

Reaching men with pharmacy-based HIV PrEP delivery in Kenya

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Background

- In many African settings, HIV pre-exposure prophylaxis (PrEP) is primarily delivered at healthcare facilities, with quarterly clinic visits for HIV testing prior to PrEP refills.
- In these settings, men often engage less with facility-based HIV services compared to women (who often access facilities for family planning and antenatal care services).
 - *This often results in men less likely to access preventive services, more likely to present with late-stage HIV (resulting in higher mortality), and more likely to drop out of HIV care services*
- Differentiated, community-based models of HIV service delivery that operate outside healthcare facilities might be better suited for reaching men
 - In these settings, men often have economic power and can potentially pay for HIV services outside the public sector
 - Private, retail pharmacies are ubiquitous in many African settings and have been underutilized for HIV service delivery; delivering HIV services here might help reach men.

Potential of pharmacy-delivered PrEP services

In many African settings:

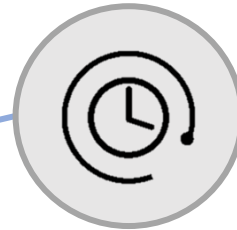


PrEP initiation & continuation
at a public HIV clinic



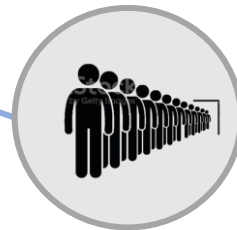
Stigma

Associated with visiting HIV clinics when HIV uninfected



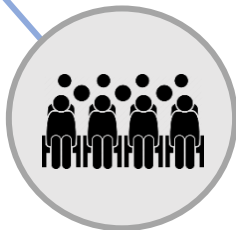
Limited hours of operation

Especially challenging for workers



Long wait times & travel distance

Associated with overcrowding, multiple PrEP stops, and limited PrEP clinics



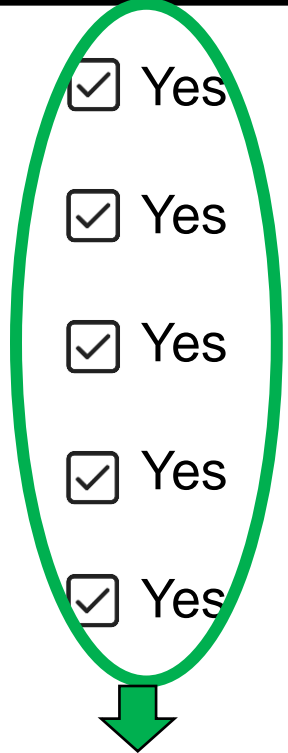
Lack of privacy

Associated with overcrowding and HIV-specific health service provision

Design of a pharmacy PrEP delivery model

- Collaboratively developed with Kenyan stakeholders in a one-day meeting (Jan 2020)
- Model informed by formative qualitative research and adapted from a model of pharmacy-delivered PrEP services ongoing in Seattle, USA (One-Step PrEP)
- Pharmacy providers deliver PrEP using a prescribing checklist overseen by a remote clinician; this checklist includes:
 - *HIV risk assessment; assessment of PrEP safety/medical eligibility; HIV testing; PrEP dispensing; referral (when necessary)*

Prescribing Checklist (simplified)		
At HIV risk?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
No recent HIV exposure?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
No contraindications?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Confirmed HIV-negative?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Counseled on adherence?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No


Prescribe and dispense PrEP

Pilot studies in Kenya



**Clinic-initiated PrEP w/
pharmacy provider-
delivered refills**

(CFAR NIA; PI: Ortblad)



**Pharmacy provider-
delivered PrEP
initiation & refills**

(NIMH R34; PI: Ortblad)

Pharmacy PrEP refill (PPR) pilot in Kenya

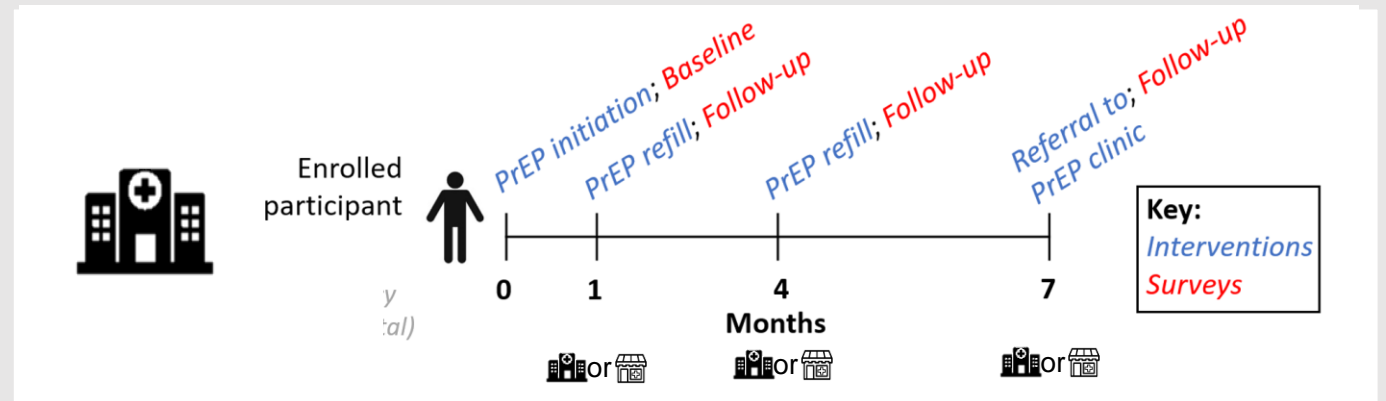


Thika, Kenya: 2 retail pharmacies,
2 public clinics



Study procedures:

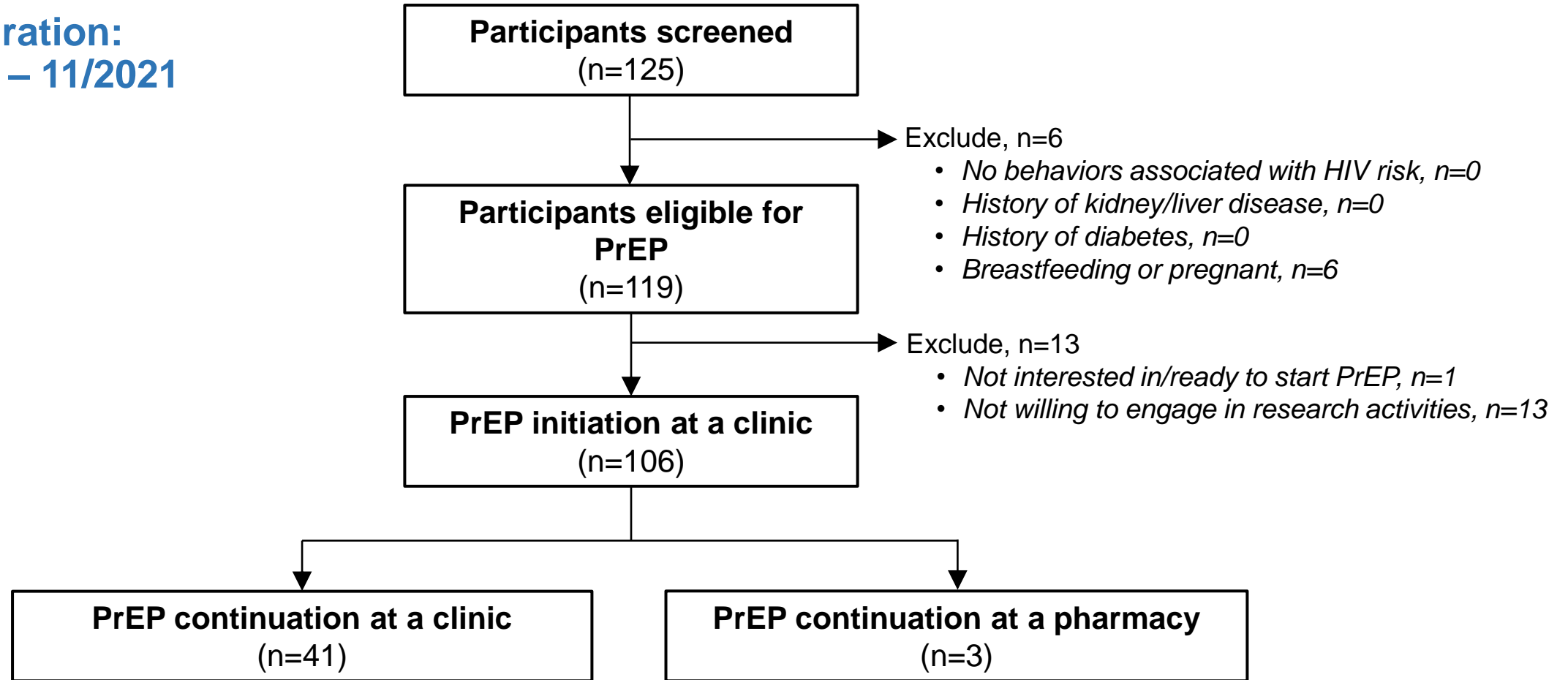
- Clients initiate PrEP at a public HIV clinic with option for PrEP refills at:
 - At the same public clinic
 - At one of two nearby pharmacies
- Pharmacies: licensed, trained on PrEP delivery, & have private room
- Eligible clients: >18 years, at HIV risk, & meet all eligibility on PrEP prescribing checklist
- Cost: 300 KSH (~\$3 USD) per visit at pharmacy, free at clinics



PPR: study participants



Pilot duration:
11/2020 – 11/2021



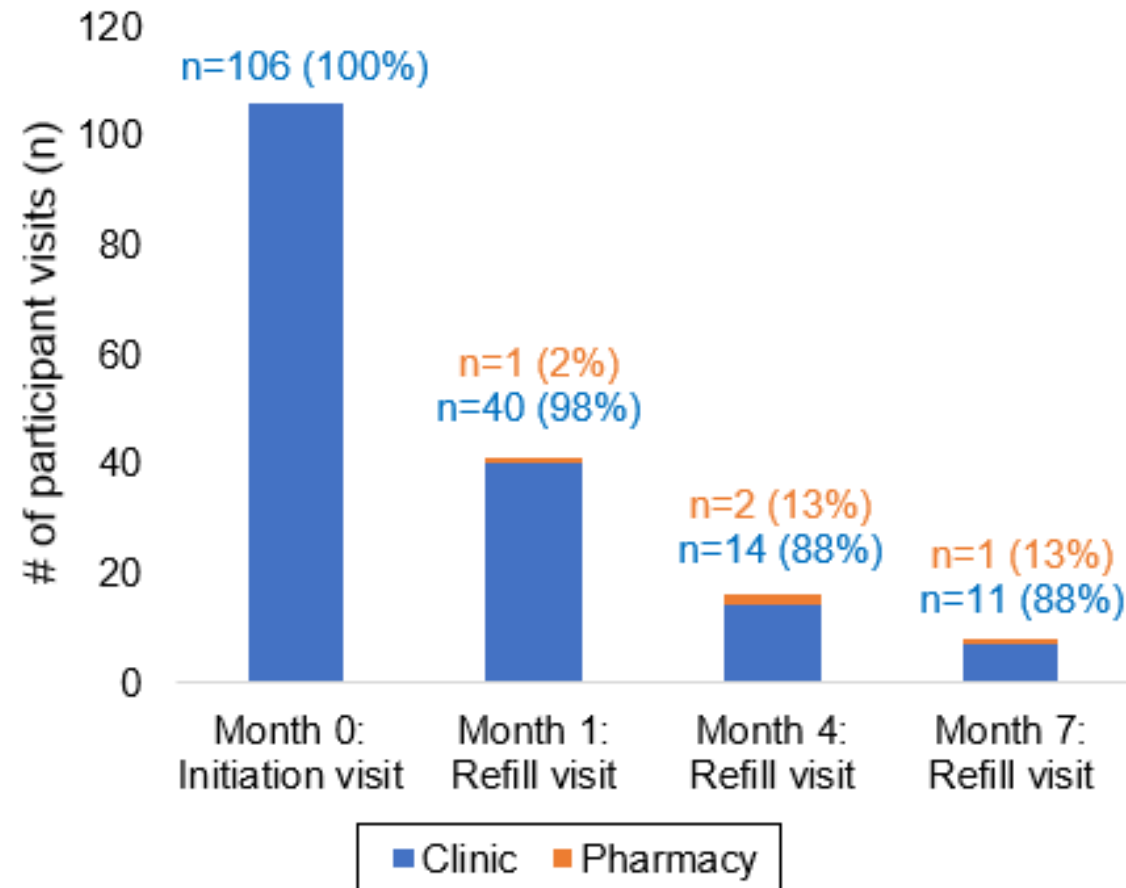
41% (n=43) men

88% (n=38) men ≥25 years old

PPR: PrEP initiation & continuation



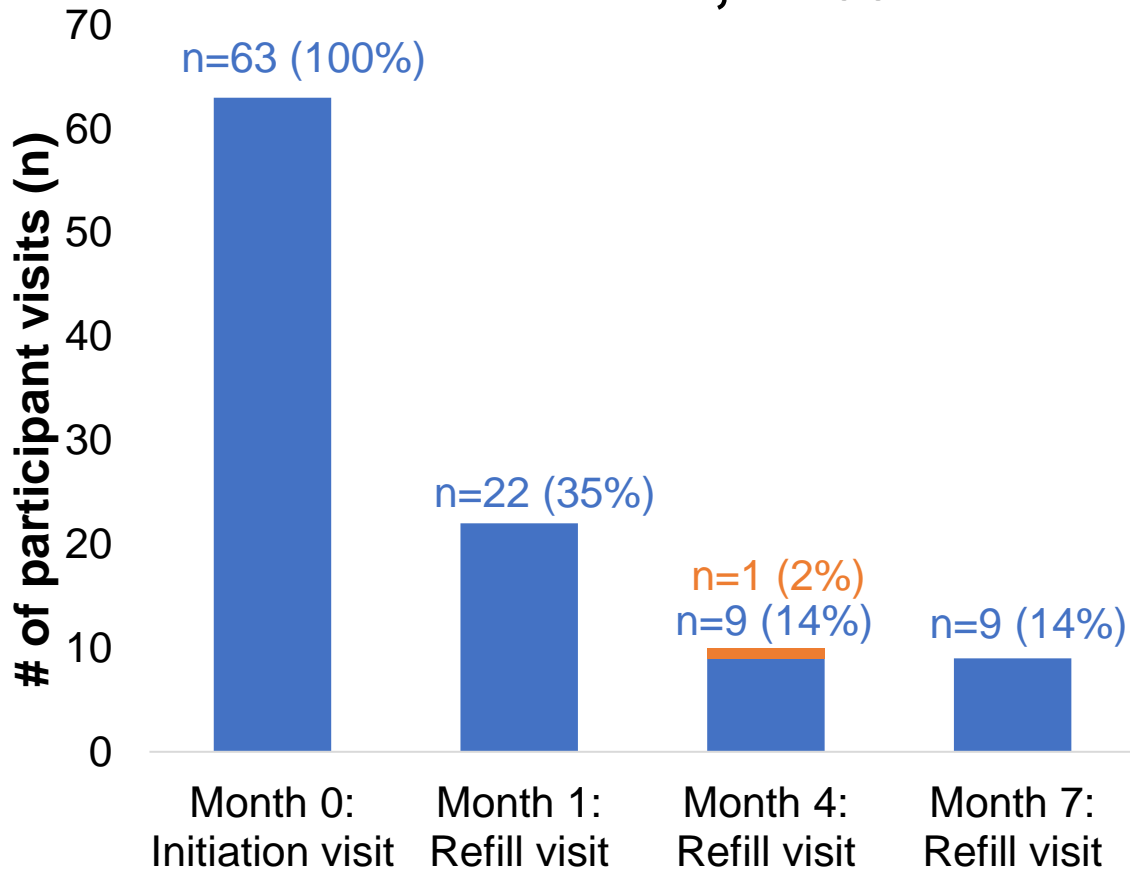
All participants, n=106



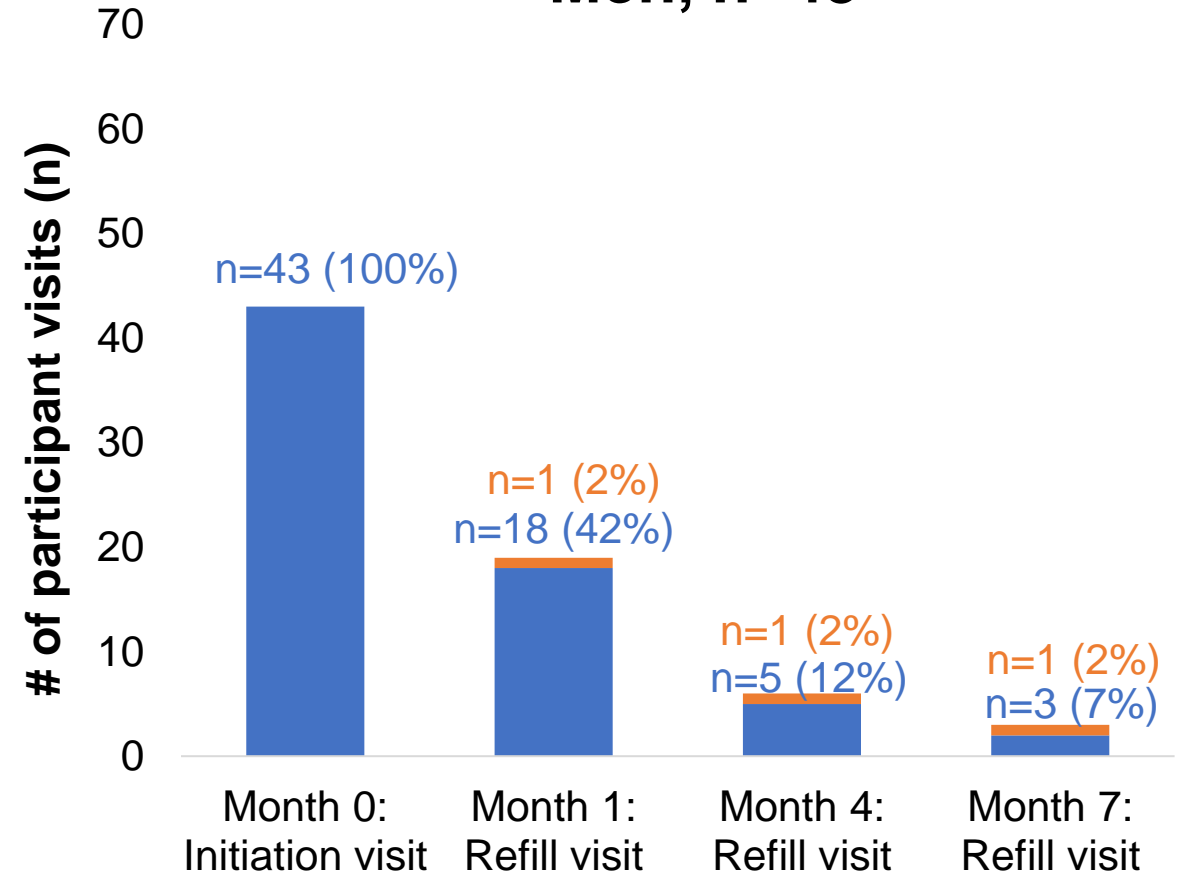
PPR: PrEP initiation & continuation, by sex



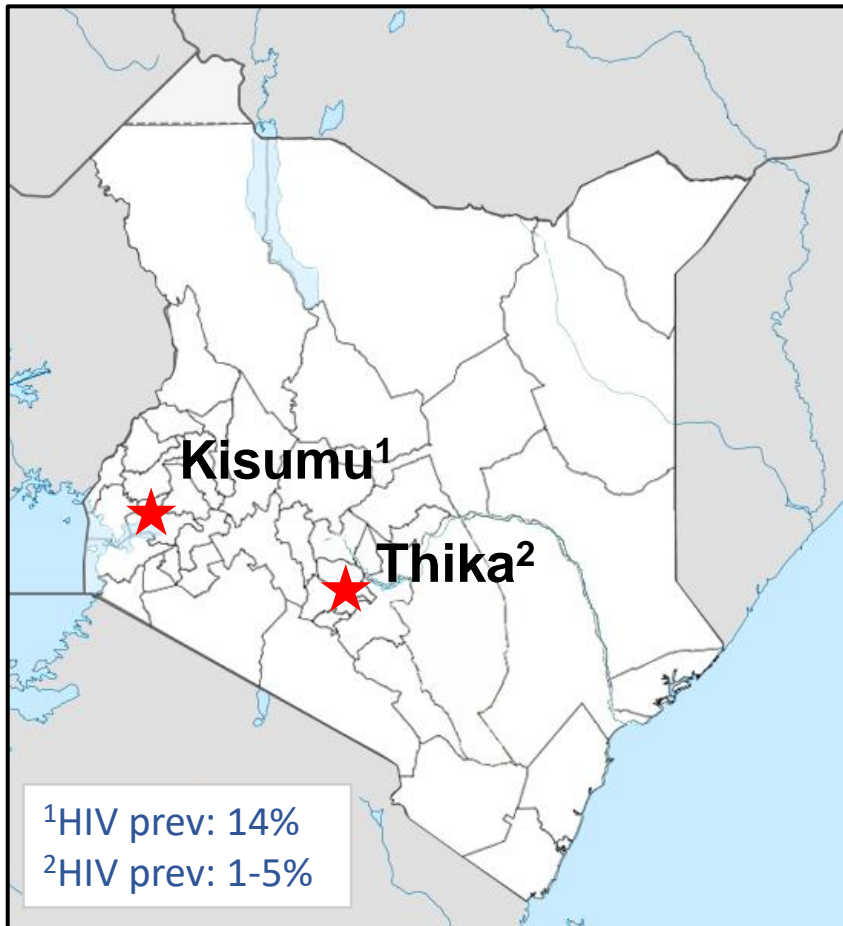
Women, n=63



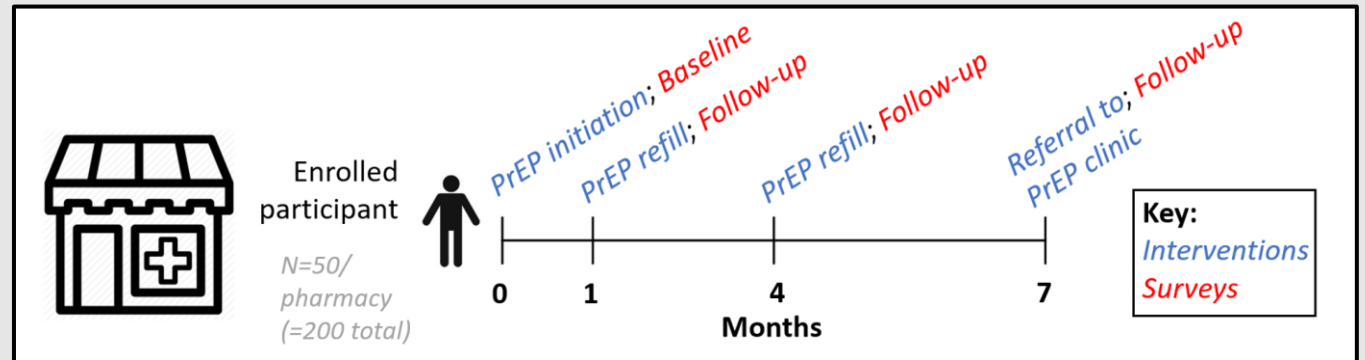
Men, n=43



Pharmacy PrEP initiation (PPI) pilot in Kenya

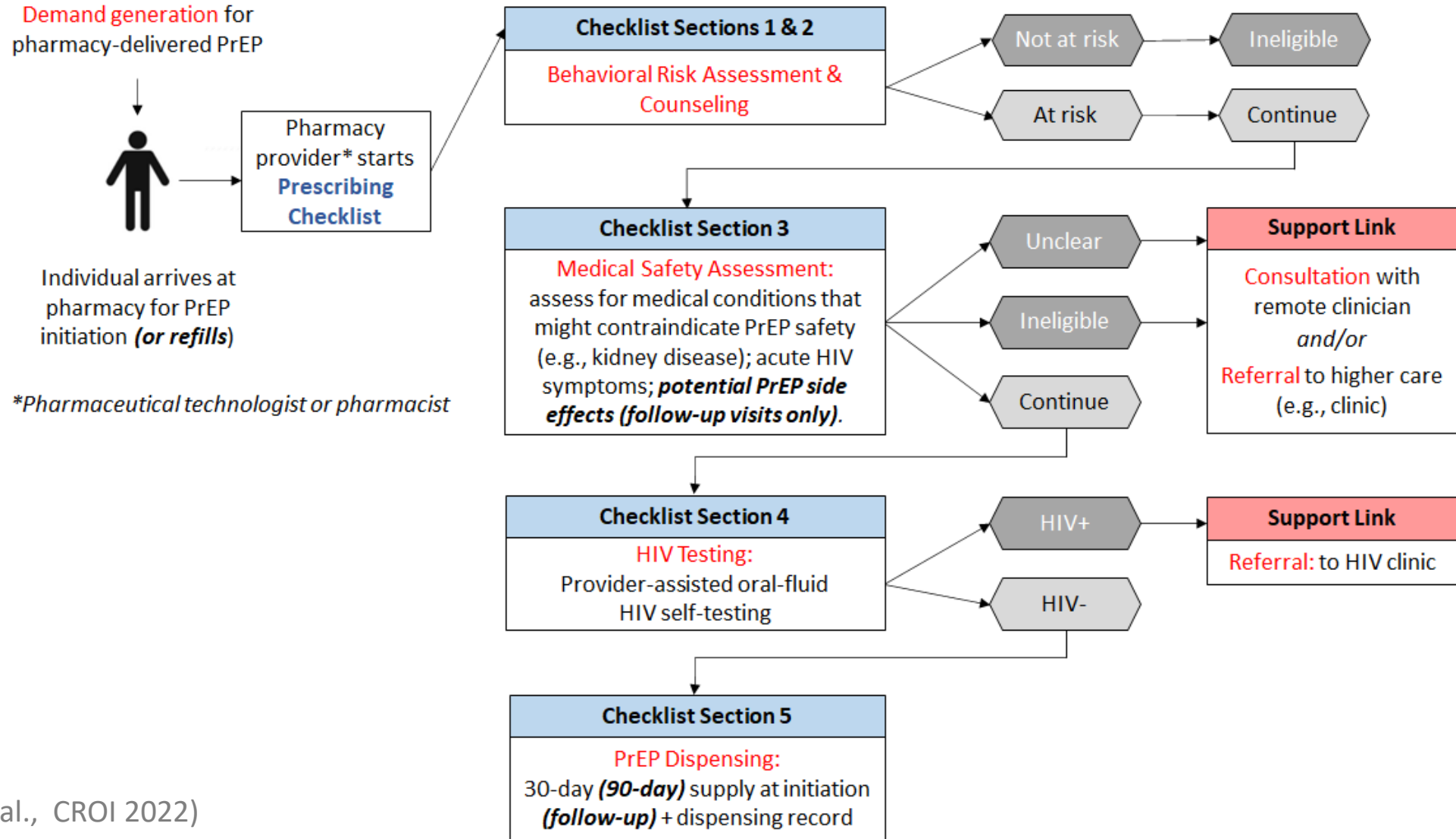


Thika, Kenya: 2 retail pharmacies
Kisumu, Kenya: 2 retail pharmacies



- Pharmacies: must be licensed, certified to deliver provider-assisted HIVST, & have private room
- Eligible clients: >18 years, at HIV risk, & meet all eligibility on PrEP prescribing checklist
- Recruitment: posters, pharmacy providers, word-of-mouth
- Cost: 300 KSH (~\$3 USD) for each pharmacy PrEP visit

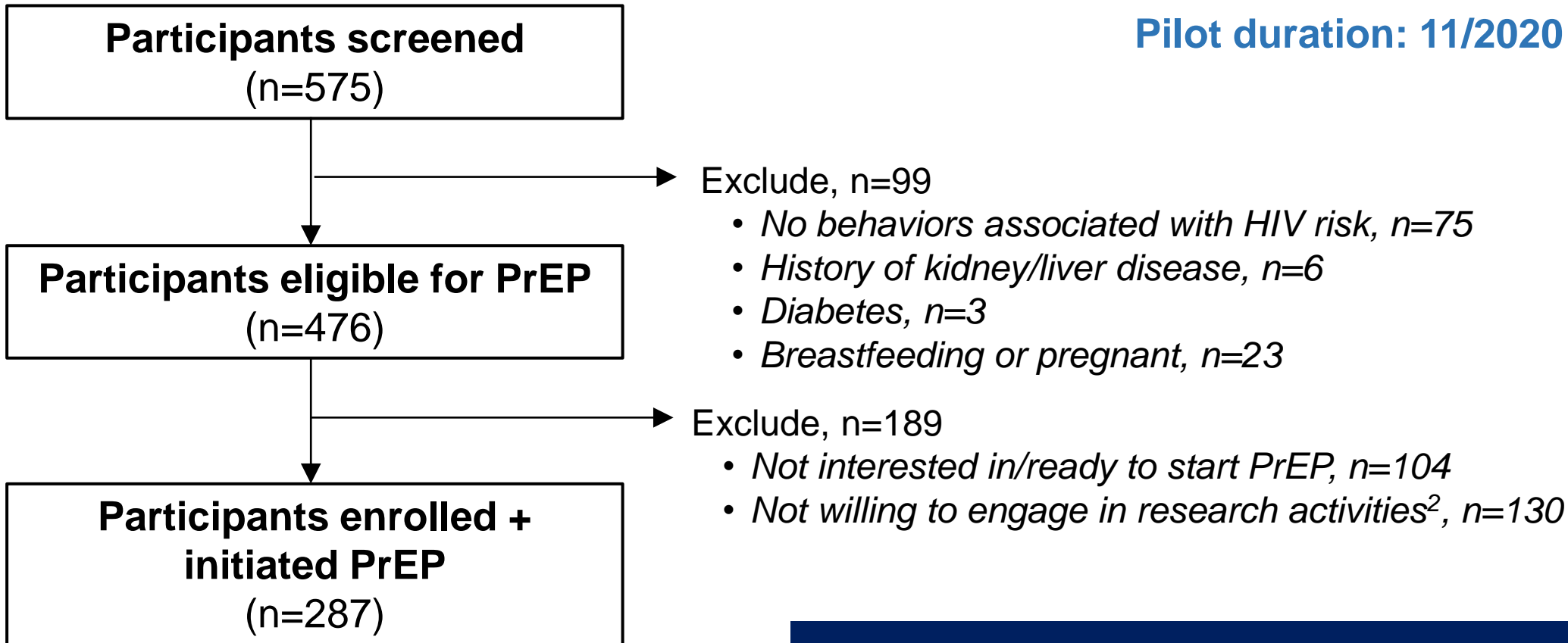
PPI: Care pathway for pharmacy PrEP delivery



PPI: Study participants



Pilot duration: 11/2020 – 10/2021

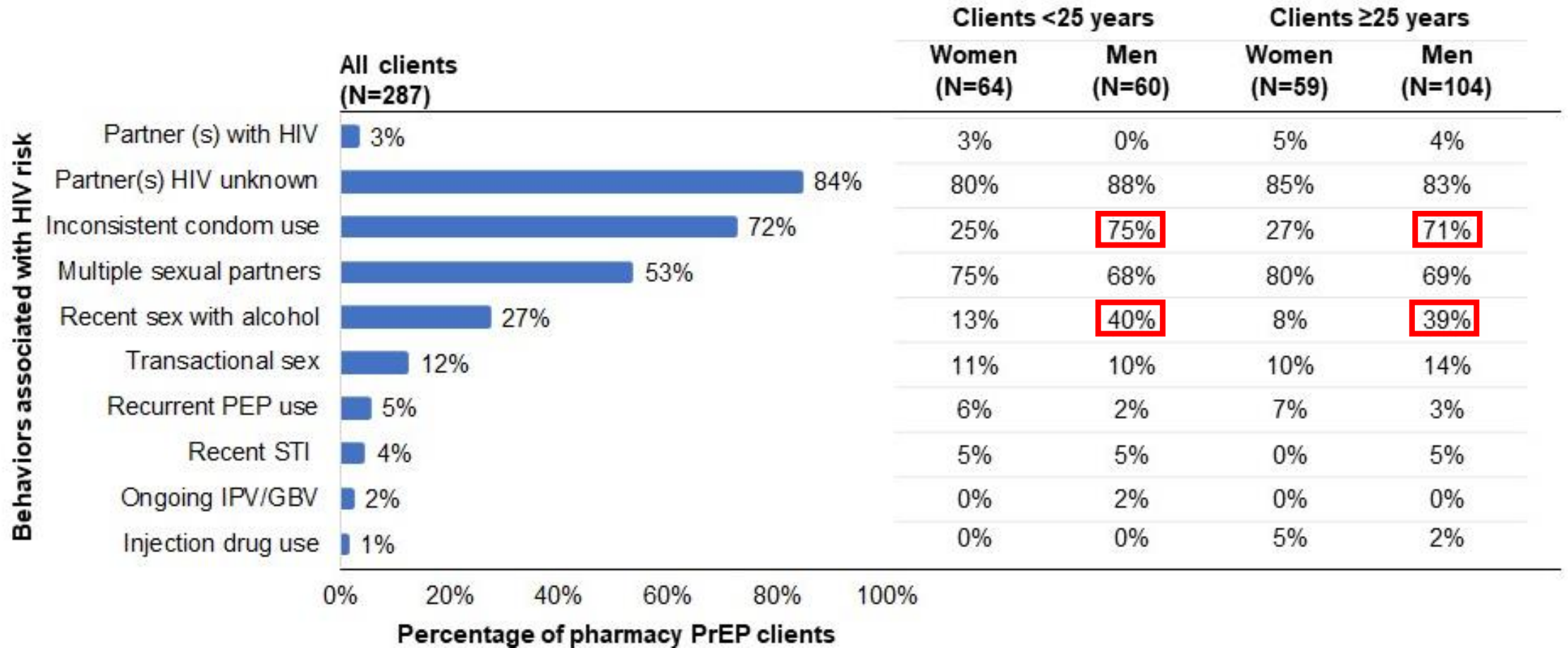


57% (n=164) men
63% (n=104) men ≥25 years old

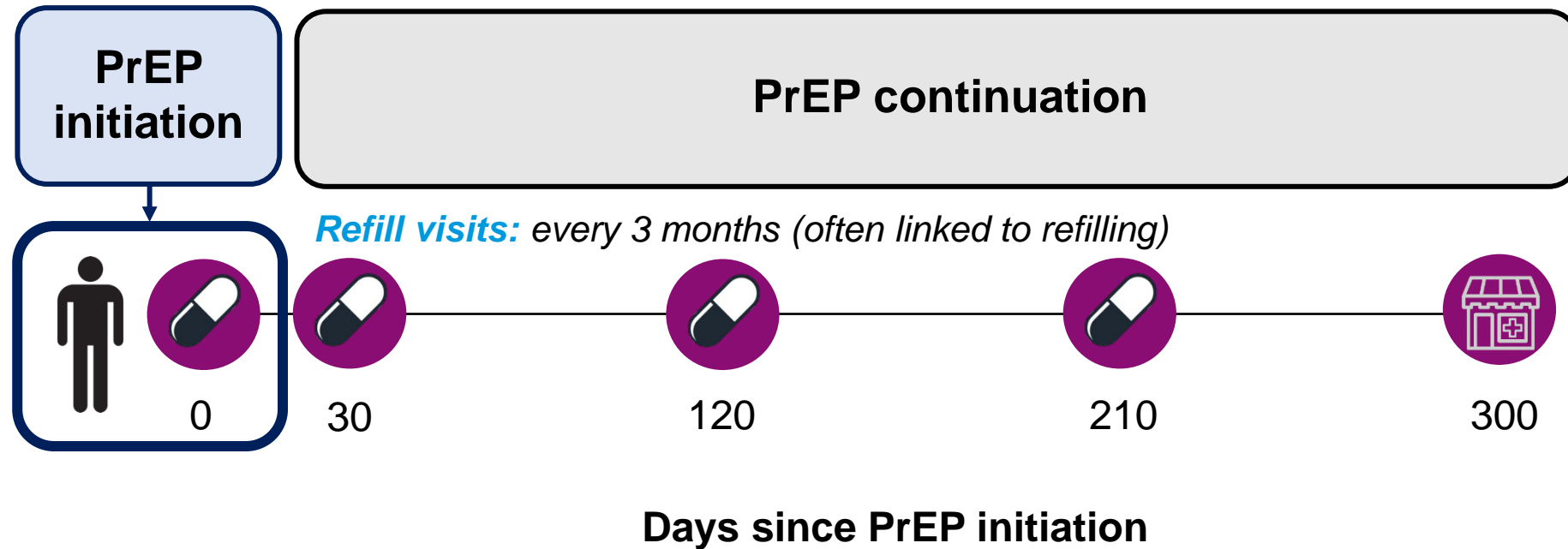


Compared to clinic-delivered PrEP services
(Partners Scale-Up)
46% (n=2258/4898 enrolled) men

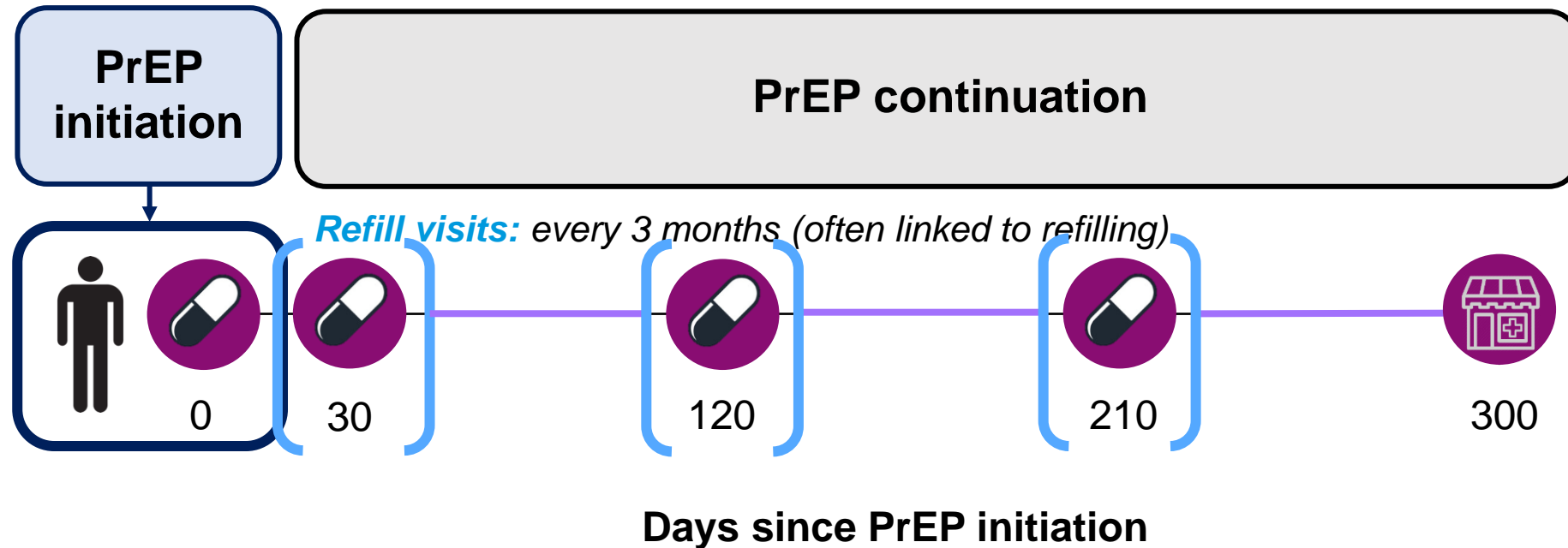
PPI: Client behaviors associated with HIV risk



PPI: Definition of study outcomes



PPI: Definition of study outcomes



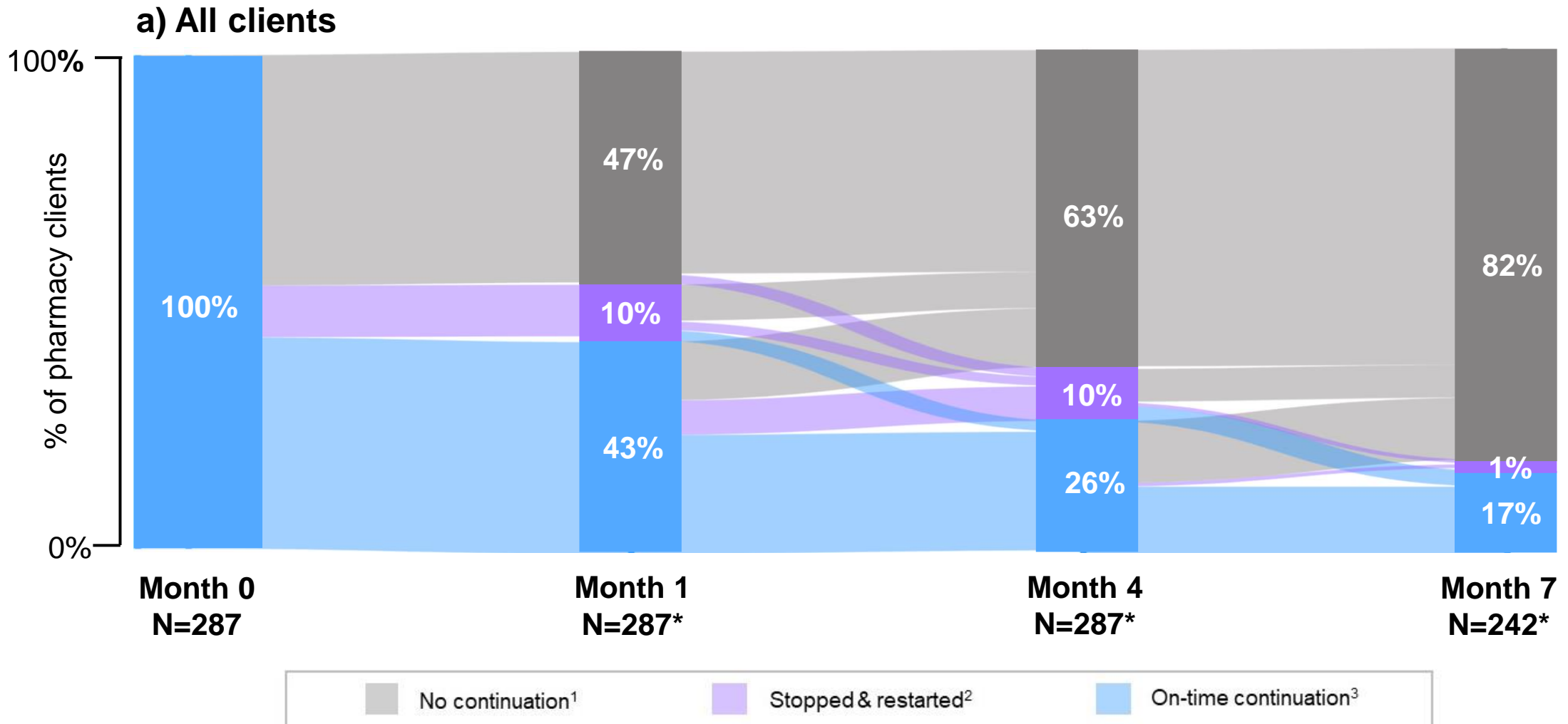
On-time continuation:

Refilling PrEP no more than 15 days after a scheduled visit

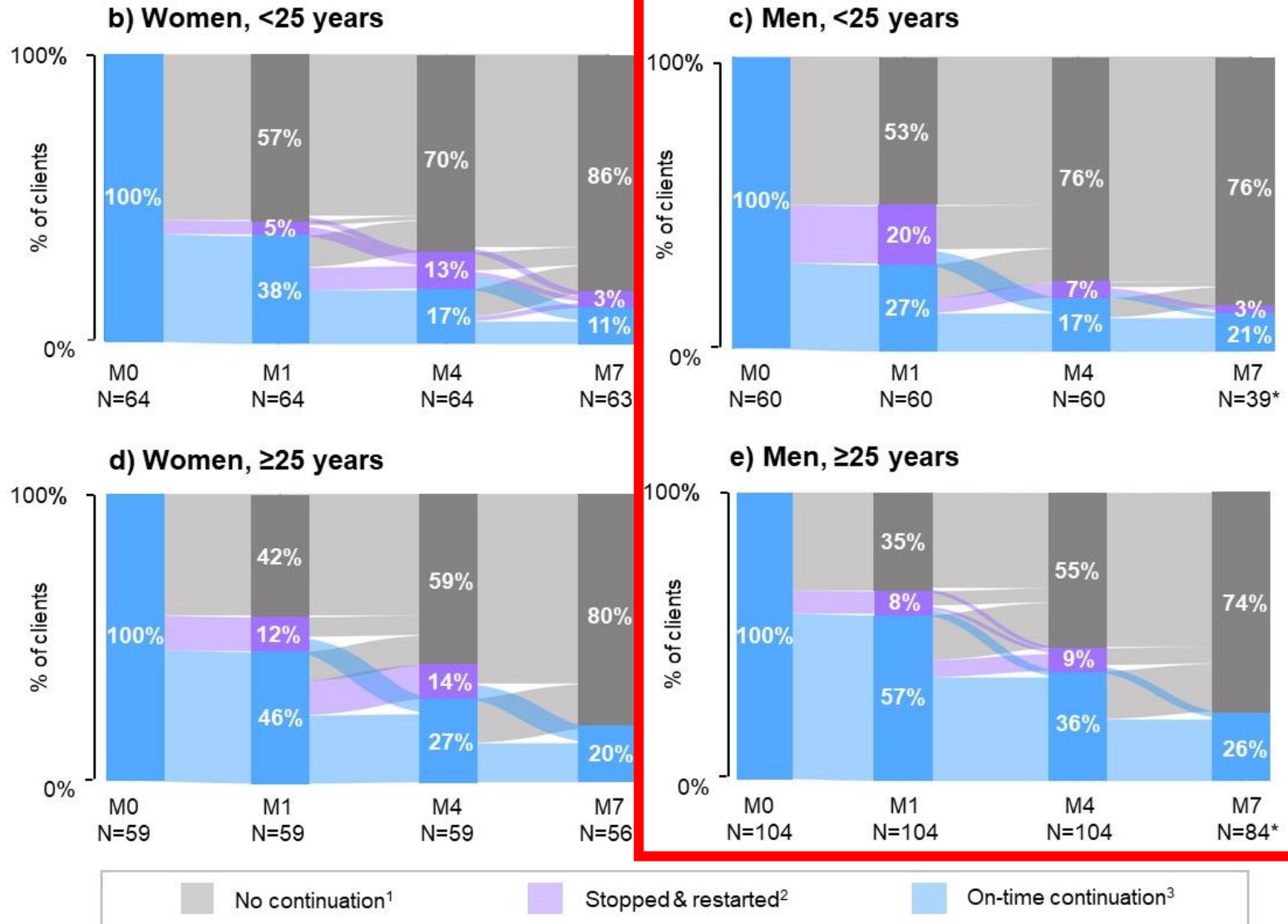
Stopping and restarting PrEP:

Refilling PrEP >15 days after a scheduled visit

PPI: PrEP initiation & continuation



PPI: PrEP initiation & continuation, by sex/age



(Ortblad KF, et. al., CROI 2022)

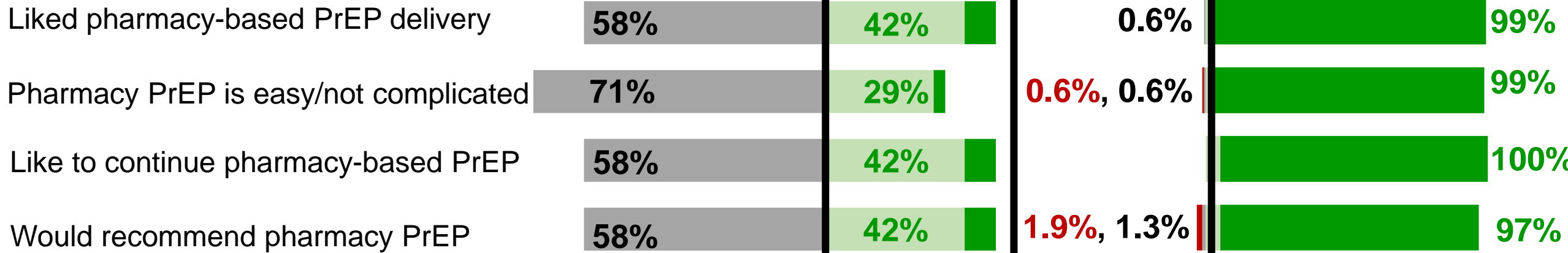
Acceptability of pharmacy-based PrEP



Both men and women

Pharmacy-PrEP refill pilot

Pharmacy-PrEP initiation pilot



Percentage of pharmacy clients

Strongly disagree

Disagree

Neither agree nor disagree

Agree

Strongly agree

Acceptability of pharmacy-based PrEP



Amongst men

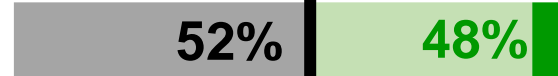
Pharmacy-PrEP refill pilot

Pharmacy-PrEP initiation pilot

Liked pharmacy-based PrEP delivery



Pharmacy PrEP is easy/not complicated



Like to continue pharmacy-based PrEP



Would recommend pharmacy PrEP



Percentage of pharmacy clients

Strongly disagree

Disagree

Neither agree nor disagree

Agree

Strongly agree

Willingness to pay (KES)



	Pharmacy PrEP Refill (PPR) (N=106)		Pharmacy PrEP Initiation (PPI) (N=287)	
% Clients willing to pay anything	88 (83%)		277 (97%)	
Women	N=57/63 (90%)		N=120/123 (98%)	
Men	N=31/43 (72%)		N=157/164 (96%)	
Amount willing to pay (KES)	Median (IQR)	Mean (STD)	Median (IQR)	Mean (STD)
Women	200 (100-300)	228 (173)	300 (200-400)	354 (309)
Men	300 (175-400)	282 (133)	300 (200-500)	354 (308)

Willingness to pay (USD)



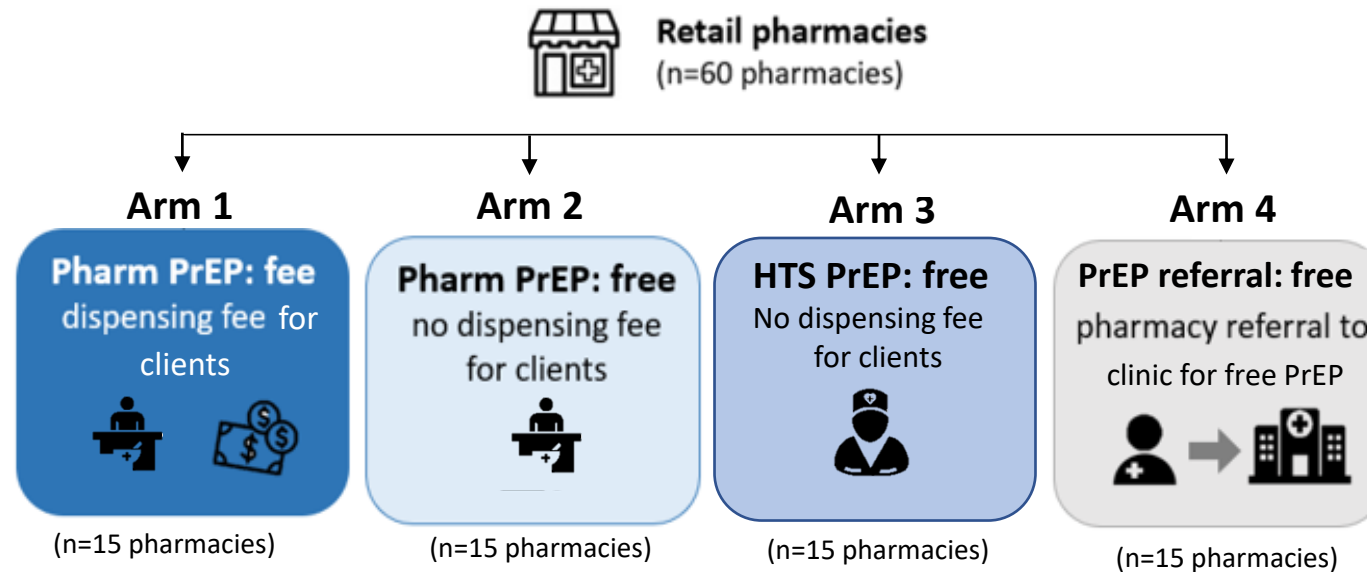
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Men	N=31/43 (72%)		N=157/164 (96%)	
Amount willing to pay (USD)	Median (IQR)	Mean (STD)	Median (IQR)	Mean (STD)
Women	1.81 (0.90-2.71)	2.06 (1.56)	2.71 (1.81-3.61)	3.20 (2.79)
Men	2.71 (1.58-3.61)	2.55 (1.20)	2.71 (1.81-4.52)	3.20 (2.78)

Summary of findings

- Clients that initiate PrEP at clinics may have already overcome barriers to PrEP access there and prefer refilling PrEP at clinics; stressing the **need for stand-alone models of pharmacy-delivered PrEP services to reach new populations.**
- A standalone model of pharmacy-based PrEP delivery **reached men who could benefit from PrEP services**, as indicated by their high prevalence of recent behaviors associated with risk of HIV acquisition.
- A standalone model of pharmacy-delivered PrEP services resulted in **high PrEP continuation among older men (≥ 25 years old)**; continuation that exceeds that often seen at public clinics.
- Pharmacy-delivered PrEP services were **acceptable**, and clients were **willing to pay.**
- Barriers to scale-up include lack of evidence on **effectiveness**, **costs** associated with delivery, and **regulatory barriers** surrounding HIVST for prescribing (research ongoing).

Future research: cRCT trial

- A four-arm cluster-randomized controlled trial (cRCT) testing different models of cost sharing to support pharmacy-delivered PrEP services in Kenya
- Trial enrollment begins May 2023!



Thank you!

Acknowledgements:

Participating providers and clients, research assistants, Kenya National AIDS & STI Control Program (NASCO), Kenya Pharmacy and Poisons Board (PPB)

Fundings:

- National Institute for Mental Health (R34MH120106, **PI: K Ortblad**; P30 AI027757, PI: C Celum; R00MH121166, **PI: K Ortblad**)



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