THE LANCET
Global Health

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Irungu EM, Mugwanya KK, Mugo NR, et al. Integration of pre-exposure prophylaxis services into public HIV care clinics in Kenya: a pragmatic stepped-wedge randomised trial. *Lancet Glob Health* 2021; **9:** e1730–39.

SUPPLEMENTARY APPENDIX

TABLE OF CONTENTS

PARTNERS SCALE UP PROJECT STUDY TEAM

Coordinating Center (University of Washington): Jared M. Baeten (principal investigator), Kenneth Mugwanya (project director), Gena Barnabee, Lara Kidoguchi, Jennifer Morton, Gabrielle O'Malley, Sue Peacock, Kathryne Peebles, Stephanie Roche, Jennifer Velloza

Study sites

Kisumu, Kenya: Elizabeth Bukusi (principal investigator), Josephine Odoyo (project coordinator), Benjamin Angasa, Magdaline Asewe, Mercelline Awuor, Annabell Dollah, Lydiah Etyang, Elizabeth Koyo, Benn Kwach, Sylvia Mugalla, Wycliffe Nelson, Bernard Nyerere, Alfred Obiero, Kenneth Odhiambo, Joel Odondi, Boblief Otieno, Lauryn Owanga, Meresa Oyier, John Bosco Tsetso

Thika, Kenya: Nelly Mugo (principal investigator), Elizabeth Irungu (country director), Elizabeth Wamoni (project coordinator), Nelson Kamau, Boaz Kipkorir, Victoria Kyengo, Peter Michira, Peter Mogere, Harrison Muigai, Peterson Mwaniki, Euticus Mwangi, Margaret Mwangi, Njoroge Mwathi, Rosemary Ngacha, Kenneth Ngure, Roy Njiru, Dickson Okello, Fernandos Ongolly, Emma Owidi, Cyrus Theuri, Winnie Waituika, Irene Wambui

TABLE A1: CONSORT CHECKLIST OF INFORMATION TO INCLUDE WHEN REPORTING A STEPPED WEDGE CLUSTER RANDOMISED TRIAL (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and Abstract			
	1a	Identification as a SW-CRT in the title.	1
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	2
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	6
	2b	Specific objectives or hypotheses.	5
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	6 & Fig 2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	NA
Participants	4a	Eligibility criteria for clusters and participants	6,8
	4b	Settings and locations where the data were collected	6, S11
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	7
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	NA
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	NA
Randomization			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatment	8
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	8
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after	8

		recruitment.	
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	8
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	9
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions	11
Blinding	11a	If done, who was blinded after assignment to sequences (e.g., cluster level participants, individual level participants, those assessing outcomes) and how.	8
	11b	If relevant, description of the similarity of treatments	NA
Statistical Methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	9-10
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analyzed for the primary outcome	Fig 2
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	Fig 2
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	Fig 1
	14b	Why the trial ended or was stopped	6
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence	12, Table 2 & Table A4
Numbers analyzed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule	12
Outcomes & Estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	12-14
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12
Ancillary analysis	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	13

Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	Table A5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalizability	21	Generalizability (external validity, applicability) of the trial findings. Generalizability to clusters or individual participants, or both (as relevant).	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	14-15
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available.	16
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	11
Research Ethics	26	Whether the study was approved by a research ethics committee, identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	11

TABLE A2: CONSORT CHECKLIST OF ITEMS TO INCLUDE WHEN REPORTING A RANDOMIZED TRIAL IN A JOURNAL OR CONFERENCE ABSTRACT

Item	Description	Reported on line number
Title	Identification of the study as randomized	Line 2 of the title
Authors *	Contact details for the corresponding author	N/A
Trial design	Description of the trial design (e.g., parallel, cluster, non-inferiority)	Line 2 of the title & Line 7
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	8,11
Interventions	Interventions intended for each group	9,10
Objective	Specific objective or hypothesis	8
Outcome	Clearly defined primary outcome for this report	12
Randomization	How participants were allocated to interventions	9
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	12
Results		
Numbers randomized	Number of participants randomized to each group	17
Recruitment	Trial status	17
Numbers analyzed	Number of participants analyzed in each group	17
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	19,20
Harms	Important adverse events or side effects	-
Conclusions	General interpretation of the results	29-31
Trial registration	Registration number and name of trial register	35
Funding	Source of funding	34

**this item is specific to conference abstracts*

TABLE A3: DELTA RECOMMENDED REPORTING ITEMS FOR SAMPLE SIZE CALCULATION

Recommended reporting items	Page and line numbers where item is reported
Core items	
(1) Primary outcome (and any other outcome on which the calculation is based)	Line 212
If a primary outcome is not used as the basis for the sample size calculation, state why	
(2) Statistical significance level and power	Line 215
(3) Express the target difference according to outcome type	Line 215
(a) Binary—state the target difference as an absolute or relative effect (or both), along with the intervention and control group proportions. If both an absolute and a relative difference are provided, clarify if either takes primacy in terms of the sample size calculation	Line 215
(b) Continuous—state the target mean difference on the natural scale, common standard deviation, and standardised effect size (mean difference divided by the standard deviation)	NA
(c) Time-to-event—state the target difference as an absolute or relative difference (or both); provide the control group event proportion, planned length of follow-up, intervention and control group survival distributions, and accrual time (if assumptions regarding them are made). If both an absolute and relative difference are provided for a particular time point, clarify if either takes primacy in terms of the sample size calculation	NA
(4) Allocation ratio	
If an unequal ratio is used, the reason for this should be stated	Study design in SW-CRT and no allocation ration was applied
(5) Sample size based on the assumptions as per above	Line 214
(a) Reference the formula/sample size calculation approach, if standard binary, continuous, or survival outcome formulas are not used. For a time- to-event outcome, the number of events required should be stated	
(b) If any adjustments (eg, allowance for loss to follow-up, multiple testing) that alter the required sample size are incorporated, they should also be specified, referenced, and justified along with the final sample size	NA

(c) For alternative designs, additional input should be stated and justified. For example, for a cluster randomised controlled trial (or an individually randomised controlled trial with clustering), state the average cluster size and intracluster correlation coefficient(s). Variability in cluster size should be considered and, if necessary, the coefficient of variation should be incorporated into the sample size calculation. Justification for the values chosen should be given	216-218
(d) Provide details of any assessment of the sensitivity of the sample size to the inputs used	None
Additional items for grant application and trial protocol	
(6) Underlying basis used for specifying the target difference (an important or realistic difference)	NA
(7) Explain the choice of target difference—specify and reference any formal method used or relevant previous research	NA
Additional item for trial results paper	
(8) Reference the trial protocol	Line 97

TABLE A4: CLUSTER LEVEL SUMMARY STATISTICS

PrEP initiations and Month 3 continuation, by clinic

	Number (% of total) initiating PrEP	Number (% of initiations) returning 3 months after PrEP initiation
Clinic 1	289 (5.9%)	136 (47.1%)
Clinic 2	139 (2.8%)	72 (51.8%)
Clinic 3	223 (4.6%)	100 (44.8%)
Clinic 4	278 (5.7%)	100 (36.0%)
Clinic 5	70 (1.4%)	30 (42.9%)
Clinic 6	126 (2.6%)	65 (51.6%)
Clinic 7	279 (5.7%)	126 (45.2%)
Clinic 8	152 (3.1%)	71 (46.7%)
Clinic 9	232 (4.7%)	129 (55.6%)
Clinic 10	280 (5.7%)	132 (47.1%)
Clinic 11	178 (3.6%)	102 (57.3%)
Clinic 12	230 (4.7%)	119 (51.7%)
Clinic 13	278 (5.7%)	127 (45.7%)
Clinic 14	114 (2.3%)	44 (38.6%)
Clinic 15	191 (3.9%)	78 (40.8%)
Clinic 16	164 (3.3%)	74 (45.1%)
Clinic 17	128 (2.6%)	39 (30.5%)
Clinic 18	305 (6.2%)	114 (37.4%)
Clinic 19	174 (3.6%)	66 (37.9%)
Clinic 20	87 (1.8%)	34 (39.1%)
Clinic 21	186 (3.8%)	79 (42.5%)
Clinic 22	306 (6.2%)	104 (34.0%)
Clinic 23	203 (4.1%)	77 (37.9%)
Clinic 24	136 (2.8%)	45 (33.1%)
Clinic 25	150 (3.1%)	72 (48.0%)

TABLE A5: TABLE OF ADVERSE EVENTS

Adverse Event	**N = 9117 follow up visits n(%)**
Gastrointestinal related symptoms	12 (0.13%)
Elevated blood pressure	6 (0.07%)
Headache	6 (0.07%)
Upper respiratory tract related symptoms	4 (0.04%)
Musculoskeletal related symptoms	4 (0.04%)
Genital-urinary related symptoms	3 (0.03%)
Other – weight-related, skin-related	4 (0.04%)
Total	**39 (0.43%)**

FIGURE A1: MAP OF PARTICIPATING COUNTIES IN KENYA

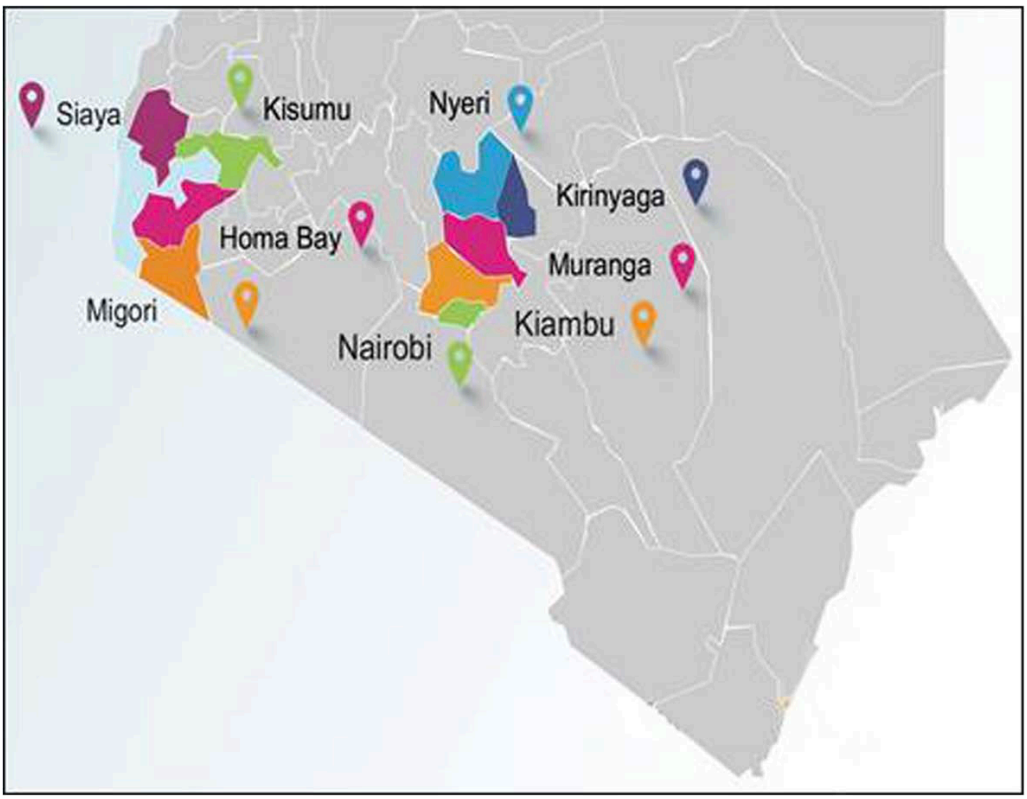


FIGURE A2: CUMULATIVE NUMBER OF PREP INITIATIONS

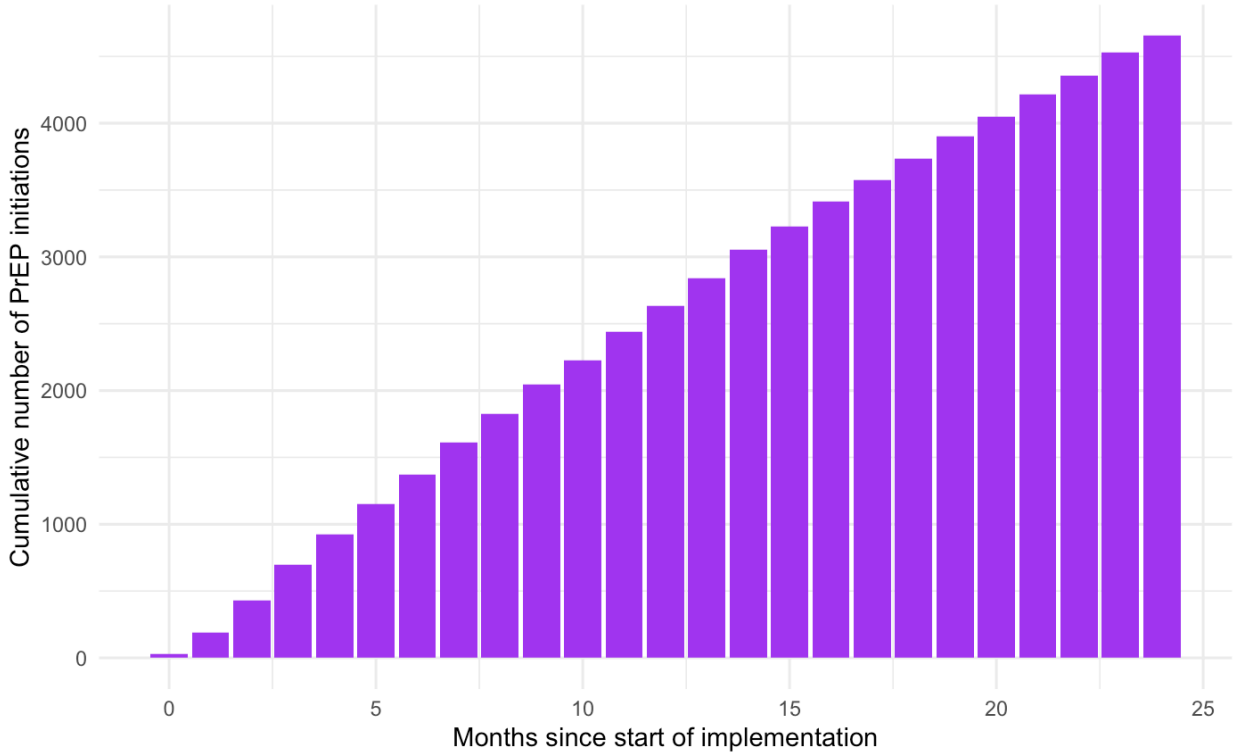
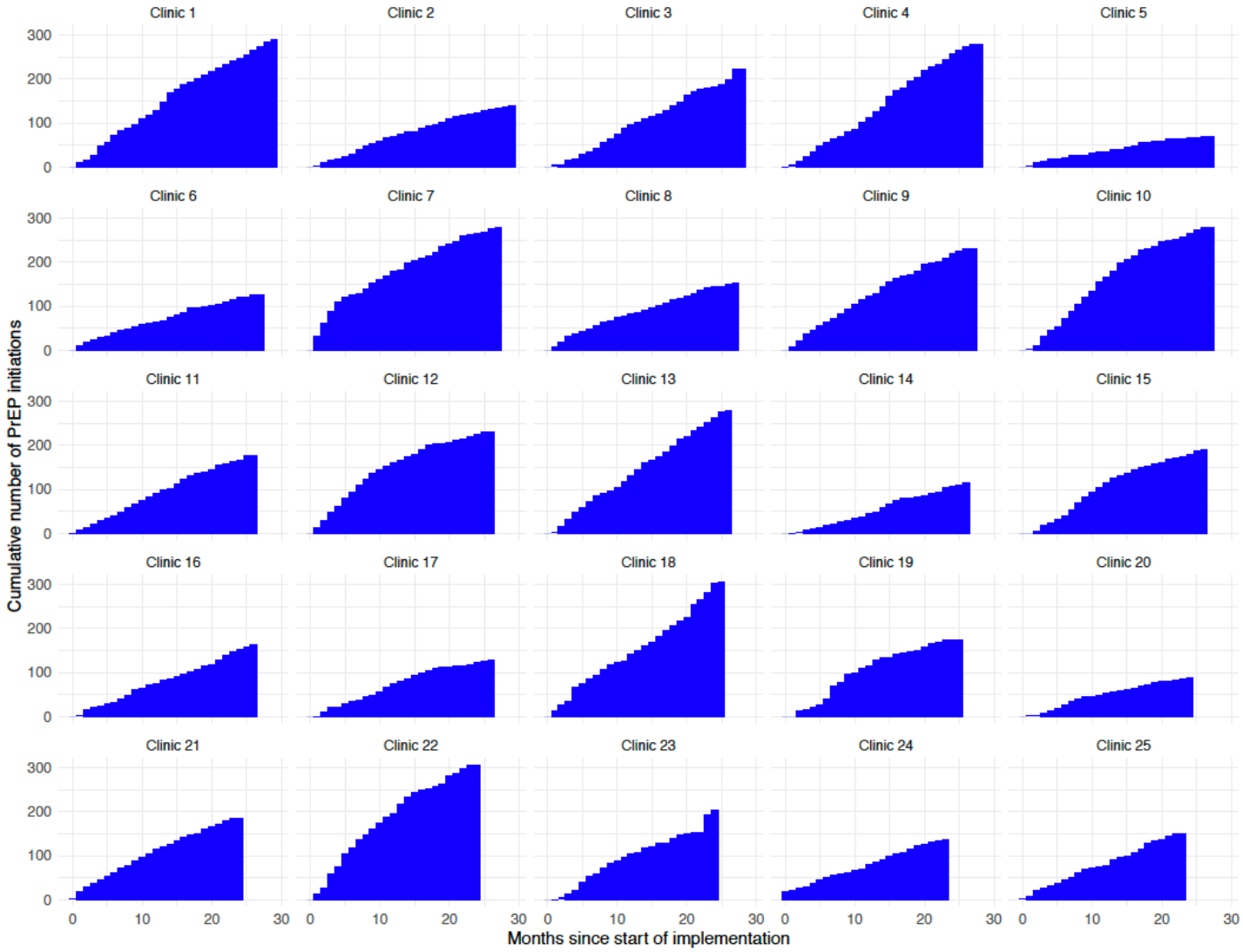


FIGURE A3: PREP UPTAKE OVER TIME, PER CLINIC



ANALYSIS PLAN FOR THE PREP COMPONENT OF AIM 1 OF PARTNERS SCALE-UP PROJECT

OVERALL AIM

To conduct an impact evaluation of the Partners Scale-Up Project, an implementation project to scale-up PrEP delivery among Kenyan HIV serodiscordant couples in public health facilities in Kenya – list the 4 key outcomes

SPECIFIC AIMS

1. Determine number of people initiating PrEP per month in 24 public health HIV care clinics during the project period comparing active vs control periods, and describe characteristics of at-risk persons initiating PrEP

2. Describe the proportion of individuals continuing to use PrEP at i) 1 month ii) 3 months, iii) 6 months, and iv) 12 months, and determine correlates of continuation

3. Describe adherence to PrEP, by self-report and drug levels, among people returning for refills

4. Determine incident HIV infections and compare this with expected HIV incidence using a counterfactual simulation scenario

5. Determine proportion of visits in which core components of PrEP delivery, including HIV testing, acute HIV assessment, and PrEP dispensing are performed.

STUDY DESIGN

This is a stepped-wedge cluster randomized design with 7 steps each containing 2-6 HIV care clinics (clusters). Twenty-four high volume HIV care clinics in central and western Kenya were randomized to the order in which they will receive intervention i.e., 2-day PrEP training for health providers and provision of technical assistance (see table below).
Training was carried out between Jan 2017 and July 2017. Upon completion of training and PrEP delivery components availed, facilities were activated to begin the intervention. Facilities that were activated in the last week of the month were assigned the following month as their activation month.
All clinics were in the maintenance phase from August 2017.

Clinic	Start Date	Assigned Start Month	Jan, 2017	Feb, 2017	Mar, 2017	Apr, 2017	May, 2017	Jun, 2017	Jul, 2017	Aug, 2017	Sep, 2017 - Jun, 2019
25	3-Aug-17	Aug, 2017	B	C	C	C	C	C	C	I	I
24	3-Aug-17	Aug, 2017	C	C	C	C	C	C	C	I	I
23	27-Jul-17	Aug, 2017	C	C	C	C	C	C	I	I	I
22	17-Jul-17	Jul, 2017	C	C	C	C	C	C	I	I	I
21	10-Jul-17	Jul, 2017	C	C	C	C	C	C	I	I	I
20	10-Jul-17	Jul, 2017	C	C	C	C	C	C	I	I	I
19	30-Jun-17	Jul, 2017	C	C	C	C	C	I	I	I	I
18	14-Jun-17	Jun, 2017	C	C	C	C	C	I	I	I	I
17	25-May-17	Jun, 2017	C	C	C	C	I	I	I	I	I
16	25-May-17	Jun, 2017	C	C	C	C	I	I	I	I	I
15	25-May-17	Jun, 2017	C	C	C	C	I	I	I	I	I
14	25-May-17	Jun, 2017	C	C	C	C	I	I	I	I	I
13	19-May-17	May, 2017	C	C	C	C	I	I	I	I	I
12	2-May-17	May, 2017	C	C	C	C	I	I	I	I	I
11	2-May-17	May, 2017	C	C	C	C	I	I	I	I	I
10	18-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
9	4-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
8	4-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
7	4-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
6	4-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
5	4-Apr-17	Apr, 2017	C	C	C	I	I	I	I	I	I
4	3-Mar-17	Mar, 2017	C	C	I	I	I	I	I	I	I
3	3-Mar-17	Mar, 2017	C	C	I	I	I	I	I	I	I
2	7-Feb-17	Feb, 2017	C	I	I	I	I	I	I	I	I
1	7-Feb-17	Feb, 2017	C	I	I	I	I	I	I	I	I

KEY OUTCOMES

- Number of people initiating PrEP per clinic per month
- Proportion of people continuing use at 1, 3, 6 and 12 months
- Proportion of those returning for refills with detectable drug levels
- HIV incidence
- Proportion of visits in which core components are performed.

OVERVIEW OF STATISTICAL ANALYSIS

Aim 1: Determine number of people initiating PrEP per month in 24 public health HIV care clinics during the project period comparing active to control periods, and describe characteristics of at-risk persons initiating PrEP.

1. Descriptive statistics of participant characteristics at PrEP initiation to be reported as Table 1 and summarized as text

2. Change in number of people initiating PrEP per month during intervention phase compared to number of people initiating PrEP per month during the control phase
    i. Immediate level change
    ii. Slope change (change in monthly trend of PrEP initiations) after implementation

    <u>Analysis approach:</u>

    a. A cluster level mixed effects negative binomial model to estimate intervention effect on number initiating PrEP with
        - fixed effects for intervention (vs control period), step, clinic volume and region
        - random effect for each clinic
    b. A cluster level mixed effects negative binomial model to determine change in monthly PrEP interventions over time after implementation of intervention
        - fixed effects for duration since start of PrEP implementation in years, region, clinic volume and calendar time
        - random effect for each clinic

Aim 2: Describe the proportion of individuals continuing to use PrEP for i) 1 month, ii) 3 months, iii) 6 months, and iv) 12 months and determine correlates of continuation

1. Descriptive statistics of continuation rates at each of the above time points will be summarized in the text
2. An alluvial plot showing continuation and restarts
3. Descriptive statistics of PrEP users with at least one refill visit within the first three months of PrEP initiation and logistic regression methods to identify predictors of having at least one refill visit within the first three months of PrEP initiation

Aim 3: Describe adherence to PrEP, by self-report and drug levels, among people returning for refills

1. Describe the proportion of persons returning for PrEP self-reporting good adherence
2. Proportion of persons returning for PrEP refills with any detectable tenofovir levels

3. Present mean intracellular tenofovir-diphosphate (TFV-DP) concentrations from DBS obtained from people returning for PrEP refills from randomly selected clinics on a random subset of days each month.

Aim 4: Provide data on incident HIV infection and compare it with expected HIV incidence using a counterfactual simulation scenario

1. Describe number of incident HIV infections. Detail days since PrEP initiation when the infection was identified.
2. Compare expected HIV incidence with observed incidence using a counterfactual simulation scenario

   Analysis approach
   - Draw counterfactual population from placebo arm of the Partners PrEP study (N=1584 couples in the placebo arm). Each sample of <4800 couples will have a distribution of HIV risk scores and duration of follow-up to match the PSUP cohort (by frequency matching).
     - Divide HIV risk score into 2-3 categories (2-4, 5-7, >7). We will check the distribution of the risk score before choosing categories (median, mean, IQR, range)
   - Mean number of HIV infections expected in the counterfactual population will be averaged over 10,000 bootstrap samples.
   - Will compute an incidence rate ratio by comparing HIV incidence in PSUP to the mean counterfactual estimate

Aim 5: Determine proportion of visits in which core components of PrEP delivery, including HIV testing, acute HIV assessment, and PrEP dispensing are performed.

1. Present the proportion of initiation and quarterly follow up visits in which HIV testing, acute HIV assessment, creatinine testing and PrEP dispensing are performed. These will be described in the text and tabulated

DEFINITIONS OF KEY VARIABLES

- PrEP uptake – documentation of having received a PrEP prescription in facility records
- Continuation - the proportion of people expected to come for a visit who had a documented PrEP refill within the visit window.
- New HIV infection – person with a completed initial visit form and has a positive HIV test results after a previously documented HIV negative result

DMC CHARTER

Partners Scale-up Project
Sponsor: University of Washington
Funder: US National Institute of Mental Health (R01MH095507)
ClinicalTrials.gov ID: NCT03052010
PI: Jared Baeten, MD, MPH

The Data Monitoring Committee (DMC) will act in an advisory capacity to the Partners Scale-up Project to evaluate the progress of the project. The Partners Scale-up Project in collaboration with the Kenya National AIDS and STI Control Programme (NASCOP), is conducting a national scale-up of PrEP delivery for HIV serodiscordant couples and other at-risk persons in 24-30+ comprehensive HIV care clinics in Central, Western and Coastal regions of Kenya.

DMC Responsibilities

The DMC responsibilities are to:

- review the project implementation protocol and plans and how it fits into the national PrEP scale up program.
- evaluate the progress of the project, including periodic assessments of accrual and retention, PrEP user risks, performance and variation of the project sites, and other factors that can affect project implementation.
- consider factors external to the project when relevant information becomes available, such as policy changes or scientific developments that may have an impact on project implementation, safety, and integration of PrEP delivery in the HIV care clinics.
- review project performance, make recommendations and advice in the resolution of challenges reported by project investigators.

Completion of DMC Activities

The DMC will remain active until written notification is received from project.

Membership

The DMC will consist of six members and three members will constitute quorum. Membership consists of individuals who have no financial, scientific, or other conflict of interest and who have expertise in the fields of medicine, HIV prevention and treatment, policy, program implementation and epidemiology.

The members are:

- Dr. Irene Mukui - NASCOP
- Dr. Vernon Mochache - University of Maryland
- Dr. Jared Mecha – University of Nairobi
- Dr. Jeremy Penner - FACES
- Dr. Carol Ngunu - Nairobi CASCO
- Mr. Churchill Alumasa - DISCOK

Meeting Process

The first meeting of the DMC will include an organizational meeting. This meeting will formally establish the DMC and begin to acquaint the DMC members with types of protocols that this DMC will be charged with monitoring. It will afford the DMC an opportunity to recommend final revisions to the Charter and the communication plan between the DMC and the project team. At the first meeting the DMC will discuss the

protocol and guidelines to project monitoring.

DMC meetings will be held approximately every 6 months. An ad hoc meeting of the DMC may be called at any time should unanticipated problems arise. Meetings will be convened as conference calls as well as in-person if needed. The project investigators will prepare the agenda to address the review of project progress, processes, modifications to the project protocol and project documents as needed.

Communications

Communications will be by email and occasionally phone call to follow up on pending issues.

Process and Format of Meeting

DMC meetings will consist of open sessions. Key members of the study team will attend the sessions and present information. Discussion will focus on the conduct and progress of the study, including participant accrual, retention and challenges encountered. The DMC may elect to hold an executive session in which generally only the DMC members are present in order to discuss project issues independently.

Meeting Materials

DMC reports will be prepared by the project staff to be reviewed and discussed by the DMC members at each meeting. The format and content of the reports will be finalized and approved at the initial DMC meeting, and changes throughout the project may be requested by the committee.

The reports will describe and summarize the status of the project and any emerging implementation and safety data. The reports generally will include administrative reports that describe participants initiated, continuing on PrEP as well as baseline characteristics of the of PrEP initiators. Other general information on project status may also be presented. The DMC may ask additions and other modifications to the reports on a one-time or continuing basis.

Minutes of the DMC Meeting

An appropriately detailed summary of the discussions of the DMC will be recorded by the project team, with any recommendations clearly documented at the end of each meeting. The minutes will be circulated to DMC members within 2 weeks of meeting. The DMC may choose to make a formal report containing the recommendations about progress or modifications of the study. Once approved by the DMC members, Principal Investigator will distribute the DMC recommendations to all co-investigators and ensure that copies are submitted to all the IRBs and other regulatory bodies associated with the project.

Confidentiality

No personal identifying information will be discussed. While the discussions of the DMC are between the committee and the study investigators, materials and proceedings of the DMC may be shared with goal of informing and advancing PrEP delivery in Kenya.

Documentation and Archiving

All documentation and communication of the DMC will be dated, filed, and archived by the project. The documents will be archived for the duration of project. Documents that will be filed and archived include, but are not limited to:

- DMC charter
- Curriculum vitae of all DMC members
- Agenda of the DMC meetings
- Minutes of the DMC meetings
- Copy of all materials sent by the DMC, including the project reports
- Recommendation(s) provided by the DMC to the project
- All official DMC correspondences.

CLINICAL ENCOUNTER FORM

Clinical Encounter Record: Oral Pre-Exposure Prophylaxis (PrEP)

Name of facility: _____ Delivery Point: _____ Tier: _____ MFL code: ___ ___ ___ ___ ___

County: _____ Sub county: _____ Ward: _____

A. Client Profile

Unique client record number: ___ ___ ___ ___ ___ / ___ ___ ___ ___ / ___ ___ ___ ___ ___ Initial visit date: *dd / mm / yyyy*

Name: First _____ Middle _____ Last _____ Telephone no: _____

Alien/National ID/passport/Birth Cert No: _____ NHIF No: _____ County of Birth _____

Sex: ☐ Male ☐ Female Date of birth: *dd / mm / yyyy* Age (years): ____ ____ If age <19, attends school: ☐ Yes ☐ No

Marital status (*select one*): ☐ Never married ☐ Cohabiting ☐ Married monogamous ☐ Married polygamous ☐ Separated/divorced ☐ Widowed

Population Type: ☐ Gen Population ☐ Discordant couple ☐ Key Population (Specify) → ☐ MSM ☐ MSW ☐ FSW ☐ PWID

B. Entry Point & Transfer Status

Referred from (*select one*):
☐ HBTC ☐ VCT site ☐ OPD ☐ MCH ☐ TB clinic ☐ IPD ☐ CCC
☐ Peer ☐ Outreach ☐ Self-referral ☐ Community ☐ Other: _____

If transferred in:
PrEP start date: *dd / mm / yyyy* Regimen: ☐ TDF-FTC ☐ TDF ☐ TDF-3TC
Facility transferred from: _____ MFL code: __ __ __ __ __ County: _____

C. Baseline Assessment

Behaviour risk assessment

Mark all that apply:

☐ Sex partner(s) is HIV+ and (*mark all that apply*):
- ☐ Not on ART
- ☐ On ART <6 months
- ☐ Suspected poor adherence to ART
- ☐ Detectable HIV viral load
- ☐ Couple is trying to conceive

☐ Sex partner(s) high risk & HIV status is unknown
☐ Has sex with >1 partner
☐ Ongoing IPV/GBV
☐ Transactional sex
☐ Recent STI (past 6 months)
☐ Recurrent use of post-exposure prophylaxis (PEP)
☐ Recurrent sex under influence of alcohol/recreational drugs
☐ Inconsistent or no condom use
☐ Injection drug use with shared needles and/or syringes

(If yes to any) →

Complete section if sex partner is HIV+

HIV+ partner CCC number: ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___ ___
or ☐ NA (not enrolled at a CCC)
or ☐ CCC number/enrollment status unknown

HIV+ partner ART start date: *dd / mm / yyyy*
or ☐ not on ART at initial visit

Time known to be HIV-serodiscordant: ___ ___ years + ___ ___ months

Sex without a condom with HIV+ partner in past 30 days: ☐ Yes ☐ No

Number of living children with HIV+ partner: ___ ___

Medical assessment & fertility intentions

Blood pressure (mm Hg): ___ ___ ___ / ___ ___ ___ Temperature: ___ ___ °C

Weight (kg): ___ ___ ___ Height (cm): ___ ___ ___

Signs/symptoms of STI : ☐ Yes; Use codes provided: _____ ☐ No

Chronic illnesses & comorbidities	Treatment
Liver disease: ☐ Yes ☐ No	
Kidney disease: ☐ Yes ☐ No	
1. *Other description*	
2. *Other description*	

Male only:
Circumcised: ☐ Yes ☐ No ☐ Unknown

Female only:
LMP: *dd / mm / yyyy*
Pregnant: ☐ Yes ☐ No
If pregnant: ☐ Planned ☐ Unplanned
Breastfeeding: ☐ Yes ☐ No
On family planning: ☐ Yes ☐ No FP methods: _____
Plan to have children (*select one*):
☐ Trying to conceive ☐ Future ☐ No ☐ Don't know

Clinical notes:

D. PrEP initiation

Lab results (*Investigations should not delay PrEP initiation. To be recorded when available.*)

Test	Result	Additional steps
Hepatitis B (HBsAg)	☐ Positive ☐ Negative ☐ Not done	If negative, vaccine series initiated: ☐ Yes ☐ No Date sample collected: dd/ mm / yyyy
Hepatitis C	☐ Positive ☐ Negative ☐ Not done	Date sample collected: dd/ mm / yyyy
Serum creatinine	___ ___ ___ (μmol/L) or ☐ Not done	If done, CrCl (mL/min): ___ ___ ___ *If creatinine is out of range, or CrCl<50 mL/min, refer for further assessment.*

Previous PrEP use: ☐ Yes ☐ No Condom Issued: ☐ Yes ☐ No
Willing to start PrEP: ☐ Yes ☐ No Adherence Counseling Done: ☐ Yes ☐ No
If not willing, reason (*mark all that apply*): ☐ None ☐ Side effects (ADR) ☐ Stigma ☐ Pill burden ☐ Taking pills for a long time ☐ Too many HIV tests

Signs/symptoms of acute HIV: ☐ Yes ☐ **No**
Medically ineligible to start PrEP: ☐ Yes ☐ **No**
Contraindications for TDF-FTC /TDF-3TC/TDF: ☐ Yes ☐ **No**

→ **Eligible for PrEP** →

Prescribed PrEP at initial visit: ☐ **Yes** ☐ **No**
Regimen: ☐ TDF-FTC ☐ TDF ☐ TDF-3TC
# of months: ___ ___
Date of initiation: *dd / mm / yyyy*

Next appointment date: *dd / mm / yyyy* **Clinician initials:**

Follow Up Visit

Unique client record number: ___ ___ ___ ___ ___/ ___ ___ ___ ___/ ___ ___ ___ ___ ___ **Name of client:** _____

Visit date: *dd / mm / yyyy*
Visit type: ☐ scheduled ☐ unscheduled

E. Medical assessment & fertility intentions

Clinical notes

Summary of findings

Blood pressure	___ ___ ___/ ___ ___ ___ mm Hg
Weight	___ ___ ___ kg Temperature___ ___°C
Signs/symptoms of STI(s)	☐ yes ☐ no If yes Use codes provided_____
Signs/symptoms of acute HIV	☐ yes ☐ no
If male, circumcised since last visit	☐ yes ☐ no ☐ na (already circumcised)

Possible adverse drug reaction ☐ none

1	*Description*	
	☐ mild ☐ moderate ☐ severe ☐ life threatening ☐ not graded	
	Action (*mark all that apply*) ☐ stop ☐ switched regimen ☐ Other _____	
2	*Description*	
	☐ mild ☐ moderate ☐ severe ☐ life threatening ☐ not graded	
	Action (*mark all that apply*) ☐ stop ☐ switched regimen ☐ Other _____	

Chronic illnesses & comorbidities		Treatment
	Liver disease ☐ Yes ☐ No	
	Kidney disease ☐ Yes ☐ No	
1	*Other description*	
2	*Other description*	

Plan to have children		☐ trying to conceive ☐ future ☐ no ☐ don't know ☐ client/partner is pregnant
If female	LMP: _____ Pregnant	☐ yes ☐ no
	Breastfeeding	☐ yes ☐ no
	On family planning	☐ none or methods(Indicate the code):_____
	If ended pregnancy since last visit	*Outcome date* *dd / mm / yyyy*
		Outcome ☐ term live ☐ preterm live ☐ induced abortion ☐ *loss*
		Birth defect(s) ☐ yes ☐ no ☐ don't know

F. Behaviour risk assessment

Mark all that apply

- ☐ Sex partner(s) is HIV+ and:
  - ☐ not on ART
  - ☐ <6 months ART use
  - ☐ poor adherence to ART
  - ☐ detectable HIV viral load
  - ☐ couple is trying to conceive
- ☐ Sex partner(s) at high risk for HIV & HIV status unknown
- ☐ Has sex with >1 partner
- ☐ Ongoing IPV/GBV
- ☐ Transactional sex
- ☐ Recent STI
- ☐ Recurrent use of PEP
- ☐ Recurrent sex under influence of alcohol/recreational drugs
- ☐ Inconsistent or no condom use
- ☐ IDU with shared needles/syringes

G. Follow up laboratory investigations

HIV test	☐ Positive ☐ negative ☐ not done	*If positive, collect sample for drug resistance. Client linked to care* ☐ Yes ☐ No
Serum creatinine (as per guidelines)	___ ___ ___ µmol/L or ☐ not done	*If creatinine is out of range, or CrCl <50 mL/min, refer for further assessment*
If creatinine done, CrCl ≥50 mL/min	☐ yes ☐ no	
Other (*write in test, results & units [if applicable]*)	1	
	2	

H. PrEP

Self-assessment of adherence since last visit	☐ Good ☐ Fair ☐ Bad ☐ n/a (did not pick up PrEP at last visit)
If Fair/ bad, reason(s) (*mark all that apply*)	☐ forgot ☐ lost/out of pills ☐ separated from HIV+ partner ☐ no perceived risk ☐ side effects ☐ sick ☐ stigma ☐ pill burden ☐ shared with others ☐ none ☐ other _____
Adherence Counseling done	☐ yes ☐ no **Condoms issued**: ☐ yes ☐ no
PrEP status	☐ continue ☐ restart ☐ discontinue
Prescribed PrEP today	☐ yes ☐ no
If yes, regimen and duration	☐ TDF-FTC ☐ TDF ☐ TDF-3TC number of months ___ ___
If discontinued, reason(s) (*mark all that apply*)	☐ HIV test is positive ☐ low risk of HIV ☐ renal dysfunction ☐ client request ☐ not adherent to PrEP ☐ viral suppression of HIV+ partner ☐ too many HIV tests ☐ other _____

Next appointment date: *dd / mm / yyyy* **Clinician initials:**

Adherence
Good: missed 0-3 doses in past 1 month
Fair: missed 4-5 doses in past 1 month
Bad: missed 6-7 doses in past 1 month

Creatinine clearance

$$\text{GFR (adult males)} = \frac{(140 - Age) \times 1.23}{\text{serum creatinine (in micromol/L)}}$$

$$\text{GFR (adult females)} = \frac{(140 - Age) \times 1.23}{\text{serum creatinine (in micromol/L)}} \times 0.85$$

FP Methods:
C = Condoms
TL = Tubal ligation/female sterilization
FA = Fertility awareness method/periodic abstinence
D = Diaphragm/cervical cap
LAM = Lactational Amenorrhea Method
IUD = Intra uterine device
IMP = Implant
INJ = Injectable
OC = oral contraceptive pills
ECP = Emergency contraceptive pills dispensed
V = Vasectomy (partner's)

STI Diagnosis:
Genital Ulcer Disease (GUD),
Vaginitis and/or Vaginal Discharge (VG),
Cervicitis and/or Cervical Discharge (CD),
Pelvic Inflammatory Disease (PID),
Urethral Discharge (UD),
Anal Discharge (AD),
Others (O)