Impact of two stakeholder selected implementation strategy bundles on PrEP delivery in maternal and child health clinics in Kenya

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Abstract

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Introduction

Women remain at substantial risk for HIV acquisition during pregnancy and breastfeeding due to changes in biological and behavioral factors. Although PrEP has been recommended as safe and effective during pregnancy by the WHO and Kenyan government, barriers still exist in its delivery in sub-Saharan Africa. Integration of PrEP during antenatal care in maternal and child health (MCH) clinics remains sub-optimal.

Methods

We piloted 2 bundles of 3 implementation strategies selected by stakeholders to enhance delivery in Western Kenya.: 1) task shifting PrEP counselling from clinicians/nurses to HIV testing services providers (HTS), training different cadres, and dispensing PrEP in MCH; 2) use of PrEP educational materials, PrEP health talks in waiting bays, and dispensing PrEP in MCH. We assessed each bundle using a difference-in-differences design, comparing the 3-month periods before and after implementation, in 8 facilities (4 intervention and 4 comparison). Absolute changes were evaluated in primary outcomes: PrEP penetration, PrEP fidelity, PrEP offer, PrEP risk screening, client PrEP knowledge & satisfaction, and timeliness (waiting and service times); and 135 Health providers reported acceptability and appropriateness of the implementation strategies.

Results

Overall, 4,872 women seeking MCH services participated, (2,450 in the first bundle and 2,422 in the second). Both strategy bundles were associated with significant improvements in PrEP fidelity, PrEP penetration, and PrEP offer. With the first bundle, PrEP fidelity increased by 15.8% points (95%CI: 7.3%, 24.3%; p<0.001), PrEP

penetration by 7.7% points (95%CI: 2.5%, 12.9%; p=0.004), and PrEP offer by 7.7% points (95%CI: 3.3%, 12.1%; p=0.001) in intervention vs comparison sites. With the second bundle, PrEP fidelity increased by 32.0% points (95%CI: 20.9%, 43.0%; p<0.001), PrEP penetration by 22.3% points (95%CI: 15.9%, 28.7%; p<0.001), and PrEP offer by 10.7% points (95%CI: 5.5%, 15.9%; p<0.001) in intervention vs comparison sites. With the first bundle, PrEP risk screening increased by 11.7% points (95%CI: 3.4%, 20.0%; p=0.006), while the second bundle was associated with a non-significant increase in PrEP risk screening (6.9% points (95%CI: -1.5%, 15.3%; p=0.106). Neither strategy bundle was associated with changes in HIV testing, client satisfaction, client service time, or waiting time (p>0.05). Both bundles were highly rated by healthcare providers on acceptability (median: 19/20 points; IQR: 16, 20) and appropriateness (median: 20/20 points; IQR: 18, 20).

Conclusion

Stakeholder-selected implementation strategy bundles addressing provider type, service location, and educational materials significantly improved PrEP implementation outcomes without affecting client satisfaction, service and waiting times.

Introduction

Women in high HIV prevalence settings in sub-Saharan Africa remain at a substantial risk for HIV acquisition during pregnancy and breastfeeding periods due to changes in biological and behavioral factors (1–3). In 2022, women and girls accounted for 46% of all new HIV infections globally and 63% in sub-Saharan Africa (4). Pre-exposure prophylaxis (PrEP) has been recommended as a safe and effective biomedical HIV prevention strategy intervention during pregnancy and breastfeeding by both the World Health Organization (WHO) and the Kenyan government (5,6) and can contribute to the elimination of vertical transmission.

While PrEP has been offered within HIV care clinics, integrating HIV prevention into other clinics is an important but underutilized strategy. Studies have found that confusion of PrEP with antiretroviral therapy (ART), as well as stigma associated with being seen in an HIV care clinic as barriers to PrEP uptake in HIV care clinics; therefore, delivering PrEP in a status neutral setting like maternal child health (MCH) clinics is ideal for women (7). MCH clinics offer the opportunity to reach a high number of women specifically because of high antenatal care (ANC) attendance. Additionally, HIV prevention services can be offered along HIV care services through prevention of mother to child transmission (PMTCT) programs for effective prevention of vertical HIV transmission (8,9). Therefore, integrating PrEP provision into family planning (FP) and MCH clinics can reach a substantial number of women (10) through leveraging available resources and supply chains system (11,12).

However, integration and scale-up of PrEP in MCH clinics remains a challenge due to healthcare system barriers. The most common barriers of integrated PrEP delivery in MCH identified from a quantitative survey with healthcare workers (HCW) in Kenya include increased workload due to shortage of healthcare workers, insufficient PrEP knowledge among HCWs due to lack of proper training, stockouts (PrEP and HIV testing commodities), and lack of space and privacy (13). Innovative implementation strategies are needed to address these barriers. Prior qualitative studies and a PrEP stakeholder workshop in Kenya suggested and prioritized implementation strategies to enhance PrEP delivery within MCH clinics (13,14). These strategies include shifting tasks for risk assessment to different cadres, fast-tracking clients to reduce waiting time, training/retraining providers to increase knowledge, and use of information, education, and communication materials. (13,14).

The PrEP in Pregnancy Accelerating Reach and Efficiency (PrEPARE) study was designed to evaluate four bundles of these diverse implementation strategies. The first bundle was a combination of video education in the waiting bay, HIV self-testing, and PrEP dispensing in the MCH clinic and was associated with improvements in PrEP implementation outcomes (including penetration (5.4%), fidelity (7.6%), PrEP offer (4.4%), and client knowledge (9.6%) (15). The second combination bundle include fast-tracking PrEP clients and retraining health providers in addition to PrEP dispensing in MCH clinic; it was also associated with improvements in PrEP penetration (6.0%), fidelity (4.1%), offer (5.8%) and client knowledge (1.17%) (Sila & Wagner, under review). Other strategy bundles suggested for piloting from the stakeholder workshop included task shifting PrEP services from nurses/clinicians to HIV testing and counselling providers; training different cadres of HCWs; use of information, education, and communication (IEC) materials; and PrEP health talks in the MCH waiting (14).

Despite task-shifting being recommended by WHO as an effective strategy to solve the shortage of human resources in healthcare in low- and middle-income countries (16,17), few countries have adopted it to improve service delivery (18). Few studies have tested the effectiveness of task shifting PrEP services from nurses/clinicians to different cadres. Findings from a study in Canada suggested consensus between clinicians and community health workers (CHWs) regarding the feasibility of task shifting PrEP services with CHWs perceived as capable of handling non-clinical tasks (19). However, there is a strong body of literature supporting task-shifting within HIV care -- rather than HIV prevention -- systems. Findings from South Africa suggested that task shifting antiretroviral therapy tasks from doctors to trained nurses improved patient care outcomes (20). IEC materials have also been recognized by WHO as a practical and cost-effective approach to achieving better health outcomes (21). Systematic reviews have consistently demonstrated that tailored IEC materials can effectively address specific target populations' concerns (22). For instance, a study in Pakistan found that use of IEC interventions significantly improved child health practices and other care seeking behaviors (23). Similarly,

a study in South Africa suggested IEC materials are important tools in clients' knowledge and decision-making in PrEP uptake and continuation (24).

In this study, we tested two combination strategy bundles, each with three implementation strategies: 1) task shifting PrEP counseling, training of different providers, and provision of PrEP in MCH, and 2) provision of IEC materials, health talks in the waiting bays, and provision of PrEP in MCH. These combinations of strategies were selected by stakeholders to enhance the implementation of integrated PrEP delivery in MCH clinics in Kenya.

Methods:

Study design:
We conducted a difference-in-differences (DiD) study to evaluate the impact of two combination strategy bundles as part of the PrEPARE study pilot tests. The study was conducted between August 2022 and November 2023 with each strategy bundle taking 6 months (3-month baseline and 3-month intervention) periods. The first strategy bundle was tested between August 2022 and April 2023 while the second was tested between May 2023 and November 2023. During the baseline period, none of the facilities received the implementation strategies, while in the intervention period, the 4 intervention facilities received the strategy bundles tested. In the second strategy bundle testing, a separate set of 4 new intervention sites were selected to participate in the baseline and intervention periods, while the original 4 comparison sites were maintained from the prior test. The study is registered at ClinicalTrials.gov (NCT04712994).

Bundle 1: Task shifting and training of different cadres: Task shifting involved shifting PrEP counseling services from nurses and clinicians to HTS providers. During the intervention, two facilities shifted the responsibilities of PrEP counseling, prescription, and dispensing to the HTS providers, while at the other two study sites, HTS personnel solely counseled women for PrEP and referred eligible and willing women to the PMTCT nurse/clinician for PrEP initiation. All HTS providers were responsible for conducting risk assessments, HIV testing, and PrEP counseling. We identified all HCWs offering PrEP services or likely to be involved in PrEP delivery for a two-day training. The training program utilized the National AIDS and STI Control Program (NASCOP) of the Ministry of Health in Kenya's PrEP training curriculum and involved didactic lectures, role plays, case studies, case scenarios, discussions, and question and answer sessions. The training covered areas key in PrEP delivery and included topics on PrEP counseling, values clarification, patient-centered communication, commodity management, and monitoring and evaluation for PrEP. Task shifting strategy targeted PrEP penetration, PrEP fidelity, PrEP offer, and timeliness (reducing waiting time). Training different HCWs enabled task-shifting strategy and its associated outcomes.

Bundle 2: IEC materials and health talks at the waiting bays: The study team designed a set of IEC materials with PrEP information for use by both the healthcare providers and women seeking services at MCH clinics. These IEC materials included HIV and PrEP counselling guide flipbooks, PrEP job aids for HCWs, and posters with key PrEP messages and frequently asked questions for clients. All the IEC materials were translated into Luo, Swahili, and English languages for better understanding of the messages. Topics covered by different posters included PrEP initiation, continuation and discontinuation and PrEP frequently asked questions. Flipbooks used both staged photographs and illustrations and contained information on HIV risk factors, ways of protecting someone from HIV, understanding of PrEP pills, myths, and misconceptions, how to take PrEP, PrEP safety, and side effects. We also included case scenarios and discussion notes to guide HCWs in health talks and answering questions during the counselling sessions. All the intervention sites received multiple copies of each IEC item for use in MCH clinics before the start of intervention phase data collection activities. The implementation outcomes targeted by this strategy bundle most directly included client knowledge as well as PrEP penetration, PrEP fidelity, and PrEP offer.

PrEP delivery in MCH: During the study period, PrEP was dispensed within MCH clinics (ANC and Child welfare clinics) or MCH pharmacies in all sites, both intervention and comparison.

Setting & population: This study was conducted in Kisumu, Homa Bay, and Siaya counties in Western Kenya, which have the highest HIV prevalence in Kenya (25,26). The study involved 12 facilities: 4 control comparison sites participating in both tests and 4 intervention sites for each combination strategy bundle; facilities were balanced between counties. The sites were purposely selected due to their participation in previous HIV research studies.

Women seeking MCH services in the study sites were approached for participation in surveys if they were ≥15 years old and provided oral consent. HCW offering PrEP in MCH also participated in evaluating the appropriateness and acceptability of the implementation strategy bundles. HCWs participated if they were ≥18 years and were working at the facility during the study period and provided oral consent.

Data collection and measurements: Anonymous client exit surveys with women seeking MCH services were administered by a trained study nurse using the REDCap mobile app after the participant received services at the MCH clinic. The client exit survey assessed participant demographics, PrEP knowledge, HIV testing, HIV risk assessment, PrEP counseling and offer, and satisfaction with services offered. For time and motion surveys, participants were asked to carry along the time and motion cards as they received services at different service delivery points while HCWs would complete time-in and time-out for each service. The participant would return the completed card to the study nurse after receiving all the services. At the end of each intervention phase, HCWs providing services at the MCH, and participating in piloting the strategies were asked to provide feedback on the acceptability and appropriateness of the strategy bundles. A unique survey link to a REDCap survey was sent via email or Short Message services (SMS) to the HCWs, and they were given two weeks to complete the survey with weekly reminders if they failed to complete the survey.

We measured implementation, service, and client outcomes. Implementation outcomes included PrEP penetration, PrEP fidelity, PrEP offer, strategy acceptability, and appropriateness scores; service outcomes included timeliness and satisfaction for client satisfaction with services (27). Client exit surveys, time and motion surveys, and HCW exit surveys were used to assess the impact of implementation strategy bundles. PrEP penetration was defined as the proportion of women screened for PrEP divided by the total number of women receiving antenatal and postnatal services. PrEP fidelity was defined as the proportion of women who received all PrEP-specific services in a visit: HIV testing, HIV risk assessment, and PrEP counseling. Timeliness was defined as waiting time and time client was receiving different services. Acceptability was defined as to how the strategy bundle met healthcare worker expectations while appropriateness as the degree to which healthcare providers perceived the strategy bundle to fit (27).

Data analysis: We compared the implementation outcomes at the baseline and intervention periods between intervention and comparison sites using a difference-in-differences approach and a multi-level mixed-effect regression model with a random effect for site. We coded intervention and comparison groups and pre/post periods as binary terms and included an interaction term between the two. The impact of the implementation strategy bundle was calculated as the interaction term and the impact was deemed statistically significant at alpha ≤0.05. All the analyses were categorized per the strategy bundle and stratified analysis conducted for women seeking first ANC service versus other services, age 15-24 years vs ≥25 years. Acceptability and appropriateness were summarized using means and standard deviation.

Ethical considerations: The study was reviewed and approved by the University of Washington Institutional Review Board (STUDY00008392), Kenyatta National Hospital/University of Nairobi Ethics & Research Committee (P907/11/2019). We also obtained approval from the Department of Health from 3 counties and health administrators from the facilities involved. All participants provided oral informed consent for participation.

Results

Service disruptions:

During the study period, we experienced service disruptions which impacted piloting of the implementation strategy bundles and overall service delivery. In piloting of the first strategy bundle, HIV stockouts affected both

intervention and comparisons sites at different time points during baseline and interventions periods, while an HCW strike impacted one site from each arm respectively **(Supplementary figure 1).** In the second strategy bundle, services disruptions were uncommon, just five days across all sites were impacted by nationwide demonstrations during the baseline period and interborder conflict for six days affected one intervention site during the intervention phase, which also affected the number of health talks given **(Supplementary figure 2).** On average, facilities were able to offer health talks 3.0 (IQR: 2.0, 3.0) days per week, this did not vary substantially clinic to clinic **(Supplementary table 1).**

Participant characteristics:
Overall, 4,872 women seeking MCH services were surveyed while testing the two implementation strategy bundles. Of this total, 2,450 women (1,682 client exit survey and 767 time and motion surveys) were enrolled in the first strategy bundle test, while 2,422 (1,654 client exit survey and 768 time and motion surveys) were enrolled in the second strategy bundle test. Among the women who participated in the client exit surveys, the median age for those involved in the first bundle assessment was 24 years (inter quartile range [IQR]: 21 - 28) and 11.5% were seeking their first ANC. Similarly, in the second bundle assessment, the median age was 24 years (IQR: 21 - 28), with 9.9% seeking first ANC (**Supplementary table 2**).

Bundle 1: Task shifting PrEP counselling from clinicians/nurses to HIV testing providers, training different health providers, and offering PrEP in MCH

Baseline assessment of implementation outcomes
In the first bundle assessment, substantial differences were noted between the comparison and intervention sites at baseline; PrEP fidelity (0.6% vs 8.6%), PrEP risk screening assessment (21.3% vs 30.2%), PrEP penetration (0.7% vs 8.7%) and PrEP offer (1.2% vs 3.5%) were all substantially higher in the intervention clinicsthan the comparison clinics. HIV testing among eligible women was low across the comparison and interventionsites (27.3% vs 41.4%) due to HIV testing kits stockouts during the baseline period. Client satisfaction scores were similar between comparison and intervention sites (median: 20 vs 21), as was client service time (12 vs 13mins) and client waiting time (33 vs 37 mins) (**Table 1**).

Implementation outcomes
The first bundle was associated with significant increases in PrEP fidelity, PrEP penetration, PrEP screening, and PrEP offer, but no significant changes in client satisfaction, client PrEP knowledge, and client waiting and service times. This bundle was associated with 15.8% points increase in PrEP fidelity (95%CI: 7.3%, 24.3%; p<0.001) and 11.7% points increase in PrEP risk screening assessment (95%CI: 3.4%, 20.0%; p=0.006) in intervention compared to comparison sites. It was further associated with 7.7% points (95%CI: 2.5%, 12.9%; p=0.004) increase in PrEP penetration and with a similar increase of 7.7% points (95%CI: 3.3%, 12.1%; p=0.001) in PrEP offer in intervention vs comparison sites (**Figure 1**). There was a non-significant decrease in HIV testing by 6.6% points (95%CI: -19.9%, 6.7%; p=0.330). In contrast, there was no difference in client satisfaction (-0.01/24 points; 95%CI: -0.35, 0.33; p=0.961) in intervention sites compared to comparison sites. The implementation strategy bundle was not associated with significant changes in service time (-0.16 minutes; 95%CI: -0.39, 0.06; p=0.156) or waiting time (+0.18 minutes, 95%CI: -0.07, 0.44; p=0.159) in intervention vs comparison sites (**Table 1**).

Stratified analysis
In our sensitivity analysis, we observed more pronounced implementation outcome changes among women aged 25+ years compared to those between 15 and 24 years. Comparing women aged 25+ years to those between 15 and 24 years, PrEP fidelity increased by 19.1% vs 14.9% points, PrEP penetration 8.7% vs 7.6% points, and PrEP offer by 9.7% vs 6.4% points respectively, in intervention sites compared to comparison sites (**Supplementary table 3**). However, regarding HIV testing, we noted a pronounced increase among women aged 25+ years while more pronounced negative changes were observed among women aged between 15 to 24 years (**Supplementary table 3**). Comparing women seeking first ANC and those seeking other MCH services, implementation outcome improvements were more pronounced among women seeking first ANC services

compared to those seeking other services. Overall, HIV testing was low among women seeking other services compared to those seeking their first ANC (**Supplementary table 4**).

Impact on client PrEP knowledge

This bundle was associated with a small but significant improvement in overall knowledge (0.27 out of 6-point increase; 95%CI: 0.04, 0.51; p=0.002) **(Table 1)** and improvement in some of the individual client PrEP knowledge questions. These included questions on the frequency of PrEP use (8.7% points increase; 95%CI: 0.6%; 16.7%; p=0.035), duration to achieve maximum protection (5.4% points increase; 95%CI: 0.9%, 9.9%; p=0.019) and potential side effects (5.4% points increase; 95%CI: 2.4%, 8.4%; p<0.001); however, the strategy was not associated with improvements in knowledge on questions on PrEP for HIV prevention, concurrent condom use, and appropriate time to discontinue PrEP (**Figure 1, Table 2**).

Bundle 2: Provision of IEC materials, PrEP health talks in the MCH waiting bays and offering PrEP in MCH

Baseline assessment of implementation outcomes

In the second bundle assessment, we observed higher baseline levels of HIV testing than in the first bundle as HIV testing kits stockouts were solved. Comparing comparison and intervention sites, we observed differences in HIV testing (61% vs 70.2%), PrEP fidelity (10.3% vs 14.3%), PrEP risk screening assessment (29.6% vs 39.4%), PrEP penetration (5.7% vs 11.7%) and PrEP offer (4.4% vs 7.6%). Despite these differences, client satisfaction was high and comparable at baseline between comparison and intervention sites (median: 21 vs 22). Client service time was similar between comparison and intervention sites (median: 15 vs 14 mins), while client waiting time was lower at comparison sites than intervention sites at baseline (median: 32.5 vs 47 mins) (**Table 1**).

Implementation outcomes

The implementation strategy bundle was associated with significant increases in PrEP fidelity, PrEP penetration, and PrEP offer, but not in HIV testing, client satisfaction, or waiting time. The bundle was associated with 32.0% points increase (95%CI: 20.9%, 43.0%; p<0.001) in PrEP fidelity, 22.3% points (95%CI: 15.9%, 28.7%; p<0.001) in PrEP penetration and 10.7% points (95%CI: 5.5%, 15.9%; p<0.001) in PrEP offer in intervention sites compared to comparison sites (**Figure 2**). The strategy test was associated with no changes in HIV testing (4.8% points; 95%CI: -8.3%, 17.9%; p=0.476), PrEP risk screening assessment (6.9% points; 95%CI: -1.5%, 15.3%; p=0.109), client satisfaction (+0.03/24 points; 95%CI: -0.29, 0.36; p=0.841), client service time (+0.17 minutes; 95%CI: -0.06, 0.40; p=0.153), or waiting time (-0.19 minutes; 95%CI: -0.43, 0.42; p=0.108) in intervention versus comparison sites (**Table 1**).

Stratified analysis:

Overall, implementation outcome changes were more pronounced among women seeking first ANC services compared to those seeking other MCH services. Specifically, PrEP fidelity increased by 49.3% vs 26.6% points, PrEP penetration by 49.7% vs 19.0% points, PrEP offer by 32.7% vs 8.1% points respectively, comparing intervention versus comparison sites (**Supplementary table 4**). Regarding the client PrEP knowledge, we observed significant changes among women seeking first ANC women and those seeking other services, with a greater magnitude among women seeking first ANC compared to those seeking other services, in intervention vs comparison sites (**Supplementary table 5)**. We observed more pronounced improvements in the implementation outcomes among women aged 15 to 24 years compared to those 25+ years; PrEP fidelity increased by 36.6% vs 29.6% points, PrEP penetration by 23.7% vs 21.5% points and PrEP offer by 11.7% vs 10.2% points (**Supplementary table 3**). On client PrEP knowledge, the magnitude was more pronounced among women aged 25+ years compared to those aged 15 to 24 years (**Supplementary table 6)**.

Impact on client knowledge

This strategy bundle was associated with a significant increase in correct responses regarding PrEP knowledge. Knowledge about PrEP for HIV prevention increased by 14.1% points (95%CI: 4.9%, 23.3%; p=0.003), frequency of PrEP use by 26.1% points (95%CI: 17.8%, 34.5%; p<0.001), time to reach maximum protection 23.8% points

(95%CI: 17.9%, 29.7%; p<0.001), condom use by 22.1% points (95%CI: 14.9%, 29.4%; p<0.001), and side effects by 9.4% points (95%CI: 5.6%, 13.4%; p<0.001). However, knowledge about PrEP discontinuation did not change (0.5% points; 95%CI: -2.2%, 3.1%; p=0.729) (**Figure 2, table 2**).

HCW assessment of the implementation strategy bundles:
Both implementation strategy bundles received high ratings by healthcare providers on acceptability and appropriateness. However, the scores were higher in the second implementation strategy bundle compared to the first. In the first implementation strategy bundle, the median acceptability score was 18/20 points (IQR: 16, 20), while the median appropriateness score was 19/20 points (IQR: 16, 20). In the second implementation strategy bundle, the median acceptability score was 20/20 points (IQR: 17, 20) while the median appropriateness score was 20/20 points (IQR: 18, 20) **(Table 1).**

Discussions
In this study, we evaluated the impact of two sets of stakeholders-selected implementation strategy bundles on implementation, service, and client outcomes for PrEP delivery in MCH clinics: 1) task shifting PrEP counselling from clinicians/nurses to HTS providers, training different cadres, and dispensing PrEP in MCH, and 2) use of IEC materials, PrEP health talks in MCH waiting bays, and dispensing PrEP in MCH. Both implementation strategy bundles were associated with significant improvements in PrEP fidelity and PrEP penetration, with high scores on HCW acceptability and appropriateness of the strategy bundles (primary outcomes). Neither strategy bundle was associated with significant improvements in client satisfaction, or client waiting and service time (primary outcomes). Both tests were associated with improvements in client PrEP knowledge; however, the magnitude of the improvements was more pronounced in the second bundle. We were unable to statistically compare PrEP uptake (secondary outcome). In our post hoc outcomes, both bundles were associated with significant improvements in PrEP offer and no significant changes in client HIV testing completion. However, the first bundle was associated with significant improvements in PrEP risk screening, whereas no significant changes were observed in the second bundle.

While it is challenging to make robust conclusions from directly comparing the results of each experiment to one another, it is worthwhile to assess large differences in magnitude, which are more likely to be associated with the strategy bundles and less likely to be due to background temporal trends. We observed that the second bundle was associated with more substantial increases in primary implementation outcomes compared to the first. Of note, the HIV testing kits stock outs experienced in the first bundle assessment likely influenced these differences. We observed logical links between implementation strategies and hypothesized implementation outcomes. The second bundle was associated with substantial improvements in client PrEP knowledge, which we believe to be related to the IEC materials and health talks; the task-shifting strategy in the first bundle was associated with improved PrEP penetration and fidelity in MCH.

These two bundles were part of a larger study that tested a total of four implementation strategy bundles to improve PrEP in pregnancy in Western Kenya (14,15). In the previous rounds of implementation strategy bundle testing, we tested video information, HIV self-testing (14,15), and PrEP dispensing in MCH and fast-tracking PrEP refill clients in MCH, retraining providers, and co-location of medication dispensing *(Sila, under review)*. In comparison with the previous implementation strategy bundles tested, the two strategy bundles tested in the present study were associated with a larger magnitude improvement in implementation outcomes (15). The strategy bundle that focused on IEC materials, PrEP health talks, and dispensing PrEP in MCH was associated with roughly 2-fold greater improvements in PrEP fidelity and roughly 3-fold greater improvements in PrEP penetration, but comparable improvements in PrEP offer as the strategy bundle focused on task shifting and training different providers. Our study findings align with existing literature on effectiveness of task shifting as a strategy to overcome resource limitations in sub-Saharan Africa (28), particularly in ART delivery (29). Systematic reviews support task-shifting as an effective approach to increasing access to various healthcare services including PrEP (30). In our study, we implemented task-shifting by reallocating PrEP-related tasks -- such as PrEP risk assessment, PrEP counselling, and PrEP dispensing -- from nurses and clinicians to HTS providers. By doing so, we allowed nurses and clinicians to focus on more complex cases, while ensuring that

women undertaking HIV testing received PrEP-related information. This pragmatic approach aimed to scale up PrEP delivery while leveraging existing resources and empowering frontline workers. Studies in high-income countries have demonstrated that task-shifting can lead to better health outcomes without compromising the quality of care (31). It is important to note that prolonged stockouts of HIV testing commodities and HCW strikes may have adversely affected service delivery in the first bundle, potentially influencing the observed outcomes. Despite these challenges, our findings underscore the potential of task-shifting PrEP services to improve healthcare access and delivery in resource-limited settings.

IEC materials are powerful tools for disseminating health information (21) . Literature review supports that most efficacious IEC materials integrate both visual and interactive elements, thereby not only capturing attention but also ensuring the information is internalized (32–34). Although posters and job aids were used and described containing visual attributes, they were complimented by flipbooks which contained visual and interactive attributes. While job aids serve as practical tools for HCWs, ensuring adherence to protocol through easy-to-follow illustrations, flipbooks allow for structured and engaging discussions especially in small groups or one-on-one (32). Our result demonstrates that a strategy bundle of IEC materials and PrEP health talk was effective in improving PrEP penetration, PrEP fidelity, and PrEP offer. In addition, this bundle substantially enhanced PrEP knowledge among the clients seeking MCH services. Of note, the magnitude of knowledge increase associated with this set of IEC materials was the second largest improvement in knowledge among all tested bundles; the video tested previously demonstrated a higher magnitude of improvement (15). We hypothesize that in addition to improving knowledge, normalizing PrEP discussion within MCH waiting areas would be able to reduce PrEP-associated stigma and enhance provider-client interaction. In resource-limited settings, IEC materials efficiently convey standardized information to a large audience, reducing the need for repeated verbal explanations and freeing healthcare providers to focus on critical tasks. Integrating IEC materials and PrEP health talks into MCH waiting bays represents a practical approach to improving PrEP delivery in MCH.

Although we piloted implementation strategies in real-world settings without additional research staff for service delivery, we allocated supplementary resources for implementing the strategy bundles, including funding for training, and designing and printing IEC materials. However, we encountered numerous service delivery disruptions, including HIV test kits stockouts, HCW strikes, nationwide demonstrations, and intercommunity clashes. These disruptions significantly impeded consistent implementation of the strategy bundle. Specifically, PrEP health talks -- an essential component of the intervention -- were not consistently conducted daily in MCH clinics, potentially underestimating the effectiveness of health talks in PrEP delivery. Additionally, selecting sites with history of research participation and better resources may have introduced selection bias potentially skewing the representativeness of the study sample. Furthermore, while facilities were allocated to intervention and comparison conditions prior to measuring baseline values, this approach may not have fully accounted for baseline characteristics and baseline differences, potentially affecting the comparability of the groups. Further research should test these strategy bundles in a broader range of clinics to validate their effectiveness and generalizability, ultimately improving PrEP delivery in MCH setting.

Conclusion:

The two stakeholder selected implementation bundles – task shifting PrEP counselling from clinicians/nurses to HTS providers, training different cadres and dispensing PrEP in MCH - and – use of IEC materials, PrEP health talks in MCH waiting bays and dispensing PrEP in MCH – improved PrEP implementation outcomes in MCH clinics. These strategies were effective without affecting waiting times or provider-client interaction time. Despite challenges like stockouts, the findings support broader implementation of these strategy tests to enhance PrEP delivery in resource-limited settings and address gaps in absolute coverage.

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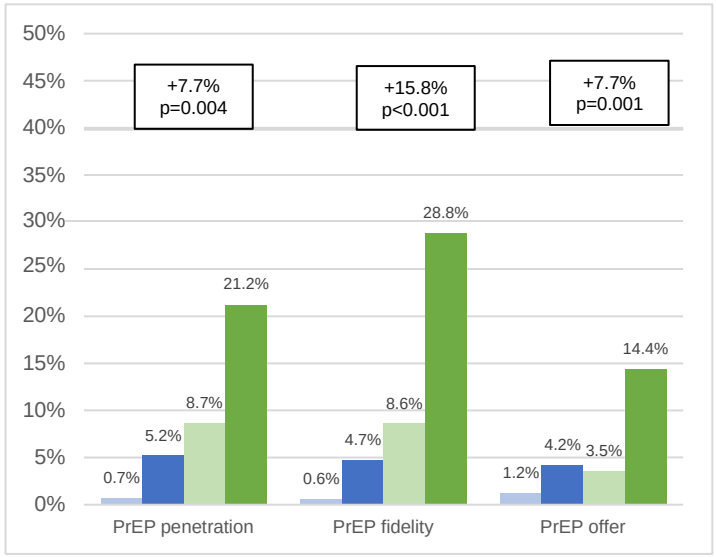
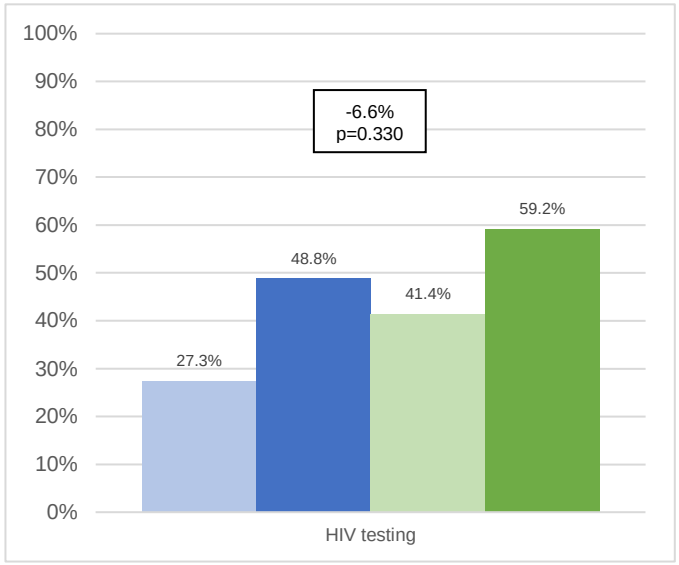
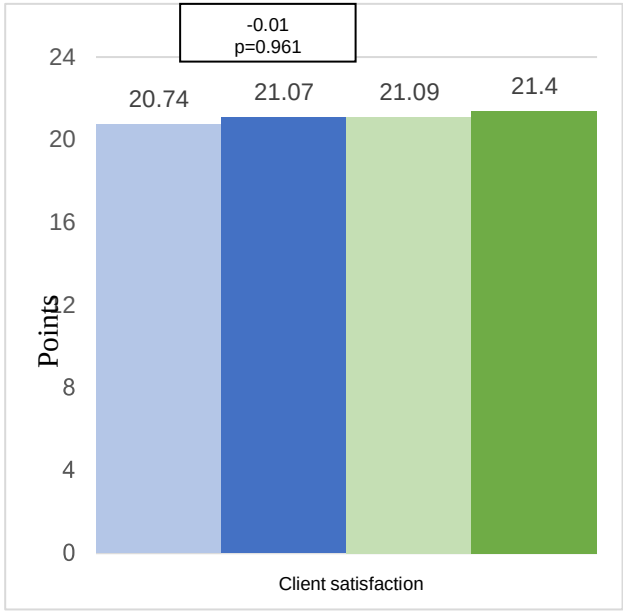
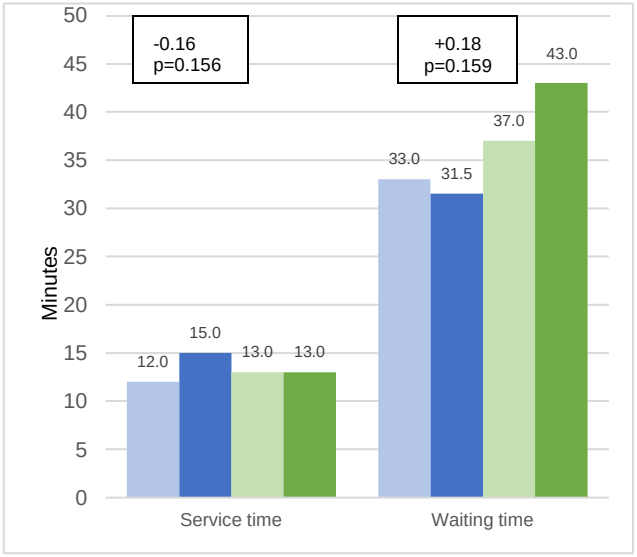
Tables & Figures

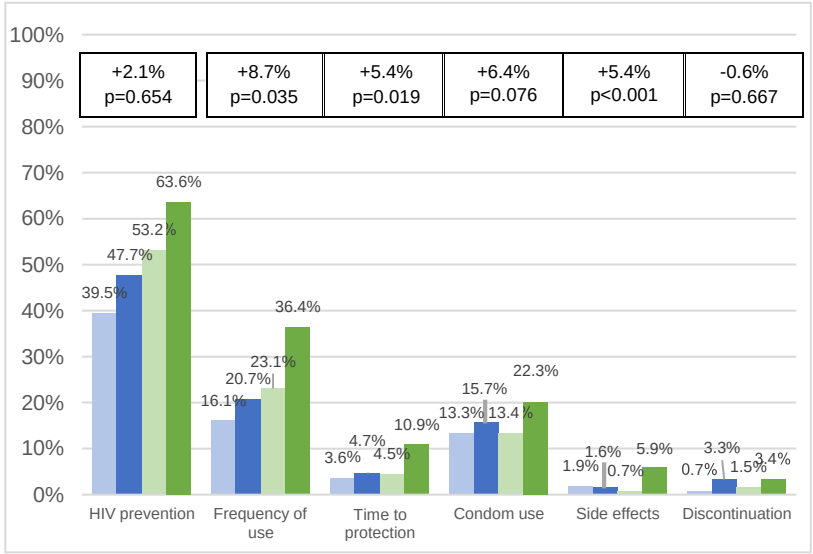
Figure 1: Difference in differences comparison of implementation, effectiveness, and service outcomes in implementation strategy bundle 1









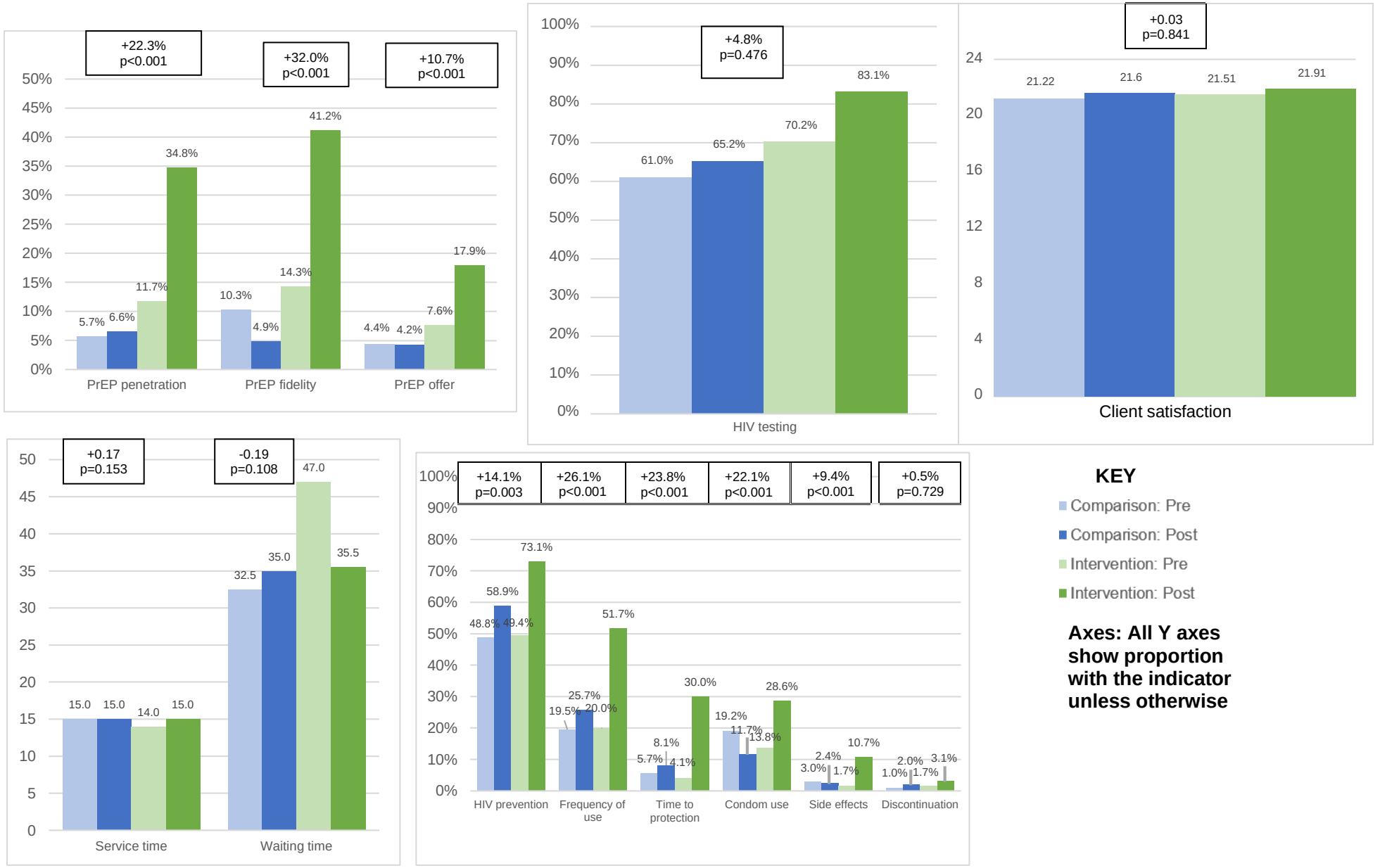


KEY

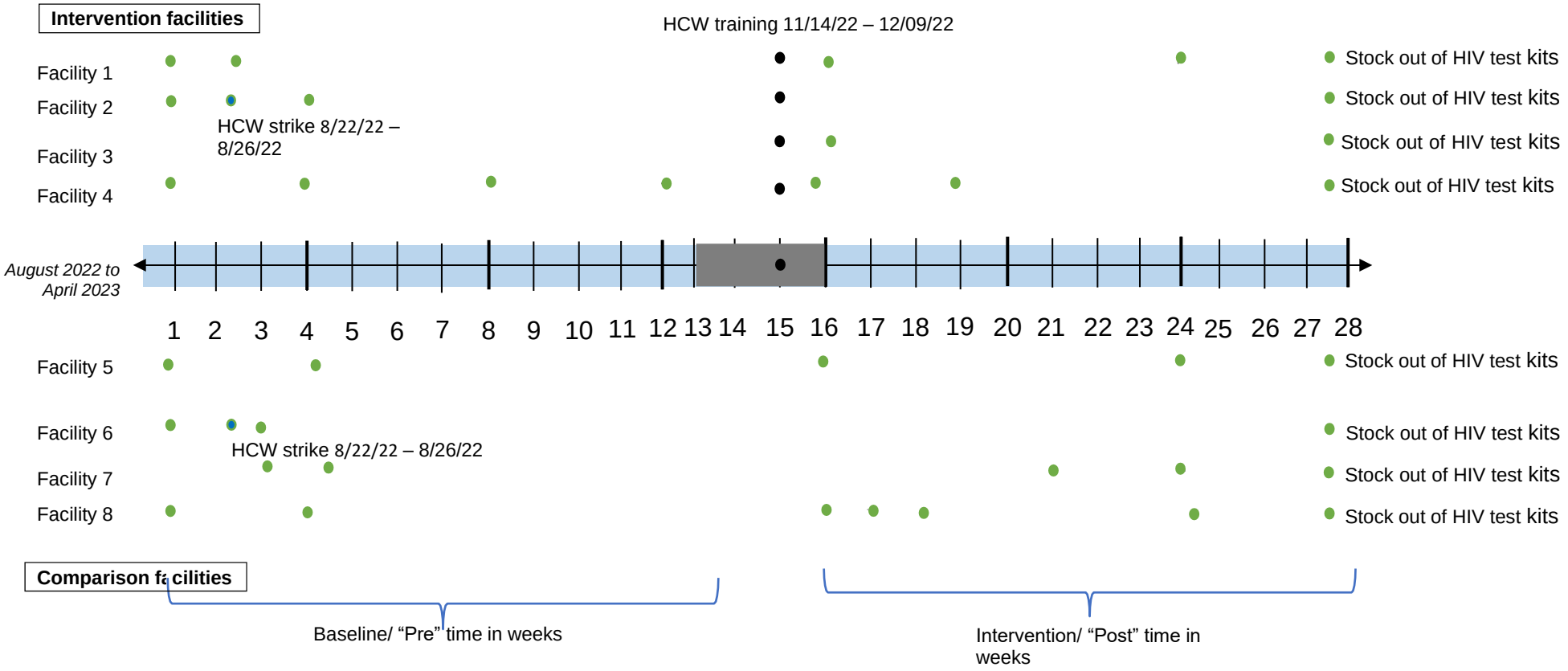
- Comparison: Pre
- Comparison: Post
- Intervention: Pre
- Intervention: Post

Axes: All Y axes show proportion with the indicator unless otherwise

Figure 2: Difference in differences comparison of implementation, effectiveness, and service outcomes in implementation strategy bundle 2



Supplementary figure 1: Implementation strategy bundle 1 timeline in weeks and background service delivery interruptions



Supplementary figure 2: Implementation strategy bundle 2 timeline in weeks and background service delivery interruptions

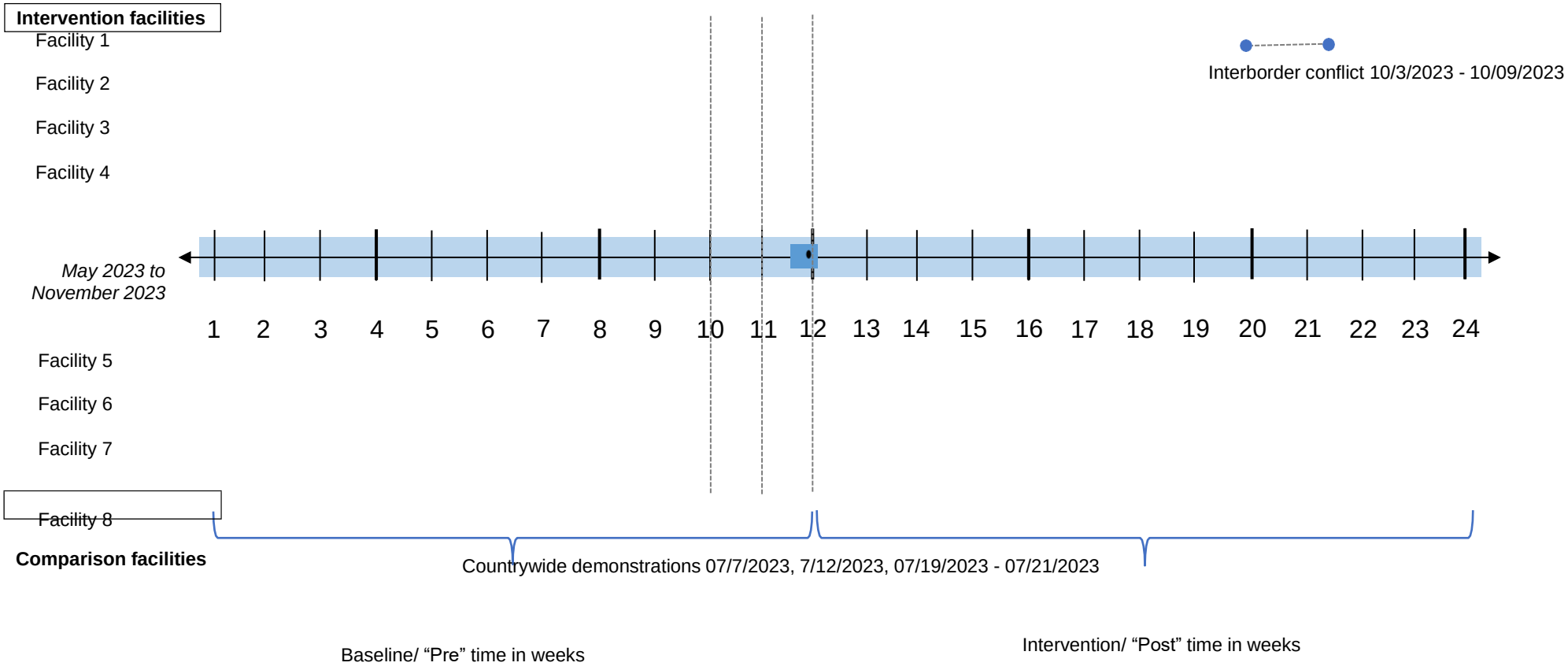


Table 1: Difference in differences comparison of effectiveness and implementation outcomes

Implementation strategy bundle 1												
		Comparison sites				**Intervention sites**				**Difference in difference** [Change (intervention) - Change (comparison)] ****Adjusted for first ANC*		
		Pre (N=415)		Post (N=426)		Pre (N=402)		Post (N=439)		Point estimate	Confidence interval	p-value
Outcome	***Definition***	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
PrEP fidelity[1]	Proportion of women who receive all PrEP specific steps in a visit (HIV testing, HIV risk screening, PrEP counseling)	172	1 (0.6%)	170	8 (4.7%)	174	15 (8.6%)	191	55 (28.8%)	15.8%	(7.3%, 24.3%)	<0.001
HIV testing[3]	HIV tested among eligible (not tested in past 6 months, not known HIV positive)	172	47 (27.3%)	170	83 (48.8%)	174	72 (41.4%)	191	113 (59.2%)	-6.6%	(-19.9%, 6.7%)	0.330
PrEP risk screening[3]	Asked questions on HIV risk behavior characteristics (yes vs no/don't know)	414	88 (21.3%)	426	157 (36.9%)	401	121 (30.2%)	439	256 (58.3%)	11.7%	(3.4%, 20.0%)	0.006
PrEP penetration[1]	Proportion of women who are counseled about PrEP / total women receiving antenatal or postnatal services	412	3 (0.7%)	426	22 (5.2%)	402	35 (8.7%)	438	93 (21.2%)	7.7%	(2.5%,12.9)	0.004
PrEP offer[3]	Offered to start or continue taking PrEP/total women receiving antenatal or postnatal services	415	5 (1.2%)	425	18 (4.2%)	402	14 (3.5%)	439	63 (14.4%)	7.7%	(3.3%, 12.1%)	0.001
	Offered to start or continue taking PrEP (among those who were HIV negative and at high risk who were screened)	25	0 (0%)	44	6 (13.6%)	32	4 (12.5%)	72	20 (27.8%)	12.7%	(-11.5%, 36.9%)	0.304
PrEP uptake[2]	Initiated PrEP today (among those offered)	5	0 (0.0%)	18	5 (27.8%)	14	2 (14.3%)	63	15 (23.8%)	--	--	--
	Initiated PrEP today (among full population)	415	0 (0.0%)	426	5 (1.2%)	402	2 (0.5%)	439	15 (3.4%)	--	--	--
PrEP continuation[2]	Already taking PrEP and will continue to take PrEP (among those offered)	5	2 (40.0%)	18	5 (27.8%)	14	2 (14.3%)	63	4 (6.4%)	--	--	--
	Already taking PrEP and will continue to take PrEP (among full population)	415	3 (0.7%)	426	8 (1.9%)	402	4 (1.0%)	439	5 (1.1%)	--	--	--
Service time[1]	Number of minutes of service receipt time	192	12 (8 - 21)	192	15 (10.5 - 26)	191	13 (9 - 23)	192	13 (9 -22)	-0.16	(-0.39, 0.06)	0.156
Waiting time[1]	Number of minutes of waiting time	192	33 (14.5 - 63)	192	31.5 (15 - 56)	191	37 (18 - 66)	192	43 (25 - 66.5)	0.18	(-0.07, 0.44)	0.159
Client satisfaction[1]	Satisfaction on a scale of 0-24 points	415	20.0 (20.0, 22.0)	426	21.0 (20.0, 22.0)	402	21.0 (20.0, 22.0)	439	21.0 (20.0, 22.0)	-0.01	(-0.35, 0.33)	0.961
HCW satisfaction[1]	Appropriateness (IAM) of implementation strategies		--		--		--	92	18 (16 - 20)	--	--	--
	Acceptability (AIM) of implementation strategies		--		--		--	92	19 (16 - 20)	--	--	--
Client PrEP knowledge[2]	All correct answers (6 questions based on content covered in counseling sessions)	415	0 (0%)	426	2 (0.5%)	402	0 (0%)	439	1 (0.2%)	-0.2%	(-1.0, 0.57)	0.561
	Number of correct answers (0-6) n (mean)	415	0.75	426	0.94	402	0.97	439	1.43	0.27	(0.04, 0.51)	0.022
Implementation strategy bundle 2												

		Comparison sites				Intervention sites				Difference in difference [Change (intervention) - Change (comparison)] ***Adjusted for first ANC		
		Pre (N=406)		Post (N=409)		Pre (N=419)		Post (N=420)		Point estimate	Confidence interval	p-value
Outcome	Definition	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
PrEP fidelity[1]	Proportion of women who receive all PrEP specific steps in a visit (HIV testing, HIV risk screening, PrEP counseling)	136	14 (10.3%)	163	8 (4.9%)	161	23 (14.3%)	148	61 (41.2%)	32.0%	(20.9%, 43.0%)	<0.001
HIV testing[3]	HIV tested among eligible (not tested in past 6 months, not known HIV positive)	136	83 (61.0%)	164	107 (65.2%)	161	113 (70.2%)	148	123 (83.1%)	4.8%	(-8.3%, 17.9%)	0.476
PrEP risk screening[3]	Asked questions on HIV risk behavior characteristics (yes vs no/don't know)	406	120 (29.6%)	409	136 (33.3%)	419	165 (39.4%)	420	208 (49.5%)	6.9%	(-1.5%, 15.3%)	0.109
PrEP penetration[1]	Proportion of women who are counseled about PrEP / total women receiving antenatal or postnatal services	405	23 (5.7%)	409	27 (6.6%)	418	49 (11.7%)	420	146 (34.8%)	22.3%	(15.9%, 28.7%)	<0.001
PrEP offer[3]	Offered to start or continue taking PrEP/total women receiving antenatal or postnatal services	406	18 (4.4%)	409	17 (4.2%)	419	32 (7.6%)	419	75 (17.9%)	10.7%	(5.5%, 15.9%)	<0.001
	Offered to start or continue taking PrEP (among those who were HIV negative and at high risk who were screened)	43	8 (18.6%)	49	5 (10.2%)	60	16 (26.7%)	82	41 (50.0%)	32.5%	(9.7%, 55.2%)	0.005
PrEP uptake[2]	Initiated PrEP today (among those offered)	18	4 (22.2%)	17	4 (23.5%)	32	7 (21.9%)	75	11 (14.7%)	--	--	--
	Initiated PrEP today (among full population)	406	4 (1.0%)	409	4 (1.0%)	419	7 (1.7%)	420	11 (2.6%)	--	--	--
PrEP continuation[2]	Already taking PrEP and will continue to take PrEP (among those offered)	18	8 (44.4%)	17	5 (29.4%)	32	5 (15.6%)	75	9 (12.0%)	--	--	--
	Already taking PrEP and will continue to take PrEP (among full population)	406	12 (3.0%)	409	8 (2.0%)	419	9 (2.2%)	420	10 (2.4%)	--	--	--
Service time[1]	Number of minutes of service receipt time	192	15.0 (10.0, 29.0)	192	15.0 (10.0, 29.0)	192	14.0 (8.0, 29.0)	192	15.0 (10.5, 28.5)	0.17	(-0.06, 0.40)	0.153
Waiting time[1]	Number of minutes of waiting time	192	32.5 (16.0, 69.0)	192	35.0 (14.0, 71.5)	192	47.0 (22.0, 81.0)	192	35.5 (23.0, 58.0)	-0.19	(-0.43, 0.42)	0.108
Client satisfaction[1]	Satisfaction on a scale of 0-24 points	406	21.0 (20.0, 23.0)	409	22.0 (20.0, 23.0)	419	22.0 (20.0, 23.0)	420	22.0 (21.0, 23.0)	0.03	(-0.29, 0.36)	0.841
HCW satisfaction[1]	Appropriateness (IAM) of implementation strategies		--		--		--	45	20.0 (18.0, 20.0)	--	--	--
	Acceptability (AIM) of implementation strategies		--		--		--	45	20.0 (17.0, 20.0)	--	--	--
Client PrEP knowledge[2]	All correct answers (6 questions based on content covered in counseling sessions)	406	0	409	0	419	0	420	0.007	-	-	-
	Number of correct answers (0-6)	406	0.97	409	1.09	419	0.91	420	1.97	0.96	(0.72, 1.21)	<0.001

[1]Primary outcome
[2]Secondary outcome
[3]Post hoc outcome

Table 2: Impact of Implementation strategy bundles on client PrEP knowledge

Implementation strategy bundle 1							
	Comparison		**Intervention**		**Difference in difference** [Change (intervention) - Change (comparison)] ***Adjusted for first ANC		
	n (%) or median IQR	n (%) or median IQR	n (%) or median IQR	n (%) or median IQR			
Indicator	Comparison: Pre (N=415)	Comparison: Post (N=426)	Intervention: Pre (N=402)	Intervention: Post (N=439)	Point estimate	95% CI	p-value
HIV prevention	164 (39.5%)	203 (47.7%)	214 (53.2%)	279 (63.6%)	2.1%	(-7.3%, 11.6%)	0.654
Frequency of use	67 (16.1%)	88 (20.7%)	93 (23.1%)	160 (36.4%)	8.7%	(0.6%, 16.7%)	0.035
Time to protection	15 (3.6%)	20 (4.7%)	18 (4.5%)	48 (10.9%)	5.4%	(0.9%, 9.9%)	0.019
Condom use	55 (13.3%)	67 (15.7%)	54 (13.4%)	98 (22.3%)	6.4%	(-0.7%, 13.4%)	0.076
Side effects	8 (1.9%)	7 (1.6%)	3 (0.7%)	26 (5.9%)	5.4%	(2.4%, 8.4%)	<0.001
Discontinuation	3 (0.7%)	14 (3.3%)	6 (1.5%)	15 (3.4%)	-0.6%	(-3.4%, 2.2%)	0.667
Implementation strategy bundle 2							
	Comparison		**Intervention**		**Difference in difference** [Change (intervention) - Change (comparison)] ***Adjusted for first ANC		
	n (%) or median IQR	n (%) or median IQR	n (%) or median IQR	n (%) or median IQR			
Indicator	Comparison: Pre (N=406)	Comparison: Post (N=409)	Intervention: Pre (N=419)	Intervention: Post (N=420)	Point estimate	95% CI	p-value
HIV prevention	198 (48.8%)	241 (58.9%)	207 (49.4%)	307 (73.1%)	14.1%	(4.9%, 23.3%)	0.003
Frequency of use	79 (19.5%)	105 (25.7%)	84 (20.0%)	217 (51.7%)	26.1%	(17.8%, 34.5%)	<0.001
Time to protection	23 (5.7%)	33 (8.1%)	17 (4.1%)	126 (30.0%)	23.8%	(17.9%, 29.7%)	<0.001
Condom use	78 (19.2%)	48 (11.7%)	58 (13.8%)	120 (28.6%)	22.1%	(14.9%, 29.4%)	<0.001
Side effects	12 (3.0%)	10 (2.4%)	7 (1.7%)	45 (10.7%)	9.4%	(5.6%, 13.4%)	<0.001
Discontinuation	4 (1.0%)	8 (2.0%)	7 (1.7%)	13 (3.1%)	0.5%	(-2.2%, 3.1%)	0.729

Supplementary table 1: Number of days the study facilities conducted PrEP health talks during implementation of strategy bundle 2

	Number of days per week (Median (IQR)
Facility 1	2.0 (2.0, 3.0)
Facility 2	3.0 (2.0, 3.0)
Facility 3	3.0 (2.5, 3.0)
Facility 4	3.0 (2.0, 3.0)
Facility 5	0.0 (0.0, 0.0)
Facility 6	0.0 (0.0, 0.0)
Facility 7	0.0 (0.0, 0.0)
Facility 8	0.5 (0.0, 1.0)
Overall	2.6 (2.4, 2.8)

Supplementary table 2: Client characteristics

Implementation strategy bundle 1					
		Comparison sites		Intervention sites	
	Overall (N=1682)	Pre (N=415)	Post (N=426)	Pre (N=402)	Post (N=439)
	n (%) or Median (IQR)				
Age	24.0 (21.0, 28.0)	24.0 (22.0, 29.0)	24.0 (21.0, 28.0)	23.5 (21.0, 28.0)	24.0 (21.0, 27.0)
Women seeking first ANC	193 (11.5%)	39 (9.4%)	48 (11.3%)	42 (10.4%)	64 (14.6%)
Tested for HIV among women seeking first ANC services	128 (66.3%)	16 (41.0%)	33 (68.8%)	22 (52.4%)	57 (89.1%)
Implementation strategy bundle 2					
		Comparison sites		Intervention sites	
	Overall (N=1654)	Pre (N=406)	Post (N=409)	Pre (N=419)	Post (N=420)
	n (%) or Median (IQR)				
Age	24.0 (21.0, 28.0)	24.0 (21.0, 29.0)	24.0 (21.0, 28.0)	24.0 (21.0, 27.0)	24.0 (21.0, 29.0)
Women seeking first ANC	164 (9.9%)	44 (10.8%)	39 (9.5%)	39 (9.3%)	42 (10.0%)
Tested for HIV among women seeking first ANC services	152 (92.7%)	41 (93.2%)	35 (89.7%)	38 (97.4%)	38 (90.5%)

Supplementary table 3: Difference in differences comparison of effectiveness and implementation outcomes stratified by age groups.

Implementation strategy bundle 1												
		Comparison sites				**Intervention sites**				**Difference in difference [(Change in intervention sites) – (Change in comparison sites)]**		
		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	Point estimate	Confidence interval	p-value
		Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post				
PrEP fidelity[1]	15 - 24	92	0 (0%)	97	4 (4.1%)	103	12 (11.7%)	107	32 (29.9%)	14.9%	(3.1%, 26.7%)	0.013
	25+	80	1 (1.2%)	73	4 (5.5%)	71	3 (4.2%)	84	23 (27.4%)	19.1%	(6.5%, 31.6%)	0.003
HIV testing[3]	15 - 24	92	25 (27.2%)	97	53 (54.6%)	103	52 (50.5%)	107	57 (53.3%)	-24.9%	(-43.9%, -5.9%)	0.01
	25+	80	22 (27.5%)	73	30 (41.1%)	71	20 (28.2%)	84	56 (66.7%)	24.8%	(4.0%, 45.7%)	0.019
PrEP risk screening[3]	15 - 24	211	47 (22.3%)	226	83 (36.7%)	237	78 (32.9%)	241	134 (55.6%)	8.5%	(-3.4%, 20.4%)	0.161
	25+	203	41 (20.2%)	200	74 (37.0%)	164	43 (26.2%)	198	122 (61.6%)	18.2%	(5.6%, 30.8%)	0.005
PrEP penetration[1]	15 - 24	209	1 (0.5%)	226	10 (4.4%)	238	22 (9.2%)	240	50 (20.8%)	7.6%	(0.4%, 14.7%)	0.038
	25+	203	2 (1.0%)	200	12 (6.0%)	164	13 (7.9%)	198	43 (21.7%)	8.7%	(0.8%, 16.5%)	0.030
PrEP offer[3]	15 - 24	211	2 (0.9%)	226	7 (3.1%)	238	10 (4.2%)	241	31 (12.9%)	6.4%	(0.7%, 12.2%)	0.028
	25+	204	3 (1.5%)	199	11 (5.5%)	164	4 (2.4%)	198	32 (16.2%)	9.7%	(2.8%, 16.5%)	0.006
PrEP uptake[2]	15 - 24	211	0 (0.0%)	226	2 (0.9%)	238	2 (0.8%)	241	10 (4.2%)	-	-	-
	25+	204	0 (0.0%)	200	3 (1.5%)	164	0 (0.0%)	198	5 (2.5%)	-	-	-
PrEP continuation[2]	15 - 24	211	1 (0.5%)	226	3 (1.3%)	238	2 (0.8%)	241	2 (0.8%)	-	-	-
	25+	204	2 (1.0%)	200	5 (2.5%)	164	2 (1.2%)	198	3 (1.5%)	-	-	-
Client satisfaction[1]	15 - 24	211	20.0 (20.0, 22.0)	226	21.0 (20.0, 22.0)	238	21.0 (20.0, 22.0)	241	21.0 (20.0, 22.0)	0.19	(-0.28, 0.66)	0.432
	25+	204	20.0 (20.0, 22.0)	200	21.0 (20.0, 22.0)	164	22.0 (20.0, 22.5)	198	21.0 (20.0, 23.0)	-0.31	(-0.81, 0.18)	0.213
Client PrEP knowledge[2] (All correct answers)	15 - 24	211	0.0%	226	0.0%	238	0.0%	241	0.4%	-	-	-
	25+	204	0.0%	200	1.0%	164	0.0%	198	0.0%	-	-	-
Number of correct answers (0-6)	15 - 24	211	0.64	226	0.80	238	0.94	241	1.36	0.26	(-0.04, 0.57)	0.092
	25+	204	0.86	200	1.09	164	1.00	198	1.51	0.28	(-0.08, 0.64)	0.132
Implementation strategy bundle 2												

			Comparison sites				Intervention sites			Difference in difference [(Change in intervention sites) – (Change in comparison sites)]		
		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	Point estimate	Confidence interval	p-value
PrEP fidelity[1]	15 - 24	65	7 (10.7%)	95	5 (5.3%)	89	12 (13.4%)	77	33 (42.9%)	36.6%	(21.8% - 52.0%)	<0.001
	25+	71	7 (9.9%)	68	3 (4.4%)	72	11 (15.3%)	71	28 (39.4%)	29.6%	(13.0% - 46.2%)	<0.001
HIV testing[3]	15 - 24	65	42 (6.6%)	95	63 (66.3%)	89	69 (77.5%)	77	66 (85.7%)	8.1%	(-10.3% - 26.5%)	0.387
	25+	71	41 (57.7%)	69	44 (63.8%)	72	44 (61.1%)	71	57 (80.3%)	11.8%	(9.7%-33.4%)	0.280
PrEP risk screening[3]	15 - 24	205	61 (29.8%)	228	79 (34.7%)	238	96 (40.3%)	220	106 (48.2%)	6.2%	(-6.0% - 18.5%)	0.319
	25+	201	59 (29.4%)	181	57 (31.5%)	181	69 (38.1%)	199	101 (50.8%)	10.1%	(-3.3%-23.5%)	0.141
PrEP penetration[1]	15 - 24	205	13 (6.3%)	228	18 (7.9%)	237	26 (11.0%)	220	77 (35.0%)	23.7%	(14.9% - 32.5%)	<0.001
	25+	200	10 (5.0%)	181	9 (5.0%)	181	23 (12.7%)	199	68 (34.2%)	21.5%	(12.1% - 30.9%)	<0.001
PrEP offer[3]	15 - 24	205	12 (5.9%)	228	11 (4.8%)	238	18 (7.6%)	219	38 (17.4%)	11.7%	(4.4% - 19.0%)	0.002
	25+	201	6 (3.0%)	181	6 (3.3%)	181	14 (7.7%)	199	36 (18.1%)	10.2%	(2.6% - 17.7%)	0.008
PrEP uptake[2]	15 - 24	205	2 (1.0%)	228	2 (0.9%)	238	5 (2.1%)	220	6 (2.7%)	-	-	-
	25+	201	2 (1.0%)	181	2 (1.1%)	181	2 (1.1%)	199	5 (2.5%)	-	-	-
PrEP continuation[2]	15 - 24	205	7 (3.4%)	228	4 (1.8%)	238	7 (2.9%)	220	5 (2.3%)	-	-	-
	25+	201	5 (2.5%)	181	4 (2.2%)	181	2 (1.1%)	199	5 (2.5%)	-	-	-
Client satisfaction[1]	15 - 24	205	21.0 (20.0, 22.0)	228	22.0 (20.0, 23.0)	238	22.0 (20.0, 23.0)	220	22.0 (21.0, 23.0)	-0.12	(-0.55 - 0.30)	0.569
	25+	201	21.0 (20.0, 23.0)	181	22.0 (20.0, 23.0)	181	21.0 (20.0, 22.0)	199	22.0 (21.0, 23.0)	0.28	(-0.22 - 0.78)	0.272
Client PrEP knowledge[2] (All correct answers)	15 - 24	205	0.0%	228	0.0%	238	0.0%	220	0.9%	-	-	-
	25+	201	0.0%	181	0.0%	181	0.0%	199	0.5%	-	-	-
Number of correct answers (0-6)	15 - 24	205	0.88	228	1.04	238	0.87	220	1.88	0.86	(0.53 - 1.19)	<0.001
	25+	201	1.06	181	1.14	181	0.95	199	2.07	1.04	(0.66 - 1.41)	<0.001

Supplementary table 4: Difference in differences comparison of effectiveness and implementation outcomes stratified by first ANC vs other services.

Implementation strategy bundle 1												
		Comparison sites				**Intervention sites**				**Difference in difference [(Change in intervention sites) – (Change in comparison sites)]**		
		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	Point estimate	Confidence interval	p-value
		Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post				
PrEP fidelity[1]	First ANC	30	1 (3.3%)	39	4 (10.3%)	34	2 (5.9%)	58	31 (53.5%)	43.0%	(19.8%, 66.1%)	<0.001
	Other MCH services	142	0 (0.0%)	131	4(3.1%)	140	13 (9.3%)	133	24 (18.1%)	5.0%	(-3.4%, 13.5%)	0.244
HIV testing[3]	First ANC	30	16 (53.3%)	39	33 (84.6%)	34	22 (64.7%)	58	57 (98.3%)	-0.2%	(-23.4%, 23.1%)	0.989
	Other MCH services	142	31 (21.8%)	131	50 (38.2%)	140	50 (35.7%)	133	56 (42.1%)	-11.3%	(-27.1%, 4.4%)	0.159
PrEP risk screening[3]	First ANC	39	24 (61.5%)	48	34 (70.8%)	42	23 (54.8%)	64	58 (90.6%)	26.6%	(2.1%, 51.0%)	0.033
	Other MCH services	375	64 (17.1%)	378	123 (32.5%)	359	98 (27.3%)	375	198 (52.8%)	10.7%	(1.9%, 19.5%)	0.018
PrEP penetration[1]	First ANC	39	1 (2.6%)	48	5 (10.4%)	42	4 (9.5%)	63	32 (50.8%)	33.9%	(13.2%, 54.6)	0.001
	Other MCH services	373	2 (0.5%)	378	17 (4.5%)	360	31 (8.6%)	375	61 (16.3%)	3.6%	(-1.6%, 8.7%)	0.175
PrEP offer[3]	First ANC	39	0 (0%)	48	2 (4.2%)	42	3 (7.1%)	64	19 (29.7%)	19.1%	(1.5%, 36.7%)	0.034
	Other MCH services	376	5 (1.3%)	377	16 (4.2%)	360	11 (3.1%)	375	44 (11.7%)	5.7%	(1.3%, 10.0%)	0.012
PrEP uptake[2]	First ANC	39	0 (0.0%)	48	1 (2.1%)	42	0 (0.0%)	64	6 (9.4%)	-	-	-
	Other MCH services	376	0 (0.0%)	378	4 (1.1%)	360	2 (0.6%)	375	9 (2.4%)	-	-	-
PrEP continuation[2]	First ANC	39	0 (0.0%)	48	0 (0.0%)	42	0 (0.0%)	64	0 (0%)	-	-	-
	Other MCH services	376	3 (0.8%)	378	8 (2.1%)	360	4 (1.1%)	375	5 (1.3%)	-	-	-
Client satisfaction[1]	First ANC	39	20.0 (20.0, 21.0)	48	20.0 (20.0, 22.0)	42	20.0 (19.0, 22.0)	64	21.0 (20.0, 22.0)	0.77	(-0.19, 1.72)	0.116
	Other MCH services	376	20.0 (20.0, 22.0)	378	21.0 (20.0, 22.0)	360	21.0 (20.0, 22.0)	375	21.0 (20.0, 22.0)	-0.09	(-0.46, 0.27)	0.622
Client PrEP knowledge[2] (All correct answers)	First ANC	39	0.0%	48	0.0%	42	0.0%	64	0.0%	-	-	-
	Other MCH services	376	0.0%	378	0.5%	360	0.0%	375	0.3%	-	-	-
Number of correct answers (0-6)	First ANC	39	0.74	48	0.92	42	0.79	64	1.91	0.95	(0.23, 1.67)	0.010
	Other MCH services	376	0.75	378	0.94	360	0.99	375	1.34	0.17	(-0.08, 0.42)	0.176

Implementation strategy bundle 2												
			Comparison sites				**Intervention sites**			**Difference in difference [(Change in intervention sites) – (Change in comparison sites)]**		
		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	Point estimate	Confidence interval	p-value
PrEP fidelity[1]	First ANC	41	6 (14.6%)	35	0 (0%)	38	9 (23.7%)	39	23 (59.0%)	49.3%	(25.5% - 73.0%)	<0.001
	Other MCH services	95	8 (8.4%)	128	8 (6.5%)	123	14 (11.4%)	109	38 (34.9%)	26.6%	(14.3% - 38.8%)	<0.001
HIV testing[3]	First ANC	41	41 (100%)	35	35 (100%)	38	0 (0%)	39	38 (97.4%)	-2.6%	(-7.6% - 2.5%)	0.321
	Other MCH services	95	42 (44.2%)	129	72 (55.8%)	123	75 (61.0%)	109	85 (78.0%)	5.4%	(-11.7% - 22.5%)	0.535
PrEP risk screening[3]	First ANC	44	36 (81.8%)	39	32 (82.1%)	39	38 (97.4%)	42	38 (90.5%)	-7.2%	(-2.7% - 12.5%)	0.474
	Other MCH services	362	84 (23.2%)	370	104 (28.1%)	380	127 (33.4%)	378	170 (45.0%)	7.8%	(-1.2% - 16.9%)	0.091
PrEP penetration[1]	First ANC	44	6 (13.6%)	39	0 (0%)	39	9(23.1%)	42	25 (59.5%)	49.7%	(27.2% - 72.3%)	<0.001
	Other MCH services	361	17 (4.7%)	370	27 (7.3%)	379	40 (10.6%)	378	121 (32.0%)	19.0%	(12.4% - 25.6%)	<0.001
PrEP offer[3]	First ANC	44	5 (11.4%)	39	0 (0%)	39	7 (18.0%)	42	17 (40.5%)	32.7%	(11.7% - 53.8%)	0.002
	Other MCH services	362	13 (3.6%)	370	17 (4.6%)	380	25 (6.6%)	377	58 (15.4%)	8.1%	(2.8% - 13.3%)	0.003
PrEP uptake[2]	First ANC	44	1 (2.3%)	39	0 (0%)	39	1 (2.6%)	42	6 (14.3%)	-	-	-
	Other MCH services	362	3 (0.8%)	370	4 (1.1%)	380	6 (1.6%)	378	5 (1.3%)			
PrEP continuation[2]	First ANC	44	1 (2.3%)	39	0 (0%)	39	1 (2.6%)	42	1 (2.4%)	-	-	-
	Other MCH services	362	11 (3.0%)	370	8 (2.2%)	380	8 (2.1%)	378	9 (2.4%)			
Client satisfaction[1]	First ANC	44	21.0 (20.0, 23.0)	39	21.0 (20.0, 22.0)	39	21.0 (20.0, 22.0)	42	22.0 (21.0, 23.0)	0.63	(-0.35 - 1.61)	0.205
	Other MCH services	362	21.0 (20.0, 23.0)	370	22.0 (21.0, 23.0)	380	22.0 (20.0, 23.0)	378	22.0 (21.0, 23.0)	-0.03	(-0.37 - 0.32)	0.875
Client PrEP knowledge[2] (All correct answers)	First ANC	44	0	39	0	39	0	42	0.024	-	-	-
	Other MCH services	362	0	370	0	380	0	378	0.005	-	-	-
Number of correct answers (0-6)	First ANC	44	1.14	39	0.51	39	0.77	42	2.48	2.19	(1.46 - 2.93)	<0.001
	Other MCH services	362	0.97	370	1.15	380	0.92	378	1.91	0.82	(0.56 - 1.08)	<0.001

Supplementary table 5: Impact of Implementation strategy bundles on client PrEP knowledge stratified by first ANC vs other services.

Implementation strategy bundle 1												
		Comparison				**Intervention**				**Difference in difference** [Change (intervention) - Change (comparison)]		
	Service sought	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
Indicator		Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post		Point estimate	95% CI	p-value
HIV prevention	First ANC	44	22 (50.0%)	39	16 (41.0%)	39	20 (51.3%)	42	34 (81.0%)	33.9%	(5.2%, 62.6%)	0.021
	Other MCH services	362	176 (48.6%)	370	225 (60.8%)	380	187 (49.2%)	378	273 (72.2%)	11.3%	(1.5%, 21.1%)	0.023
Frequency of use	First ANC	44	7 (15.9%)	39	2 (5.1%)	39	6 (15.4%)	42	26 (61.9%)	57.3%	(34.5%, 80.1%)	<0.001
	Other MCH services	362	72 (19.9%)	370	103 (27.8%)	380	78 (20.5%)	378	191 (50.5%)	22.5%	(13.6%, 31.3%)	<0.001
Time to protection	First ANC	44	1 (2.3%)	39	0 (0%)	39	0 (0%)	42	16 (38.1%)	40.4%	(24.6%, 56.2%)	<0.001
	Other MCH services	362	22 (6.1%)	370	33 (8.9%)	380	17 (4.5%)	378	110 (29.1%)	21.9%	(15.5%, 28.2%)	<0.001
Condom use	First ANC	44	11 (25.0%)	39	2 (5.1%)	39	2 (5.1%)	42	18 (42.9%)	57.6%	(35.0%, 80.2%)	<0.001
	Other MCH services	362	67 (18.5%)	370	46 (12.4%)	380	56 (14.7%)	378	102 (27.0%)	18.1%	(10.4%, 25.8%)	<0.001
Side effects	First ANC	44	3 (6.8%)	39	0 (0%)	39	2 (5.1%)	42	8 (19.1%)	20.6%	(4.6%, 36.7%)	0.012
	Other MCH services	362	9 (2.5%)	370	10 (2.7%)	380	5 (1.3%)	378	37 (9.8%)	8.3%	(4.4%, 12.3%)	<0.001
Discontinuation	First ANC	44	0 (0%)	39	0 (0%)	39	0 (0%)	42	2 (4.8%)	4.8%	(-1.8%, 11.4%)	0.158
	Other MCH services	362	4 (1.1%)	370	8 (2.2%)	380	7 (1.8%)	378	11 (2.9%)	0.0%	(-2.8%, 2.9%)	0.994
Implementation strategy bundle 2												
		Comparison				**Intervention**				**Difference in difference** [Change (intervention) - Change (comparison)]		

		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
Indicator			Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post	Point estimate	95% CI	p-value
HIV prevention	First ANC	39	12 (30.8%)	48	23 (47.9%)	42	19 (45.2%)	64	50 (78.1%)	15.7%	(-10.9%, 42.4%)	0.248
	Other MCH services	376	152 (40.4%)	378	180 (47.6%)	360	195 (54.2%)	375	229 (61.1%)	-0.3%	(-10.3%, 9.7%)	0.954
Frequency of use	First ANC	39	7 (18.9%)	48	11 (22.9%)	42	8 (19.0%)	64	33 (51.6%)	27.5%	(2.5%, 52.6%)	0.031
	Other MCH services	376	60 (16.0%)	378	77 (20.4%)	360	85 (23.6%)	375	127 (33.9%)	5.9%	(-2.6%, 14.3%)	0.176
Time to protection	First ANC	39	2 (5.1%)	48	0 (0.0%)	42	2 (4.8%)	64	10 (15.6%)	16.0%	(1.5%, 30.5%)	0.030
	Other MCH services	376	13 (3.5%)	378	20 (5.3%)	360	16 (4.4%)	375	38 (10.1%)	3.8%	(-0.9%, 8.5%)	0.112
Condom use	First ANC	39	7 (18.9%)	48	8 (16.7%)	42	4 (9.5%)	64	18 (28.1%)	19.9%	(-2.4%, 42.1%)	0.080
	Other MCH services	376	48 (12.8%)	378	59 (15.6%)	360	50 (13.9%)	375	80 (21.3%)	4.6%	(-2.8%, 12.0%)	0.221
Side effects	First ANC	39	1 (2.6%)	48	1 (2.1%)	42	0 (0.0%)	64	8 (12.5%)	13.0%	(0.6%, 25.4%)	0.040
	Other MCH services	376	7 (1.9%)	378	6 (1.6%)	360	3 (0.8%)	375	18 (4.8%)	4.2%	(1.2%, 7.3%)	0.006
Discontinuation	First ANC	39	0 (0.0%)	48	1 (2.1%)	42	0 (0.0%)	64	3 (4.7%)	2.6%	(-5.5%, 10.7%)	0.529
	Other MCH services	376	3 (0.8%)	378	13 (3.4%)	360	6 (1.7%)	375	12 (3.2%)	-1.1%	(-4.1%, 1.9%)	0.473

Supplementary table 6: Impact of Implementation strategy bundles on client PrEP knowledge stratified by age group

Implementation strategy bundle 1												
		Comparison				**Intervention**				**Difference in difference** [Change (intervention) - Change (comparison)]		
	Age group	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
Indicator		Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post		Point estimate	95% CI	p-value
HIV prevention	15 - 24	211	79 (37.4%)	226	95 (42.0%)	238	122 (51.3%)	241	145 (60.2%)	4.3%	(-8.5%,17.1%)	0.508
	25+	204	85 (41.7%)	200	108 (54.0%)	164	92 (56.1%)	198	134 (67.7%)	-0.8%	(-14.7%,13.1%)	0.915
Frequency of use	15 - 24	211	31 (14.7%)	226	40 (17.7%)	238	55 (23.1%)	241	85 (35.3%)	9.2%	(-1.6%, 19.9%)	0.094
	25+	204	36 (17.6%)	200	48 (24.0%)	164	38 (23.2%)	198	75 (37.9%)	8.4%	(-3.9%, 20.6%)	0.181
Time to protection	15 - 24	211	4 (1.9%)	226	9 (4.0%)	238	12 (5.0%)	241	26 (10.8%)	3.5%	(-2.3%, 9.4%)	0.233
	25+	204	11 (5.4%)	200	11 (5.5%)	164	6 (3.7%)	198	22 (11.1%)	7.3%	(0.4%, 14.3%)	0.039
Condom use	15 - 24	211	21 (10.0%)	226	28 (12.4%)	238	29 (12.2%)	241	51 (21.2%)	6.6%	(-2.3%, 15.5%)	0.149
	25+	204	34 (16.7%)	200	39 (19.5%)	164	25 (15.2%)	198	47 (23.7%)	5.7%	(-5.4%, 16.8%)	0.318
Side effects	15 - 24	211	1 (0.5%)	226	2 (0.9%)	238	3 (1.3%)	241	14 (5.8%)	4.1%	(0.4%, 7.9%)	0.030
	25+	204	7 (3.4%)	200	5 (2.5%)	164	0 (0.0%)	198	12 (6.1%)	6.9%	(2.0%, 11.9%)	0.006
Discontinuation	15 - 24	211	0 (0.0%)	226	7 (3.1%)	238	3 (1.3%)	241	7 (2.9%)	-1.5%	(-5.0%, 1.9%)	0.393
	25+	204	3 (1.5%)	200	7 (3.5%)	164	3 (1.8%)	198	8 (4.0%)	0.2%	(-4.5%, 4.8%)	0.939
Implementation strategy bundle 2												
		Comparison					**Intervention**			**Difference in difference** [Change (intervention) - Change (comparison)]		
		N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR	N	n (%) or median IQR			
Indicator		Comparison: Pre		Comparison: Post		Intervention: Pre		Intervention: Post		Point estimate	95% CI	p-value
HIV prevention	15 - 24	205	90 (43.9%)	228	122 (53.5%)	238	115 (48.3%)	220	151 (68.6%)	11.4%	(-1.3%, 24.0%)	0.078
	25+	201	108 (53.7%)	181	119 (65.7%)	181	92 (50.8%)	199	155 (77.9%)	15.4%	(2.0%, 28.8%)	0.024
Frequency of use	15 - 24	205	38 (18.5%)	228	60 (26.3%)	238	43 (18.1%)	220	109 (49.5%)	25.4%	(14.2%, 36.6%)	<0.001
	25+	201	41 (20.4%)	181	45 (24.9%)	181	41 (22.7%)	199	107 (53.8%)	26.8%	(14.3%, 39.2%)	<0.001
	15 - 24	205	13 (6.3%)	228	18 (7.9%)	238	11 (4.6%)	220	63 (28.6%)	23.3%	(15.3%, 31.3%)	<0.001

Time to protection	25+	201	10 (5.0%)	181	15 (8.3%)	181	6 (3.3%)	199	63 (31.7%)	25.0%	(16.3%, 33.8%)	<0.001
Condom use	15 - 24	205	32 (15.6%)	228	27 (11.8%)	238	32 (13.4%)	220	65 (29.5%)	18.8%	(9.0%, 28.5%)	<0.001
	25+	201	46 (22.9%)	181	21 (11.6%)	181	26 (14.4%)	199	54 (27.1%)	24.4%	(13.4%, 35.4%)	<0.001
Side effects	15 - 24	205	6 (2.9%)	228	5 (2.2%)	238	3 (1.3%)	220	20 (9.1%)	8.3%	(3.4%, 13.3%)	0.001
	25+	201	6 (3.0%)	181	5 (2.8%)	181	4 (2.2%)	199	25 (12.6%)	10.7%	(4.5%, 16.9%)	0.001
Discontinuation	15 - 24	205	2 (1.0%)	228	6 (2.6%)	238	4 (1.7%)	220	5 (2.3%)	-1.1%	(-4.7%, 2.5%)	0.562
	25+	201	2 (1.0%)	181	2 (1.1%)	181	3 (1.7%)	199	7 (3.5%)	1.8%	(-2.1%, 5.6%)	0.368