Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya (PrIYA-SP)

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ClinicalTrials.gov Number: NCT03875950

Statistical Analysis Plan

September 2021

STUDY SUMMARY

Background: The incidence of HIV in adolescent girls and young women (AGYW) continues to rise despite promising innovation in female-controlled HIV prevention strategies. Pre-exposure prophylaxis (PrEP) is an effective HIV preventive intervention that can be female-controlled. PrEP effectiveness is threatened by low adherence. Improved health counseling may improve uptake of and adherence to PrEP. Standardized patient actors (SPs) can help health providers to improve communication and counseling skills.

Goal: To facilitate AGYW uptake of and adherence to PrEP through a SP clinical training program to improve HCW communication skills and delivery of PrEP counseling services.

RCT Aim: To evaluate the effectiveness of an SP training intervention to improve HCW quality of PrEP counseling, including communication and counseling skills and accuracy in conveying information per national PrEP guidelines .

Methods: We will conduct a baseline assessment of PrEP counseling practices using unannounced SP actors as 'mystery shopper' evaluators at 24 facilities in Western Kenya. We will then randomly assign 12 facilities to an SP training intervention and 12 facilities to the control arm which will continue standard of care. Outcomes will be assessed by SP mystery shoppers who visit both intervention and control facilities.

Population: HCWs who provide PrEP services in Western Kenya.

Outcomes: The primary outcome will be the difference in mean PrEP competency score percent between the intervention and standard of care facilities, which reflects quality of the PrEP counseling session, defined as adherence to NASCOP guidelines of PrEP counseling/delivery and use of non-judgmental interpersonal skills, and measured as a score on a SP checklist after unannounced visits. A secondary outcome among intervention training participants will be change in interpersonal skills mean score percent between the first and last session.

Timeframe: January 2019 to August 2020

STUDY OUTCOMES

The primary outcome of the trial will be quality of PrEP counseling, summarized by an SP checklist score at unannounced clinic visits that will assess communication (e.g. listening without interruption, encouraged questions) and adherence to national guidelines on PrEP counseling and delivery (e.g. risk assessment, counseling on key messages, correct medication recommended). The secondary outcome, assessed in intervention arm will be change in interpersonal skills mean score percent between the first and last session. Communications and interpersonal skills measures are adapted from the Kalamazoo Consensus Statement (31) and other published tools (32-34)

SAMPLE SIZE CONSIDERATIONS

Primary trial outcome: Given a fixed number of clusters (24 facilities), we estimated the minimum number of SP encounters required to detect a 20 percentage-point difference in PrEP counselor competency score between intervention and control arms. Because it is uncertain what baseline PrEP competency will be, we estimated sample sizes to detect a 10-percentage point difference between the intervention and control arm varying the baseline competency percent, shown in Table 2. Under these assumptions, if PrEP competency is 61% in the control arm using baseline data and standard deviation of 17.7%, we would need an estimated 112 to 120 total SP encounters (4 to 6 per site). We will plan to conduct 6 visits per site (120 total), which assumes we only have 20 facilities, to ensure we have adequate power. Higher baseline competency would require a larger sample size to detect the same difference. The expected upper limit of SP encounters is 400.

Table 1. Sample sizes of SP encounters to detect a 10-percentage point difference in competency at 80% power, correlation coefficient (k) of 0.15, α=0.05 and 24 facilities

Control group competency %	Intervention group competency %	Minimum cluster per arm required	SP encounters per cluster	Total SP encounters
0.61	0.71	14	4	112
0.61	0.71	11	5	110
0.61	**0.71**	**10**	**6**	**120**
0.61	0.71	8	7	112
0.61	0.71	8	8	128
0.61	0.71	7	9	126
0.61	0.71	6	10	120
0.61	0.71	6	11	132
0.61	0.71	6	12	144

STATISTICAL ANALYSES AND DESCRIPTION OF MAIN TABLES

Cluster RCT of PriYA-SP intervention

Question: Does the SP training intervention improve *quality* of provider delivery of PrEP services?

Overview: The primary analysis will evaluate effectiveness of the SP clinical training intervention on provider counseling skills and adherence to national guidelines

Primary outcome: Provider competency score using the endline unannounced SP checklist, expressed as a mean %, at the individual level. Each provider will receive a total score (% correct) from the checklist, rescaled to be out of 100.

Computing the total score per provider:

- The unannounced SP checklist contains 12 questions on adherence to PrEP guidelines with binary (done/not done) response options and 7 items on communication quality with 4 scaled response options (strongly agree to strongly disagree). Higher total scores represent higher competency.
- Each binary response option will be assigned 1 for 'done' and 0 for 'not done' for a total possible sub-score of 12.
- Communication items number #4, and 6-10 will be scored 3=strongly agree, 2=agree, 1=disagree, 0=strongly disagree. Question #5 is reverse coded (it is a negative question) as 3=strongly disagree, 2=disagree, 1=agree, 0=strongly agree, for total possible sub-score of 21.
- Each domain score will be converted a percentage of points possible. Total scores will be computed by adding the converted percentages and dividing by 2 (the number of domains), so that each domain is weighted equally.

Exposure: 12 Facilities that received the SP training intervention compared to 12 facilities without the SP intervention.

Adjustment variables: Pre-specified facility size/level, any baseline factors that differ between arms at $p<0.05$ level in addition to the primary exposure (intervention v. control) and stratification variables.

Clustering: Individuals within facilities

Data sources: HCW surveys, Facility survey, unannounced SP actor checklists

Primary analysis of trial endpoints: Primary analysis will be intention-to-treat (ITT).

A CONSORT diagram will be used to show the number of facilities and HCWs by arm during the trial, numbers excluded, and reasons for exclusion (Figure 1).

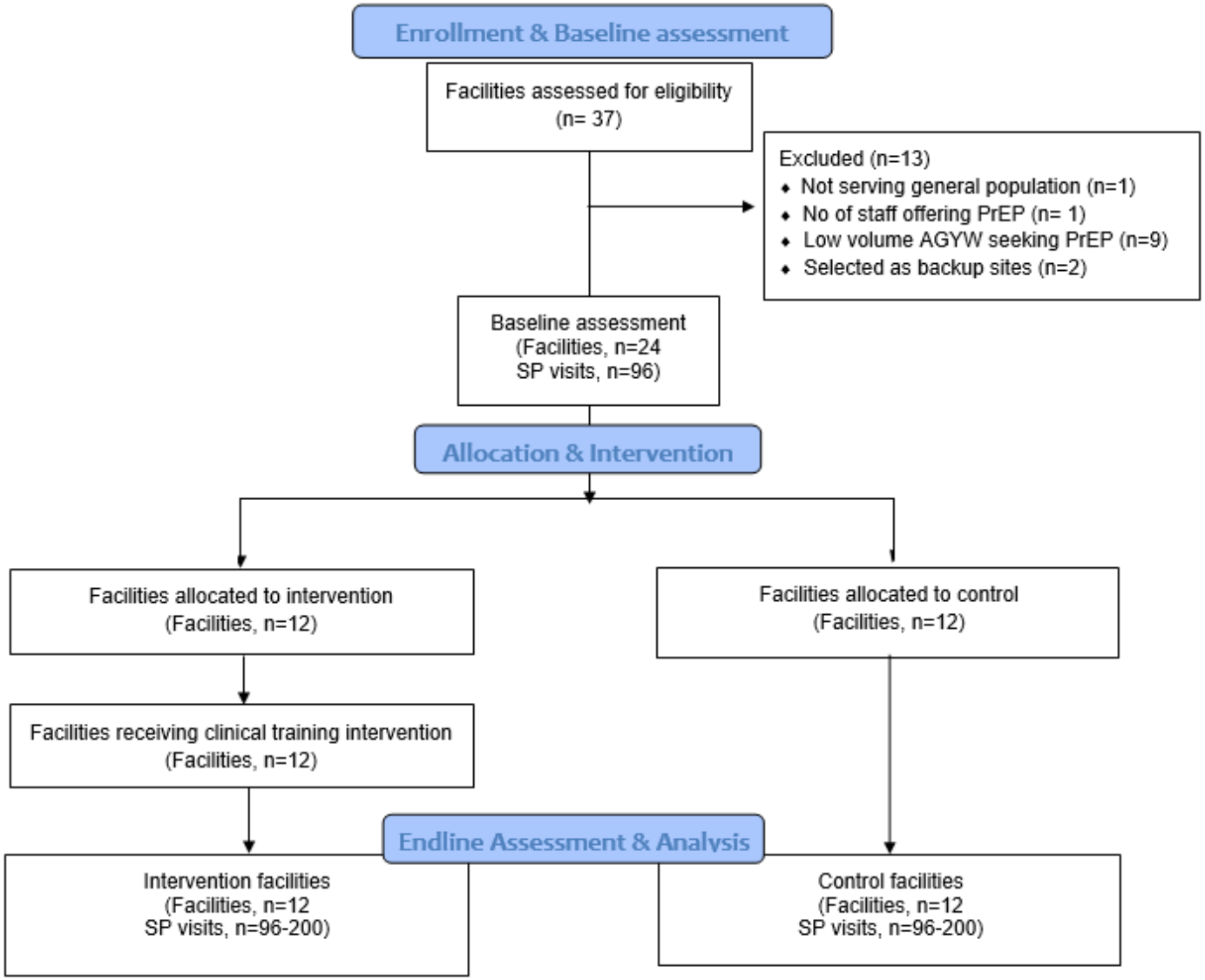
- Descriptive statistics, including means, medians, and proportions of data from baseline surveys and SP checklists will be generated including facility size, staffing, HCW age, gender, PrEP training exposure, and years providing HIV prevention services (Table 5). Baseline unannounced SP checklist scores will be presented as mean %. These data will be presented by trial arm in Table 1 to determine whether randomization achieved balance by potential confounding factors. Chi square and ranksum tests will compare differences in categorical and continuous variables by arm. Variables that differ between arms at the $p<0.05$ will be included *a priori* in the regression model.

- An intention-to-treat (ITT) analysis will be used to evaluate whether the SP training intervention resulted in higher mean competency score % at intervention compared to control facilities. The primary outcome will be at the individual level, adjusted for relevant baseline characteristics by arm and baseline evaluation scores. Generalized linear models (GLMM) with a Gaussian distribution and identity link, will be used to the difference in mean score %s between the intervention and standard of care facilities, accounting for facility cluster as a random effect (Table 6). We will consider individual SP as another random effect.

- In sensitivity analyses, we will evaluate the intervention effect on individual components of PrEP competency and communication quality in separate GLMM regression models as well as differences in overall mean % scores between cases, where case is entered as a fixed effect (a covariate).

Data sources: HCW surveys, Facility Surveys, Unannounced SP checklists, Exit Surveys

Figure 1. PrIYA-SP CONSORT diagram



5. APPENDICES

APPENDIX 1: DATA SOURCES

Data source	Description	Timing of data collection	Analysis purpose
Unannounced SP checklist	Standardized SP checklists to evaluate the HCW encounter with the SP actor at baseline and endline unannounced visits	Baseline and end of study	*Primary outcome* End of study scores will be compared between RCT arms; Baseline scores used as an adjustment variable
Facility Survey	Anonymous survey will be administered to a health facility manager at baseline to capture facility characteristics	Baseline	Assess adequacy of randomization; Provide data for potential adjustment of ITT analysis
HCW surveys	Pre/post surveys to assess knowledge of and self-rated competency in provision of PrEP to AGYW	Baseline and end of study	Assess change in knowledge/attitudes between baseline and end of study, all sites Compare end of study scores between trial arms
SP training checklist	Standardized SP checklists to evaluate quality of the simulated visit with HCWs in the intervention training	Immediately after each SP encounter among trial participants	*Secondary outcome* Change in mean competency % among intervention participants between the first and last session

APPENDIX 2: TABLE SHELLS FOR RCT
* Tables 2-4 suggested for EAC

Table 2. Baseline enrollment summary (N=24 facilities)

Population	# Recruited	# Enrolled	# Withdrawals
Facilities			
Facility Managers			
HCWs			

Table 3. Trial enrollment summary

Facility	# HCW enrolled in study	# HCW trained in study intervention	% trained among enrolled
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

Table 4. Intervention evaluation progress, Month XXX

Facility	Case 1	Case 2	Case 3	Case 4	Total SP visits
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
TOTAL VISITS					

Table 5: Baseline characteristics of HIV care facilities and HCW delivering PrEP to AGYW in PrIYA-SP (N=24)

Facility-level characteristics	**Overall N or Median, % or IQR**	**Intervention arm (12 Facilities) N or Median, % or IQR**	**Control arm (12 Facilities) N or Median, % or IQR**
MCH FP CCC Other			
Any adolescent friendly service training			
HCWs trained to prescribe PrEP per facility (all cadres combined)			
Copies of NASCOP PrEP Guidelines (2017) available at this facility (Yes)			
PrEP Services for Adolescents and Young Adults			
Any adolescent-specific PrEP services			
Information about PrEP for AGYW available			
Stockouts of PrEP in last 30 days			
HCW participants (n=XX)			
Female			
Age (years)			
Cadre			
Medical Officer/Doctor			
Clinical Officer/Adherence counselor/Other			
Nurse			
Years of experience providing HIV prevention services to AGYW			
Any prior training in offering HIV prevention (including PrEP) to AGYW			
Baseline provider competency (facility mean score)			
Attitudes about AGYW (facility mean score)			
HIV-related stigma attitudes (facility mean score)			

Table 6. ITT Analysis: Effect of PrIYA-SP intervention on quality of PrEP counseling for AGYW

Outcome	Intervention sites N=12	Control sites N=12	β, 95% CI, p-value	β*, 95% CI, p-value
Primary HCW quality of PrEP counseling mean score % evaluated by SP using SP checklist				
Sensitivity				
HCW PrEP competency mean score % using SP checklist				
HCW Communication quality mean score % using SP checklist				
Other outcomes				
Self-rated HCW competency				

*Adjusted for pre-specified factors and baseline confounding factors

APPENDIX 3: CFAR ACKNOWLEDGEMENT.
https://depts.washington.edu/cfar/discover-cfar/acknowledge-cfar

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