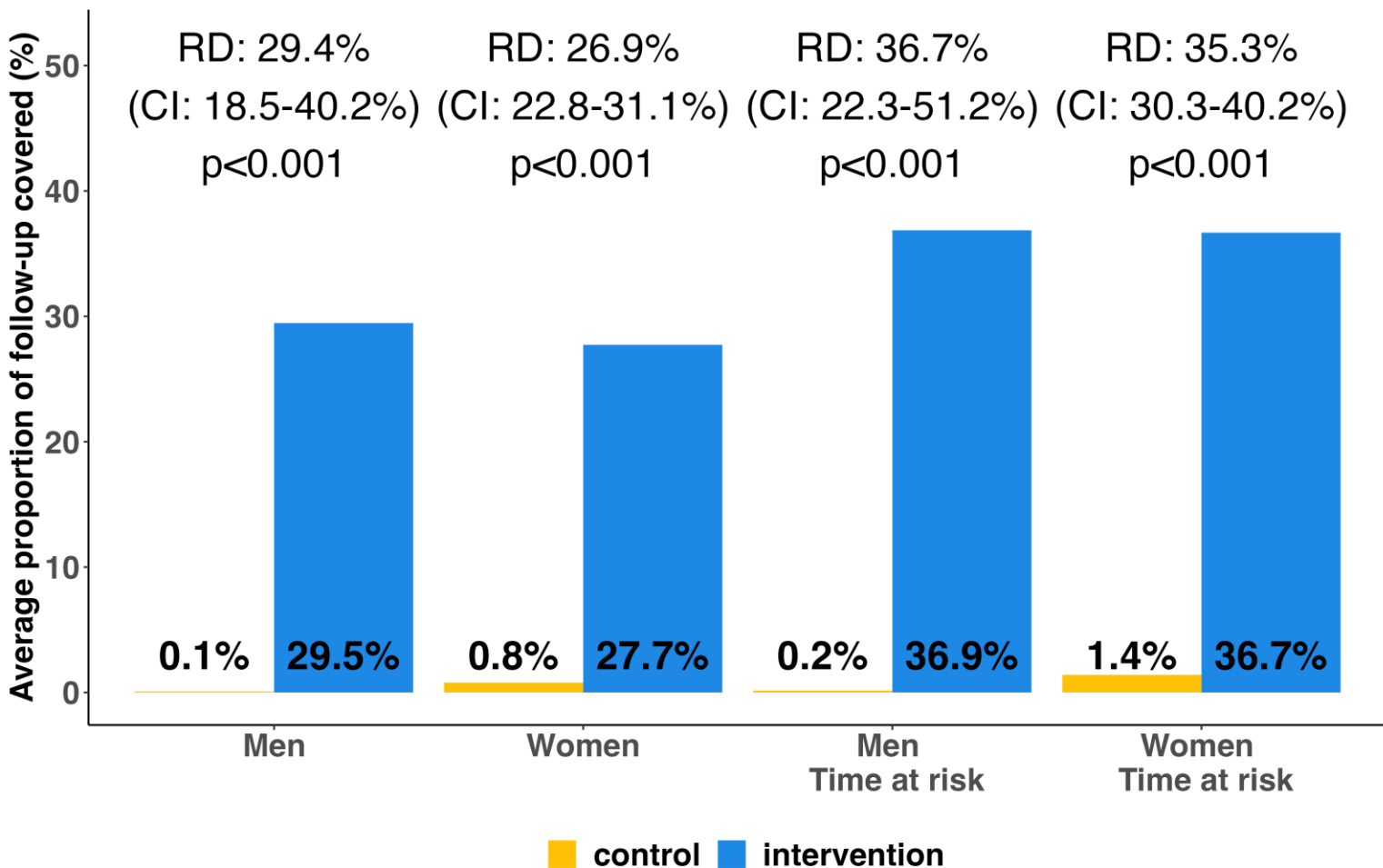


Results: Dynamic Choice intervention increased biomedical coverage in the Outpatient Department



- Among men, coverage was 48.2% in the intervention vs. 17.2% in the control for a 31.0.% increase
 - Slightly larger effect among men than women
- During periods of self-reported HIV risk, coverage was 68.2% in the intervention vs. 23.1% in the control for a 45.1.% increase
 - Again larger effect among men

Dynamic Choice intervention also increased biomedical coverage in the community



- Among control participants in the community, coverage was ~0%
- Among men, the intervention increased coverage by 29.4% overall and 36.7% during periods of HIV risk
- Similar but slightly smaller effects among women

Barriers and Enablers for men

Barriers to PrEP/PEP use

- Pill burden and size
- Fear of side effects
- Fear of being perceived as HIV+
- Fear of partner knowing
- Travel and/or being at school
- Forgetting to take pills

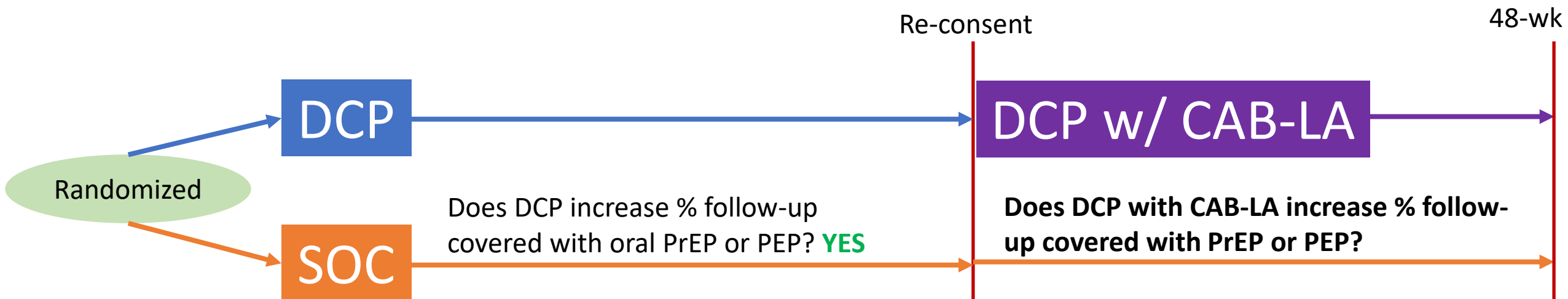
Enablers to PrEP and PEP use

- Clinic and peer education
- Patient centered, non-judgmental care
- Client choices prioritized and supported by providers even when there is ongoing risk and provider may think PrEP might be more effective
- Option to go on and off PEP
- Visit location choice to reduce stigma/IPV concerns
- Pill in pocket

Highlights: PrEP and PEP uptake with the Dynamic Choice HIV Prevention intervention

- Our DCP intervention increased prevention coverage by greater than two fold compared to standard of care among men
- Men embraced the opportunity to change strategies over time
- Uptake of biomedical prevention differed among men by the setting
- There is still a gap in coverage and need for additional options

CAB-LA extension to Dynamic Choice Trials



Summary

- Men with risk factors can and should be reached for prevention services in SSA
- SEARCH Dynamic choice prevention model with patient centered delivery model offered higher prevention coverage than SOC for men
- Men are interested in long acting CAB-LA and are initiating it.

Acknowledgements: Study Participants and Communities

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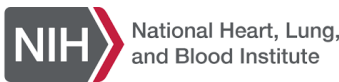
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And so many others on the SEARCH team!



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Other and Backup slides

Results: Characteristics of all participants

| | OPD | VHT | Overall |
|-------------------------------------------|-----------|-----------|-----------|
| N | N=403 | N=430 | N=833 |
| Female | 245 (61%) | 244 (57%) | 489 (59%) |
| Age 15-24 | 149 (37%) | 150 (35%) | 299 (36%) |
| Country | | | |
| -Kenyan | 201 (50%) | 210 (49%) | 411 (49%) |
| -Ugandan | 202 (50%) | 220 (51%) | 422 (51%) |
| Marital status | | | |
| -Single (Unmarried) | 108 (27%) | 114 (27%) | 222 (27%) |
| -Married/Cohabiting | 276 (69%) | 287 (67%) | 563 (68%) |
| -Divorced/separated/widowed | 17 (4%) | 29 (7%) | 46 (6%) |
| Occupation | | | |
| -Farmer | 152 (38%) | 169 (39%) | 321 (39%) |
| -Student | 56 (14%) | 74 (17%) | 130 (16%) |
| -Manual labor/construction | 20 (5%) | 37 (9%) | 57 (7%) |
| -Transportation | 21 (5%) | 8 (2%) | 29 (3%) |
| Partner HIV+/unknown in past 6mo | 353 (88%) | 235 (55%) | 588 (71%) |
| Alcohol use (any, prior 3mo) | 50 (12%) | 40 (9%) | 90 (11%) |
| Highly mobile (at least 1 night away/3mo) | 118 (30%) | 196 (49%) | 314 (39%) |
| Any PrEP in past 6mo | 24 (6%) | 5 (1%) | 29 (3%) |
| Any PEP in past 6mo | 9 (2%) | 2 (0%) | 11 (1%) |

SEARCH Post-Exposure Prophylaxis (PEP)



- SEARCH: multi-disciplinary, international research collaboration examining population-level approaches to reduce HIV incidence and improve Community Health in rural east Africa
- In SEARCH 1.0, we developed a PEP Delivery Model based on rationale that PEP was
 - Effective
 - Underutilized for HIV prevention
 - Useful for unplanned exposures
 - An entry point for PrEP
 - Added biomedical prevention options to current menu

Methods: PEP in SEARCH 1.0

- We conducted a pilot PEP study in five rural communities in Kenya and Uganda between December 2018 and May 2019
- Community sensitization, health leader and provider training
- PEP package: available 7 days/week; hotline; option for out-of-facility medication delivery



Results: PEP in SEARCH 1.0

1

- 124 people sought PEP
- **1/3** were male
- **1/4** were <25 years
- **41%** were fisherfolk

2

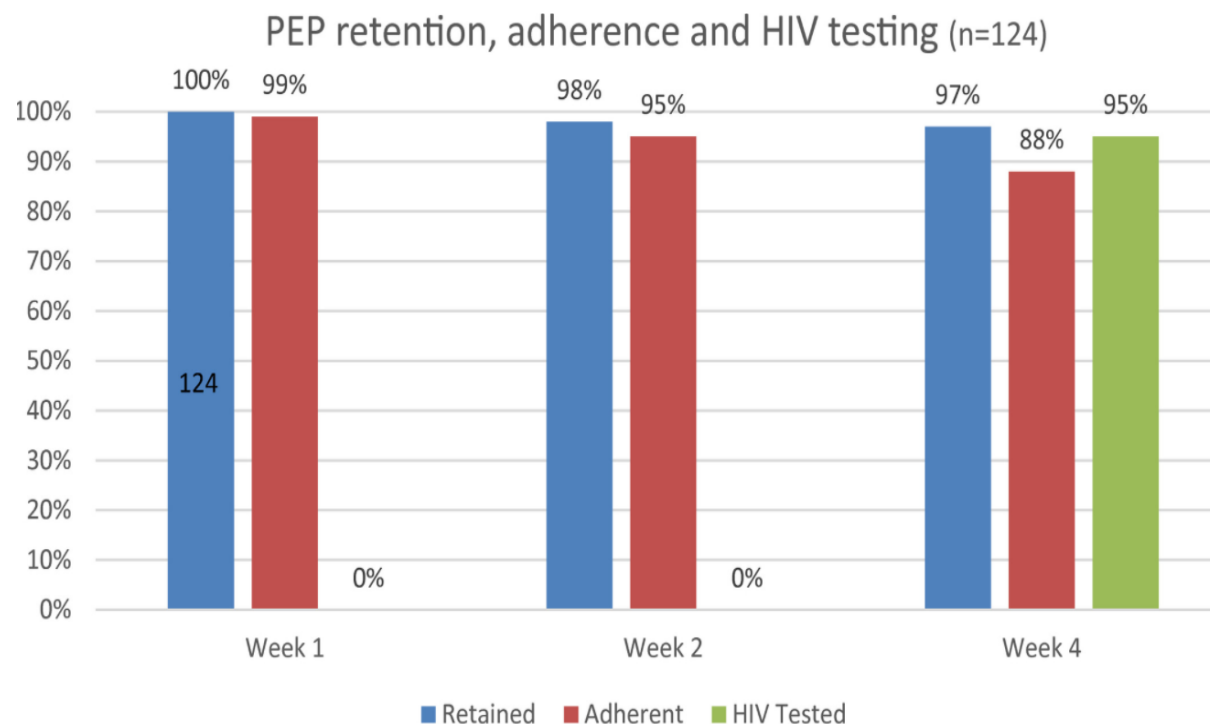
Exposures

- **20%** reported exposure with a **sero-different** partner
- **72%** with a **new** or **existing relationship**
- **7%** from **transactional sex**

Visits

- 12% of all visits conducted at out-of-facility sites
- 35% of participants had ≥ 1 out-of-facility visit.

3



4

No SAEs reported
No Seroconversions

SEARCH 2.0: Dynamic Choice HIV Prevention

- We evaluated **Dynamic Choice HIV Prevention** on biomedical HIV prevention coverage in rural Kenya and Uganda*
- In randomized pilot trials in 3 settings
- Here, we focus on PrEP and PEP uptake among men

| | N | Aged 15-24 | Men |
|--------------------------|----------|-------------------|------------|
| Antenatal clinics | 400 | 52% | 0% |
| Outpatient department | 403 | 37% | 59% |
| Out-of-clinic, community | 429 | 35% | 43% |

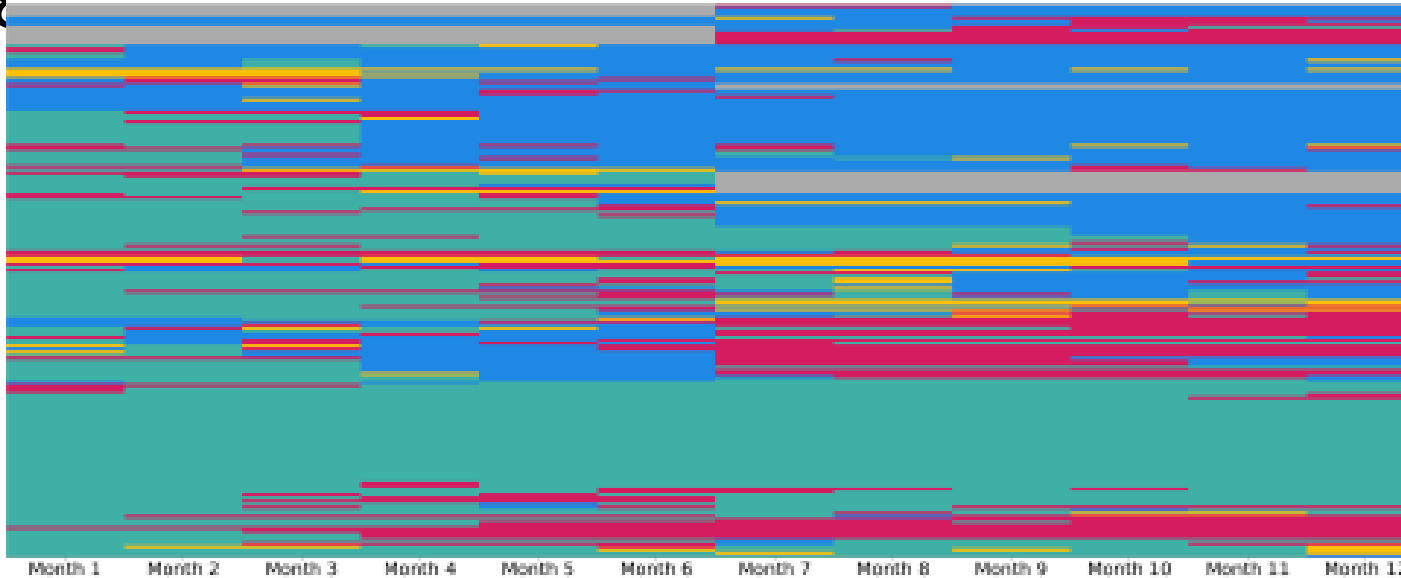
*Presented at CROI2023: Kabami et al. Randomized trial of dynamic choice HIV prevention in ante/postnatal care clinics (Abstract128);
Koss et al. Randomized trial of dynamic choice prevention at outpatient department in East Africa (Abstract975);
Kakande et al. Randomized trial of community health worker delivered dynamic choice HIV prevention. (Abstract124)

Results outline

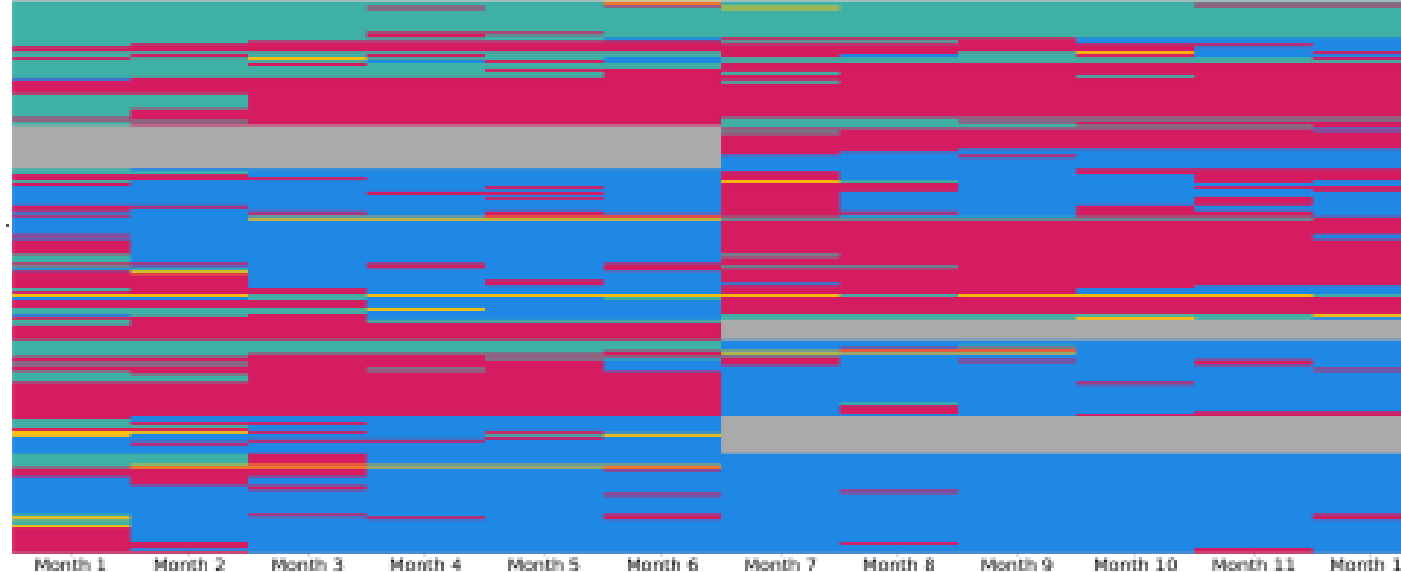
- Table1 – baseline characteristics - who are the men?
- Product choice
 - In OPD – vary over time – similarities to women
 - In VHT – vary by setting (compare OPD to VHT)
- Testing and location choice -
 - As above
- Summary – lead into uptake
- Summary of uptake – both PrEP AND PEP
- OPD heatmap of USE overtime
- VHT heatmap of USE overtime
- Primary endpoint: overall by sex on biomedical covered time
- Barriers and enablers

OPD – combined by {

4a. DCP intervention



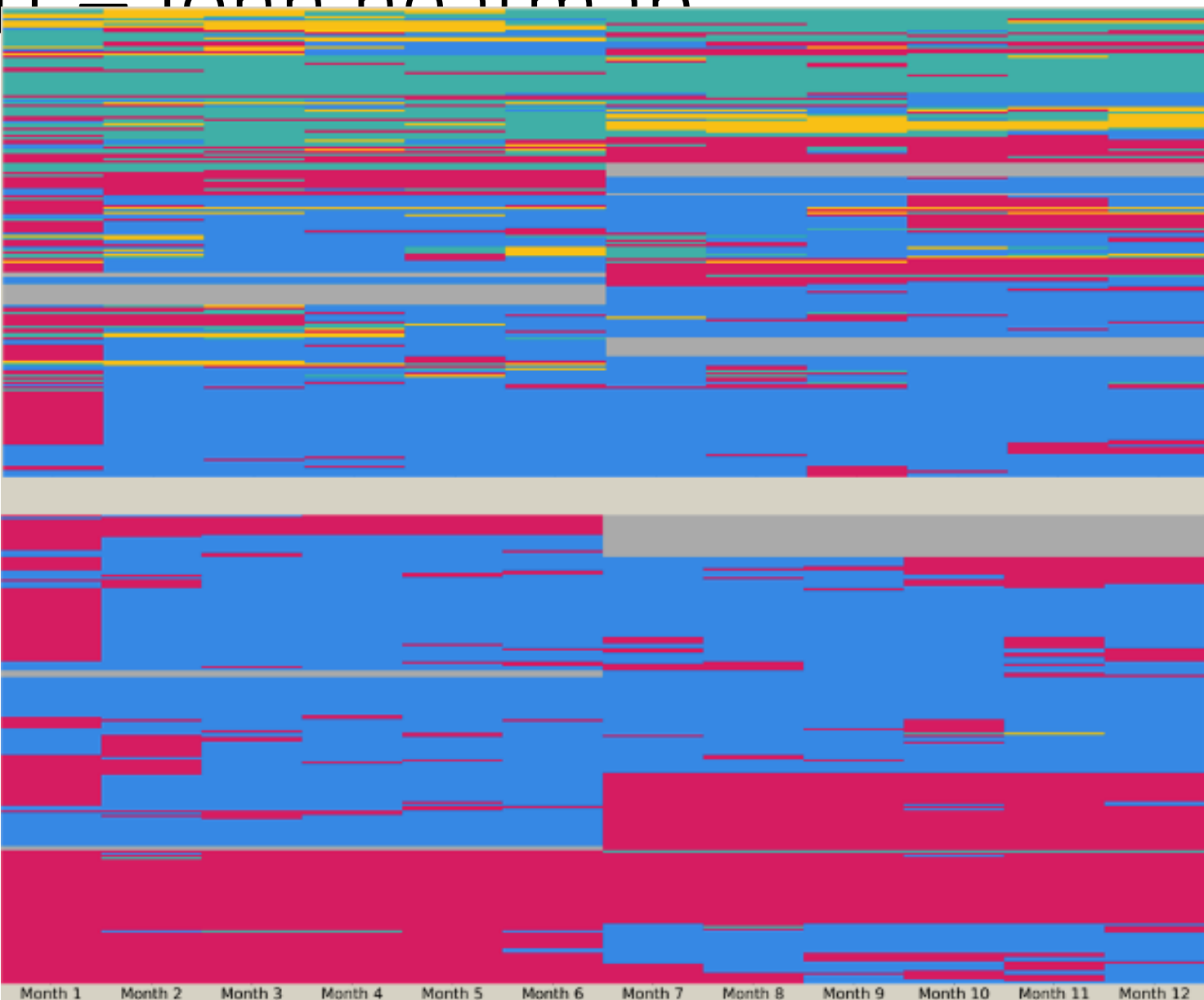
4b. Standard of care



VHT – John boatman

Intervention

Control



- Risk, PrEP/PEP
- Risk, No PrEP/PEP
- No Risk, PrEP/PEP
- No Risk, No PrEP/PEP
- Missing

Month 1 Month 2 Month 3 Month 4 Month 5 Month 6 Month 7 Month 8 Month 9 Month 10 Month 11 Month 12

Summary & Conclusions

- PEP was successfully incorporated into a Dynamic Choice HIV Prevention Model, delivered from the clinic and in the community
 - Persons at HIV risk both chose PEP (pill in pocket) and used PEP during the 1 year follow-up
 - Clients went both from PEP to PrEP and from PrEP to PEP
 - Clients preferred out of clinic PEP delivery
- Including a PEP option increased the biomedical prevention coverage in the SEARCH Dynamic Choice Prevention Model*
- Recommendations to expand PEP use should provide guidance on overcoming barriers
- SEARCH is now adding CAB-LA to the Dynamic Prevention Choice Model in a continuation of the 3 randomized trials and will be studying on a population-level in community randomized trial in Phase B