Selecting strategies for implementation and comparing strategy prioritization methods for improving PrEP delivery in maternal and child health clinics in Kenya

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Abstract

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In high HIV prevalence settings, women are at elevated risk for HIV during pregnancy and postpartum, and pre-exposure prophylaxis (PrEP) is recommended during this period. Integration of PrEP into maternal and child health (MCH) clinics requires implementation optimization. Furthermore, there is a lack of consensus about how to prioritize potential implementation strategies. The PrEP in Pregnancy, Accelerating Reach and Efficiency study (PrEPARE; NCT04712994) engaged stakeholders to identify determinants of PrEP implementation and identify and prioritize PrEP delivery implementation strategies at 55 facilities in Kenya through quantitative surveys and a stakeholder workshop. Strategies were prioritized using: 1) surveys with experienced practitioners reflecting on implementation experience (N=182); 2 & 3) ranking surveys before and after small group discussion with diverse stakeholders (N=44 & 40); 4) “go-zone” quadrant plots of perceived effectiveness vs feasibility. A stepwise elimination process was used to identify seven strategies for empirical testing. Facilitator debriefing reports from the workshop were used to qualitatively assess the decision-making process. We also compared the four strategy prioritization methods using Kendall’s correlation analysis. Additionally, the participants grouped strategies in three bundles with up to 4 strategies each by phone and online survey. Among 146 health care workers, the strongest reported barriers to PrEP delivery were: insufficient providers and inadequate training, insufficient space, and volume of patients. Sixteen strategies were assessed, 14 of which were included in the final analysis. Using rankings from 182 healthcare workers and 44 PrEP policymakers and

implementers, seven strategies were eliminated based on low post-workshop ranking scores (bottom 50th percentile) or falling outside the go-zone (perceived low feasibility and low effectiveness) for at least 50% of the workshop groups. The top three strategies included 1) delivering PrEP within MCH clinics instead of pharmacies, 2) fast tracking PrEP clients to reduce waiting time, and 3) delivering PrEP-related health talks in waiting bays. All top seven ranked strategies were grouped into bundles for subsequent testing. Facilitator debriefing reports generally aligned with go-zone rankings but noted how stakeholders' decision-making changed when considering the impact of strategies on facility staff and non-PrEP clients. The strategy ranking correlation was strongest between the pre- and post-small group rankings (Tau = 0.648; $p<0.001$). There was moderate correlation between go-zone plots and post-small group rankings (Tau = 0.363; $p=0.079$) and between past-experience surveys and post-small group rankings (Tau = 0.385; $p=0.062$). Strategy rankings remained similar between pre- and post-small group discussions; exceptions were in cases of feasibility concerns raised during discussions by experienced stakeholders. In both strategy bundle formats, participants primarily chose bundles of strategies in the order in which they appeared in the list, reflecting option ordering bias. Individuals who completed the phone survey with oversight from study staff were more likely to select the correct number of strategies per bundle. The most impactful barriers to integrated PrEP delivery in MCH clinics focused on insufficient staffing and space. Implementation strategies prioritized through multiple methods of stakeholder input focused on co-location of services and increasing clinic efficiency. Both experienced and inexperienced stakeholder participants' strategy rankings tended to prioritize strategies that had been previously tested. Small group discussions focused on feasibility and effectiveness revealed moderately different priorities than individual rankings. The strategy bundling approach tested a less time- and resource-intensive method but was not effective. Future research should compare the relative agreement and pragmatism of methodologies to prioritize implementation strategies.

Chapter 1

Selecting implementation strategies to test to improve implementation of integrated PrEP for pregnant and postpartum women in Kenya

Introduction

Women remain at elevated risk for HIV acquisition during pregnancy and the postpartum period.[1,2] Women diagnosed with HIV during pregnancy and the postpartum period disproportionately and increasingly contribute to infant HIV infections globally.[3–5] For these at-risk individuals, pre-exposure prophylaxis (PrEP) provides a woman-controlled and risk-period-specific method of HIV prevention.[6,7] PrEP is recommended by WHO and Kenyan guidelines during pregnancy and postpartum.[8,9] Several previous and ongoing studies have demonstrated that PrEP use in pregnancy is safe.[10–13] However, despite potential benefits and a track record of safety, PrEP is not often not provided for perinatal women, even in high burden settings, highlighting gaps in implementation.

Several projects have been implemented in Kenya to provide PrEP for pregnant and postpartum women.[14] Qualitative work conducted among adolescent girls and young women in Kenya demonstrated that motherhood was a central reason for initiating PrEP among these women as a means to protect their children and remain healthy to fulfill their responsibilities to their families. These findings highlighted the need for integrated maternal and child health (MCH) and PrEP services.[15] Two projects delivered integrated PrEP within MCH clinics across Kenya's public health sector.[16–22] In one of these studies, qualitative focus group discussions were conducted among 50 health care workers (HCWs) offering PrEP in maternal and child health and family planning clinics.[21] Using the Consolidated Framework for Implementation Research (CFIR) as a guide, participants were asked about the perceived benefits and challenges of implementing PrEP in MCH clinics as well as potential strategies to overcome the implementation barriers.[21] HCWs felt that PrEP delivery in MCH clinics would be highly feasible and acceptable as it would improve PrEP coverage and decrease stigma compared to PrEP delivered in HIV care clinics.[21] However, HCWs also noted several implementation challenges, such as increased workload for MCH staff due to documentation and increased demand for HIV testing services, physical space constraints, drug stockouts, and competing priorities with implementing partners.[21] HCWs identified a range of implementation strategies that could

possibly overcome these barriers, such as task shifting HIV testing, fast tracking PrEP clients, conducting PrEP health talks to increase demand, and enhanced provider education on PrEP.[21] While some MCH clinics have organically implemented various combinations of these strategies, there has been no formal prioritization or testing of the strategies' ability to overcome the implementation barriers identified by HCWs.

Existing literature has focused primarily on strategies that address individual- and provider-level determinants, but few studies have tested strategies that address high-level determinants such as facility space constraints and suboptimal human resources to address PrEP demand in MCH.[23] In the present analysis, we aim to quantitatively investigate participants' prioritization of these determinants and strategies and use strategy prioritization methods to identify three PrEP delivery strategy bundles to pilot and evaluate in Kenyan MCH clinics.

Methods

Study design: The *PrEP in Pregnancy, Accelerating Reach and Efficiency* (PrEPARE; NCT04712994) study gathered qualitative and quantitative data from stakeholders to identify determinants of PrEP implementation and PrEP implementation strategies. This study is a cross-sectional evaluation of three strategy prioritization methods and one method for strategy grouping. Data was collected sequentially. Past experience surveys and the strategy bundling exercise were completed from October 2020 to July 2021; the post-workshop rankings and go-zone plots were collected during a workshop in August 2021.

Study setting and participants: Each component of this study was conducted in three counties in Kenya which rank among the top 5 Kenyan counties for high HIV prevalence at 9% or higher: Kisumu, Homa Bay, and Siaya Counties.[24] For the past experience surveys, data was collected from HCWs with prior experience delivering PrEP to pregnant and postpartum populations who worked at one of the 55 unique study facilities. The post-workshop rankings and go-zone plot data were collected in Kisumu County at an in-person stakeholder workshop, including PrEP policymakers, implementers, and other national- and county-level officials from the Kenyan Ministry of Health. Other key stakeholders (PrEP users, HCWs, and representatives from the County and National AIDS and STD Control Program (NASCOP)) were

purposively sampled and identified through existing networks. All participants were ≥18 years, except adolescent PrEP users who were ≥15 years.

Data collection:

Implementation determinants and implementation strategy past experience survey:

Previous qualitative work using CFIR helped identify barriers to PrEP implementation and potential strategies to address these barriers.[21,25] To assess determinants' perceived impact and HCW's previous experience using mitigating strategies, a survey was administered in-person, over telephone, or online through RedCap with PrEP-experienced HCWs. First, participants ranked the barriers on a 1-5 Likert scale to assess their impact ("None" to "Strong") on PrEP delivery. Participants were also asked to rate 16 PrEP delivery strategies based on what had been tried at their facility and the perceived strength of influence that strategy had on improving PrEP delivery. Strategies were rated with the following values: "Tested and improved delivery," "Tested but did not improve delivery," and "Did not test."

Implementation strategy prioritization workshop surveys and go-zone plots:

The stakeholder workshop utilized the nominal group technique (NGT), a group prioritization method that democratizes decision-making.[26,27] The NGT begins with group generation of ideas, individual ranking of the generated strategies, and small group discussions to gather group consensus. Workshop participants were placed in cadre groups to minimize potential power imbalances and focus stakeholder expertise on strategies relevant to their experience. In small groups, participants were asked to rank each strategy on a 5-point Likert scale for perceived feasibility and effectiveness. Go-zone plots were created based on individuals' ratings to facilitate the group discussions.[28,29] Each group's mean feasibility and effectiveness scores were plotted; strategies whose mean feasibility and effectiveness scores each averaged 2.5 or higher fell within the "go-zone." Afterwards, participants were asked to respond to an online RedCap survey and individually rank a set of 16 PrEP delivery strategies on their perceived effectiveness. In these post-workshop rankings, strategies were sequentially ranked from 1 (most effective) to 16 (least effective).

Implementation strategy prioritization workshop small group qualitative notes:

Trained small group facilitators compiled notes during the small group discussions to track the pros and cons of each strategy's feasibility and effectiveness. Facilitators also took notes on the small groups' overall reflections about each strategy after viewing the go-zone plots and additional group suggestions for implementation considerations. We utilized debriefing reports, completed by discussion facilitators, to evaluate the small group decision-making process. The debriefing reports followed a structured format to collect key takeaway messages from the small group discussions; in a previous evaluation of structured debriefing reports, they were found to accurately reflect the key thematic content from full in-depth interview transcripts.[30]

Data Analysis:

To determine the top three PrEP delivery strategy bundles, all 16 strategies were first ranked using the past experience surveys from PrEP-experienced HCWs. Rankings were determined by the percentage of HCWs who indicated that the strategy had been tested at their facility and improved PrEP delivery. Strategies were then excluded if they ranked in the bottom 50% of post-workshop strategy rankings or fell outside the go-zone for the majority of stakeholders. In the post-workshop rankings, strategies' scores were averaged across participants. Strategies were also excluded if they fell outside of the go-zone for more than 50% of the go-zone plots in which it was evaluated.

To analyze the facilitator debriefing reports, we used the Framework Method, a targeted content analysis approach that uses deductive categories based on a conceptual model.[31] The categories used in this analysis were: pros and cons of feasibility and effectiveness, overall group reflections on each strategy, and additional considerations for each strategy's implementation. A matrix was created to organize and synthesize small group discussions into these categories. A second reviewer evaluated the matrix, and a consensus approach was used to resolve any discrepancies in feasibility and effectiveness categorization.

Results

Participant demographics are described in Table 1, and demographic characteristics were similar among both PrEP experienced healthcare workers and the stakeholder workshop participants. In both populations, slightly more than half of the participants identified as female (62.8% and 56.5% respectively). The median age of participants was 32 among healthcare workers and 40 among workshop participants. Nearly all participants reported attending a college or university (95.6% and 93.5% respectively), and participants had spent a median of 2.33 and 3 years providing PrEP to individuals of any age. For the past experience surveys, 185 HCWs were invited to participate, and 182 (98.4%) respondents completed the surveys. A total of 48 participants were invited to participate in the stakeholder workshop; of these, 44 (91.7%) completed the go-zone plots, and 40 (83.3%) completed the post-workshop rankings.

In the past experience surveys, HCWs identified determinants that had a high impact on the ability to deliver PrEP: insufficient provider-patient ratios, inadequate provider training, lack of physical space for PrEP services, and documentation burden. Barriers that had little to no impact on PrEP delivery included PrEP and document stockouts, HIV testing burden, competing partner priorities, and language barriers (Figure 1).

To prioritize strategies for implementation and testing as part of the PrEPARE study, 16 strategies identified through prior qualitative work were evaluated using the three different prioritization approaches.[21] However, two of the strategies were dropped from the overall analysis. “Coordination with adolescent friendly services” was erroneously grouped with “Provision of communication aids” in the go-zone analysis, and small group facilitators were instructed to direct participants to only discuss communication aids during group activities. “Task shifting any other component of PrEP counseling, assessment, or dispensing” was also dropped as it was erroneously excluded from the go-zone plot discussions. The final rankings presented below only include the 14 strategies that had official ranks between all three data sources.

A total of seven PrEP delivery strategies were selected utilizing the three prioritization methods (Table 2). Seven strategies were eliminated from the list based on low post-workshop ranking scores (bottom 50th

percentile) or falling outside the go-zone plot for at least 50% of the workshop groups. Of these seven eliminated strategies, four were excluded using the criteria from both the post-workshop rankings and go-zone plot analyses while three were excluded based on low post-workshop rankings alone. The go-zone plots did not exclude any additional strategies, and the two strategies whose scores were missing for the go-zone plots were also previously excluded by the post-workshop rankings.

The highest scoring strategies using the past experience surveys were “delivering PrEP commodities within MCH clinics instead of pharmacies,” “fast tracking PrEP clients to reduce waiting time within MCH,” and “delivering PrEP related health talks in waiting bays.” These three strategies were also in the top 50th percentile for the go-zone plots and the post-workshop surveys. The remaining strategies had heterogeneous rankings across the three ranking approaches, without clear patterns. The “retraining providers” strategy was the second lowest ranked strategy in the past experience surveys but highly ranked in both the go-zone and post-workshop survey and therefore included in the final list of strategies to be tested; importantly, 48% of PrEP-experienced healthcare workers indicated that this strategy had not been tested at their facilities (Figure 2).

The summary of facilitator notes is provided (Supplementary Table 2). Overall, small group discussions of the pros and cons of each strategy’s feasibility and effectiveness aligned with the strategies’ rankings in the go-zone plots. For example, group members who discussed “Delivering PrEP commodities within MCH clinics instead of pharmacy” described the benefits of this strategy as reducing waiting times for clients, reduced drop-out rates and improved PrEP uptake, increased client satisfaction with services, and reduced stigma; these findings mirror the high feasibility and effectiveness ratings that this strategy received. The participants did note some drawbacks to this strategy such as increased MCH nurse workload and the potential difficulties of documenting drug dispensing, but the detailed list of effectiveness pros for this strategy left the groups feeling that this strategy was very feasible and effective. In notable contrast, strategies that were rated with very low feasibility and effectiveness scores such as “Task shifting documentation” and “Dedicating certain physical spaces as PrEP delivery rooms” had significantly longer lists of feasibility and effectiveness cons in the debriefing reports.

The group facilitator notes also offered insight into the thought processes behind the small groups' ranking decisions in the go-zone plots. For example, "Fast tracking clients in MCH clinics" was ranked number one in the pre-workshop rankings but fell to number 9 in the go-zone plot rankings. The facilitator debriefing reports indicated that this strategy would place undue burden on MCH clinic staff and that this model of service delivery would unfairly disadvantage clients who are not receiving PrEP by increasing their wait times. Conversely, the facilitator notes on "retraining providers," which was ranked number 10 in the pre-workshop rankings and number 3 in the go-zone plots, highlighted several strong pros for feasibility and effectiveness with relatively few cons. The participants felt that this would be easy to implement using computer-based training programs, and that a skills-based training would improve overall service delivery quality at the implementing sites. The small group discussions about each of the strategies offered significant room for strategy ranking changes through consideration of how these strategies would impact the facility staff and all client groups.

Strategies to be tested in MCH based on the strategy priorities identified:

The identified top strategies will be tested in a series of interrupted time series studies in MCH clinics in the next 2 years. A total of seven strategies were selected and grouped for three rounds of future testing within MCH clinics . The first set of strategies includes "Fast tracking PrEP clients" and "Retraining providers on PrEP"; the second and third sets respectively include "Task shifting PrEP counseling to HTS providers" and "Training different providers" as well as "Delivering PrEP-related health talks in waiting bays" and "Providing communication aids". Delivering PrEP in MCH clinics will be tested in all three rounds as this strategy was the most highly ranked. Audit and feedback will also be provided per the request of clinic staff. Each round of testing involves an additional two strategies which were grouped together after discussion with study staff. Furthermore, a recent large cluster randomized trial by our team revealed that risk scores provide no additional benefit in appropriate allocation of PrEP (Kinuthia et al, CROI 2021), suggesting that risk score-guided PrEP should not be prioritized for continuation in Kenya. As a result, "Task shifting any PrEP risk assessment from nurses to HIV testing services/HTS providers" was removed from the list of potential strategies to continue with.

Discussion

The three strategy prioritization methods used in this study enabled the identification of seven unique strategies that may be feasible and effective in incorporating PrEP into MCH clinics in Kenya. Overall, PrEP-experienced HCWs identified several substantial barriers to PrEP implementation including insufficient provider-patient ratios, lack of provider training, and documentation burden; the highest ranked strategies across all prioritization methods will be able to alleviate their impact. For example, inadequate provider training can be addressed through retraining providers on PrEP and training different providers to assist in PrEP delivery. Task shifting and fast tracking will be able to ameliorate the burden on HCWs to integrate PrEP in MCH clinics. The two populations surveyed as part of this study demonstrated good agreement on overall strategy prioritization.

In a recent systematic review on PrEP in pregnancy and implementation science, the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) Framework was used to evaluate current scientific evidence in PrEP implementation through determinants, outcomes, and strategies at the individual, provider, facility, and program levels.[23,32] Of the 12 completed, ongoing, and planned studies in this review, eight focused on individual determinants, including demographic and behavioral risk factors and perceived risk for HIV acquisition.[18,22,23] Three ongoing studies looked at individual-level determinants of implementation while a fourth planned study looked at implementation determinants at the facility level.[23] In our prior qualitative study, HCWs noted many barriers to PrEP implementation in MCH clinics, including workload and documentation for staff, physical space constraints, drug stockouts, competing partner priorities, and increases in HIV testing.[21] These provider- and facility-level barriers generally aligned with the perceived barriers identified in the surveys in our present study. However, HCWs in this survey indicated that PrEP stockouts, competing priorities, and HIV testing were less impactful barriers to successful PrEP implementation than other barriers, findings that provide a useful prioritization-oriented complement to the qualitative information. There is need for studies to test provider- and facility-level strategies to address these barriers. Most studies planned to test strategies that would improve individual PrEP uptake through targeted counseling and other behavioral interventions.[23] One study sought to test a new provider training model using role-playing with patient-actors, but no other studies tested or planned to test strategies to

address PrEP implementation determinants in health systems.[23] The PrEPARE study provides a unique perspective by combining the experience of diverse stakeholders to prioritize strategies that will address provider- and facility-level determinants such as task shifting, fast-tracking, and improving provider education on PrEP.

While the strategies identified in this study have not yet been tested for impact on integrated PrEP delivery, several have been demonstrated to be effective in other settings and contexts. For example, a study in the Democratic Republic of the Congo showed that ART fast tracking services improved patient retention.[33] Similarly, task shifting has been shown to be an effective strategy in HIV care; one systematic review found that task shifting ART counseling and delivery results in improved clinic efficiency, maintained or improved quality of care, reduced client waiting times, and reduced loss to follow-up.[34] A cluster RCT of ART task shifting in South Africa showed no differences in mortality or virological outcomes.[35] Provider training has had mixed efficacy in previous studies; when provided with task shifting, training different providers on ART delivery demonstrated increased uptake with no change in quality of care.[34] Similarly, training in adolescent-friendly care resulted in increased retention in one study.[36] However, a systematic review from sub-Saharan Africa indicated limited improvement in antenatal care with training.[37] This conflicting evidence highlights the need for specialized training on HIV-related topics and further studies to assess impact of retraining teams on peripartum PrEP delivery. Additionally, few studies have evaluated the efficacy of providing health talks specific to PrEP and HIV in clinic waiting bays despite the fact that this is recommended.[38] Qualitative work with HCWs who have participated in a recent clinical trial involving PrEP for HIV prevention showed that this strategy was preferred by PrEP-experienced HCWs.[39]

The facilitator notes from the debriefing reports aligned with the strategies' feasibility and effectiveness score ratings as well as the overall go-zone rankings. However, it is important to note that there are different cultural interpretations of the words 'feasibility' and 'effectiveness.' In this study, feasibility was described as, "How easy would it be to do strategy X?", and effectiveness was described as, "How much of an impact would strategy X have?". These descriptions were chosen instead of using the Feasibility of Intervention Measure after consultation with teams who had experience adapting descriptions of implementation

outcomes in a Kenyan setting.[40,41] Implementation science measures and terminology have been primarily developed in the United States and Canada, and the understanding of these words and concepts must be taken into account when applying implementation science terminology in other settings. For example, one study that evaluated 33 agencies in 9 countries found 29 unique terms that were used to refer to the implementation science concept of 'knowledge to action.'[42] The heterogeneity with which these terms are used has the potential to lead to great confusion and a lack of generalizable findings in the field as a whole.[43] Efforts to adapt and validate psychometric evaluations in different cultural contexts offers a promising example of cross-cultural adaptation of implementation science terminology.[44–46]

Our study has several strengths. First, we evaluated perspectives of a diverse group of stakeholders. Collecting strategy rankings from PrEP-experienced healthcare workers in addition to from policy makers and individuals living with HIV enabled us to incorporate diverse perspectives regarding what will be feasible and effective to implement. The past experience rankings survey is, to date, the largest data collection effort in the world that focuses on healthcare workers' experiences in PrEP in pregnancy. Obtaining feedback from a variety of stakeholders allowed us to take a more holistic approach in evaluating which strategies should be implemented and evaluated as part of the PrEPARE study. The use of the democratic process in achieving stakeholder consensus is a unique contribution of this study.

Our study has several limitations. First, the past experience rankings from healthcare workers may have had recall bias. There were power differences between the stakeholder workshop participants who were national- and county-level officials, healthcare workers, and PrEP users. These power differences may have stifled discussion and potentially introduced social desirability bias, but the NGT was used to democratize decision-making by giving all group members equal voice in go-zone plot creation. Additionally, cadre groups were assigned a set of strategies that best aligned with their experiences and expertise to ensure that all participants could make meaningful contributions to the small group discussions. Each of the three strategy ranking methods used during the stakeholder workshop were also conducted individually with participants to minimize social desirability bias. Finally, purposive sampling was used to recruit participants for the stakeholder workshop. While purposive sampling is not statistically representative, the

goal of this study was to gain knowledge from content experts and understand stakeholder perspectives on PrEP implementation in MCH clinics.

Conclusions

This study sought to identify three bundles of PrEP delivery strategies to implement and test in Kenyan maternal and child health clinics. Through engagement with PrEP-experienced healthcare workers, we identified several high priority barriers to integrating PrEP delivery into MCH clinics including insufficient staff and space, inadequate provider knowledge of PrEP, and increased volumes of patients. Through the past experience surveys and the workshop activities, we identified a set of seven strategies that might address these barriers. Strategies included task shifting and fast tracking to increase clinic efficiency and reduce provider workload as well as retraining current providers and training new providers to bolster knowledge of PrEP and quality of care across services. The use of health talks in waiting bays and communication aids also seek to improve the efficiency of patient-provider communication regarding PrEP. Future testing of these strategies will allow for assessment of effectiveness and implementation outcomes at the individual, provider, and facility levels.

Tables & Figures

Table 1: Participant demographics

Characteristic		PrEP experienced healthcare workers (N = 183) n (%) or median (IQR)	Workshop Participants (N = 46) n (%) or median (IQR)
Female		115 (62.8)	26 (56.5)
Age in years		32 (29, 38)	40 (34, 46)
Highest educational attainment	None	0 (0)	0 (0)
	Primary	0 (0)	0 (0)
	Secondary	2 (1.1)	2 (4.4)
	Polytechnic	6 (3.3)	1 (2.2)
	University/College	175 (95.6)	43 (93.5)
Years providing PrEP to individuals of any age		2.33 (1.50, 3.3)	3 (1.00, 4.0)
Years providing care to pregnant or postpartum women (N = 182)		4.33 (3.10, 7.1)	-
Years providing PrEP to pregnant or postpartum women		2.25 (1.50, 3.3)	-
Received training to pregnant or postpartum women		125 (68.3)	-
Received training in providing PrEP adherence counseling to pregnant or postpartum women		113 (61.8)	-

Table 2: Identification of highly ranked strategies from three strategy ranking methods

Strategy	Past Experience Survey Score*	Post-Workshop Ranking Score**	Go-Zone Plots***	Inclusion in Final List
Delivering PrEP commodities within MCH clinic instead of pharmacy	78.88	5.6	100	Yes
Fast tracking PrEP clients to reduce waiting time within MCH	77.47	6.1	100	Yes
Delivering PrEP related health talks in waiting bays	70.88	7.8	100	Yes
Fast tracking PrEP clients to reduce waiting time within pharmacy	62.64	10	33	No
Task shifting any PrEP counseling from nurses to HIV testing services/HTS providers	60.44	5.95	67	Yes
Provision of communication aids	60.99	8.1	100	No
Fast tracking PrEP clients to reduce waiting time within lab	58.24	9.7	33	No
Conducting patient education in a different format than waiting bays	56.59	9.6	100	No
Coordination with adolescent friendly services	53	5.8	-	-
Task shifting any PrEP risk assessment, including RAST, from nurses to HIV testing services/HTS providers	52.2	6.4	67	Yes
Training different providers	51.65	6.4	100	Yes
Dedicating certain physical space, rooms or tents, to be PrEP delivery rooms	51.65	12.8	0	No
Fast tracking PrEP clients in some other way	43.41	10.7	100	No
Retraining providers	41.21	6.9	100	Yes
Task shifting any other component of PrEP counseling, assessment, or dispensing****	40	10	-	-
Task shifting documentation or data entry from nurses to a different cadre	28.02	11.5	0	No

**Percentage of PrEP-experienced healthcare workers reporting the strategy was tested at their facility and improved PrEP delivery.*
***Mean post-workshop ranking on scale of 1-16.*
****Proportion of groups that rated the strategy in the go-zone for both feasibility and effectiveness scores (%).*
*****This strategy was not evaluated during the go-zone plot creation.*

Figure 1: Past experience survey results on PrEP implementation determinants

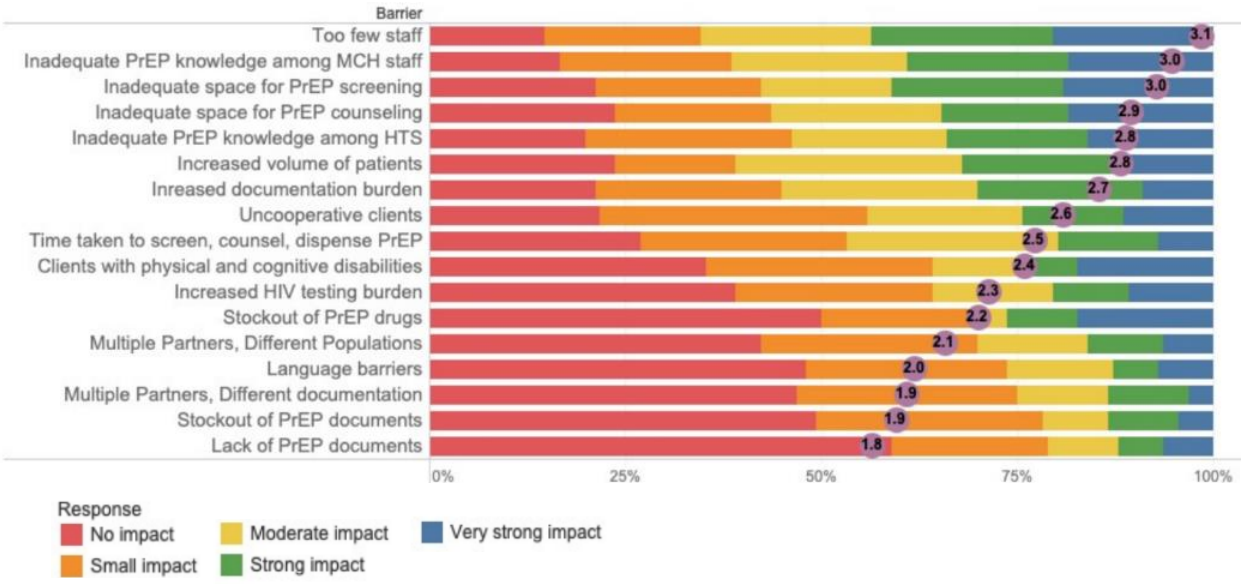
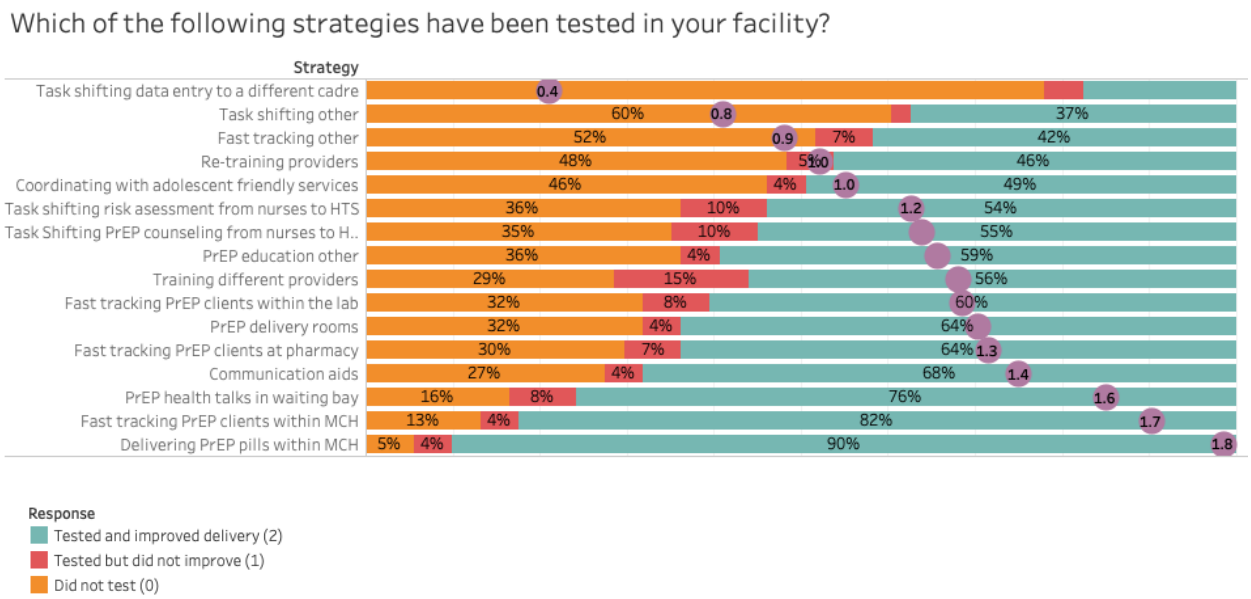


Figure 2: Past experience survey on previously tested strategies



Chapter 2

Comparison of methods to engage diverse stakeholder populations in prioritizing implementation strategies for testing in resource-limited settings

Introduction

Prioritization of implementation strategies remains a considerable challenge in IS, particularly selecting strategies to address existing barriers relevant to stakeholders. Limitations of existing literature include lack of context specificity; lack of conceptual models, theories, and frameworks in selecting strategies; and the high degree of variation in the implementation context as barriers to selecting implementation strategies for testing and evaluation.[47,48] Several methods for strategy prioritization have been identified, including intervention mapping, concept mapping, Delphi methods, nominal group techniques, and consensus development conferences, as well as ranking methods.[47] Intervention mapping is an iterative, stepwise framework for planning and evaluating health promotion interventions.[49] In intervention mapping, interventions are planned such that highly impactful barriers identified during planning can be mapped to appropriate strategies using a theoretical understanding of the relationships between barriers and strategies.[49] Concept mapping is another strategy prioritization method wherein relationships between ideas are explicitly drawn out; this data can be used to understand what ideas are most promising based on how frequently particular concepts or strategies are grouped together.[50] The use of the Delphi method, nominal group technique, and the consensus development conference are also consensus-generating tools where stakeholder expertise can be obtained while prioritizing problems and solutions during group discussions.[51,52] Creation of “go-zone” plots is another visual method of strategy prioritization that allows stakeholders to evaluate strategies on perceived feasibility and effectiveness, or other factors.[53] Finally, a variety of ranking approaches (best-worst choice, ranking attributes, constant sum scaling, conjoint analysis, discrete choice experiment, etc.) may be used to individually rank strategies for prioritization.[54–58]

There is a lack of consensus about how to prioritize health promotion strategies for implementation in real world contexts; the existing methods of strategy prioritization described above have varying time and resource complexity profiles. There is a notable lack of comparative data about the use of these methods

in low- and middle-income country (LMIC) settings; previous work has highlighted the need for comparative testing of different strategy selection methods to determine stakeholder feasibility and acceptability, the diversity of prioritized strategies selected by each method, and the efficiency of prioritization methods to match contextual determinants and appropriate strategies.[47] To address this gap, we utilized a variety of strategy ranking approaches to determine whether more or less time- and resource-intensive methods could provide similar prioritization profiles. Stakeholder engagement has been shown to increase acceptability of proposed interventions, enhance community buy-in, and ensure cultural appropriateness of the intervention.[52,59,60] We sought to compare PrEP delivery strategy prioritization among the five tested methods in the PrEPARE study and provide a nuanced description of the similarities and differences in ranking outcomes between methods. This analysis will ultimately inform best practices for implementation strategy prioritization methodology, including identifying potential benefits and drawbacks to using less time- and resource-intensive strategy prioritization methods.

Methods

Case study context: Pregnancy and the postpartum period remain high-risk periods during which HIV acquisition can occur.[1,2] Pre-exposure prophylaxis (PrEP) is an evidence-based medication for HIV prevention that has demonstrated efficacy and safety during pregnancy.[10,61,62] However, PrEP is not typically provided to women during pregnancy or the postpartum period.[6–9] Integrating PrEP into maternal and child health clinics (MCH) has been shown to be a feasible means of PrEP provision for this at-risk population.[19] Several projects in Kenya have sought to implement and evaluate the provision of PrEP for peripartum and postpartum women. The *PrEP Implementation for Mothers in Antenatal Care (PrIMA)* and *PrEP Implementation for Young Women and Adolescents (PrIYA)* studies have partnered with Kenya's public health sector to integrate PrEP into antenatal care (ANC) clinics.[16,17] These studies have highlighted that shifting PrEP delivery to MCH clinics was feasible, but several potential barriers to successful implementation were noted, including the need for additional staff training, potential overburdening of healthcare workers in MCH clinics, and the resultant potential to detract from the clients' experience receiving services. To expand on this prior work, the ongoing *PrEP in Pregnancy, Accelerating Reach and Efficiency (PrEPARE)* study utilized stakeholder engagement to obtain both qualitative and quantitative

data regarding determinants of PrEP implementation and the prioritization of PrEP implementation strategies in MCH clinics in Kenya.

Study design & participants: This was a cross-sectional study to evaluate four strategy-prioritization methodologies and one method for strategy-grouping prioritization as part of the PrEPARE study. As previously described, the data for this study was collected in Kisumu, Homa Bay, and Siaya Counties in Kenya, (Chapter 1). Two distinct populations contributed to the sequential data collection in this study: (1) 185 healthcare workers from one of the 16 PrEPARE study facilities between October 2020 and July 2021, and (2) 48 stakeholders who attended the in-person PrEPARE stakeholder workshop held in August 2021, (Chapter 1). The nominal group technique (NGT) was used during the stakeholder workshop to facilitate stakeholder consensus generation; as such, three of the four prioritization methods from this analysis were conducted as part of the NGT.

Data collection: Study participants were asked to rate and rank 16 unique PrEP delivery implementation strategies (which had been identified in previous qualitative work)[21] in each of four prioritization methods: 1) surveys with experienced practitioners reflecting on implementation success experience (N=182); 2 & 3) ranking surveys before and after small group discussion with diverse stakeholders (N=44 & 40); 4) "go-zone" quadrant plots of perceived effectiveness vs feasibility. The strategies that were ultimately selected for testing are detailed elsewhere (Chapter 1). Data collection for the four prioritization methods has previously been described (Chapter 1). All data was collected through online surveys; a summary is included in Table 1.

Surveys with PrEP experienced HCWs: (*previously described in Chapter 1*)

Rankings from the stakeholder workshop: From the PrEPARE stakeholder workshop, pre-workshop rankings were collected in addition to go-zone plot rankings and post-workshop rankings. In the pre-workshop rankings, participants were asked to respond to an online RedCap survey and individually rank

a set of 16 PrEP delivery strategies on their perceived effectiveness to improve PrEP delivery in MCH for pregnant women. Strategies were sequentially ranked from 1 (most effective) to 16 (least effective).

Strategy bundling exercise: The strategy bundling exercise was conducted with the participants who had completed the past experience surveys. They were asked which of the 16 pre-identified PrEP delivery strategies they thought would work best in combination and were asked to create three combination packages using up to four strategies in each package; strategies could be used in more than one bundle, and some strategies were not used at all. They were also given the opportunity to describe why they selected the strategies in each package and how they envisioned the packages might be implemented.

Data analysis: Two strategies were excluded from the original list of 16. “Coordination with adolescent friendly services” was grouped with “Provision of communication aids” in the go-zone analysis, and small group facilitators were instructed to direct participants to only discuss communication aids during group activities. “Task shifting any other component of PrEP counseling, assessment, or dispensing” was also dropped as it was erroneously excluded from the go-zone plot discussions (Chapter 1). We used Kendall’s correlation analysis to determine the similarities between strategy prioritization profiles among each of the prioritization methods used.[63] To compare the correlation of strategy prioritization profiles between each of the four strategy prioritization methods, a total of 17 comparisons were made. In each of the four methods used, participants rated or ranked 14 strategies; *rating* involved assigning a value to each strategy while *ranking* involved assigning each strategy a place on a scale of one to 14 relative to one another.

For this analysis, participant ratings were converted to rankings where all 14 strategies were placed on a list from 1 to 14 with 1 representing the highest aggregate rating and 14 representing the lowest. The past experience survey ratings were converted to ranks in two ways: 1) the percentage of respondents who reported the strategy as having been tested and improving PrEP delivery (versus not tested or tested and did not improve delivery), and 2) the percentage of respondents who reported having tested the strategy at all, regardless of whether or not PrEP delivery improved.

The go-zone plot rankings for each strategy were calculated as an average of averages: mean feasibility and effectiveness scores from each group were calculated, and then an overarching group average was calculated for the strategies' overall ranks. Pre- and post-workshop rankings for each strategy were obtained by averaging the rank position across all workshop participants. After the four ranked lists were created, a Kendall's correlation analysis was used to provide a correlation metric between ranking profiles between each of the 17 possible methodology comparisons.[64]

For the strategy bundling exercise, one hundred and thirty participants were asked to create the strategy bundles over the phone with a study nurse and online using a self-administered e-survey; an additional 85 facility in-charges were only asked to complete the strategy bundles online. For both survey methods, a composite list of all unique strategy bundles was created. The top three and four strategy bundles were identified by phone and online surveys respectively by calculating the frequency of respondents that selected each bundle.

Results

Participant demographics:

As previously described, the demographic characteristics of PrEP-experienced healthcare workers and the PrEPARE stakeholder workshop participants were similar in age, sex, and educational attainment, with median age 32 and 40, 62.8% and 56.5% female, as well as 95.6% and 93.5% having attended college or university across HCWs and workshop participants respectively (Chapter 1). Among the PrEP-experienced healthcare workers, there was a median of 2.3 years providing care to pregnant and postpartum women and providing PrEP to this population. Additionally, 61.8% of healthcare workers had received training on providing PrEP adherence counseling to pregnant and postpartum women.

Correlation between prioritization methodologies' ranking profiles:

We tested for statistical significance of the correlation coefficients for each of the comparisons (Table 2). The strategy ranking correlation was strongest and significant between the pre- and post-small group rankings (Tau = 0.648; p = <0.001). There was a moderate and insignificant degree of correlation between

the go-zone plots and the post-small group rankings (Tau = 0.363; p = 0.079) and between the past-experience surveys and the post-small group rankings (Tau = 0.385; p = 0.062). Strategy rankings remained relatively unchanged by small group discussions of the go-zone plots, except where stakeholders' feasibility concerns were raised to the group.

When go-zone plot rankings were separated into average feasibility and effectiveness scores, correlation to feasibility rankings were stronger than the overall go-zone plot rankings across all methodological comparisons. This was particularly true for post-workshop rankings (Tau = 0.398, p = 0.055). Across methodological comparisons, each method's correlation to effectiveness rankings was weaker than the correlation to the overall go-zone plot rankings.

When past experience survey rankings were re-computed focusing on strategies that had been tested overall (strategy was tested regardless of delivery improvement versus tested and improved delivery), there was stronger correlation across to all methodological comparisons. For example, when comparing the ranking profiles of the past experience surveys and the post-workshop rankings, the rankings were significantly correlated and with a stronger correlation coefficient when calculated with ranking of strategies tested overall compared to strategies that were tested and improved delivery (Tau = 0.451, p = 0.026 using strategies tested overall; Tau = 0.385, p = 0.062 using strategies that were tested and improved delivery).

Strategy bundling approaches – accuracy and pragmatic considerations:

The strategy bundles were very similar between the HCWs who completed the surveys over the phone compared to online. Among the phone surveys, 226 unique strategy bundles were identified. Of these, 179 bundles (79.2%) were selected by a single participant, 29 (12.8%) were selected by 2 participants, and 18 (8.0%) were selected by three or more participants. The top three strategy bundles are outlined in Table 3 and aligned most with the order in which the strategies appeared in the list. The strategy bundle that was most frequently identified by participants included all four strategies that related to task shifting in different PrEP delivery locations (n=38; strategies 1, 2, 3, 4 in the list). Participants also identified strategy bundles

that focused on fast tracking PrEP clients (n=31; strategies 5, 6, 7, 8 in the list) as well as patient PrEP education and provider training (n=9; strategies 9, 10, 11, 12 in the list).

Among the online surveys, 350 unique strategy bundles were identified. Like the phone surveys, 300 bundles (85.7%) were identified by one participant, 32 (9.1%) were identified by 2 participants, and 18 (5.1%) were identified by three or more. The top four strategy bundles also focused on fast tracking (n=20; strategies 5, 6, 7, 8 in the list), task shifting (n=6; strategies 1, 2, 3, 4 in the list), and patient education (n=5; strategies 9, 10, 15, 16 in the list). However, the online survey respondents included “provision of communication aids” and “coordination with adolescent friendly services” in the patient education bundle rather than focusing on provider training.

We evaluated whether this approach of strategy grouping was feasible to use with healthcare workers; we assessed how commonly participants in each type of survey were able to select exactly four strategies per bundle (Figure 1). In the phone surveys, there were a total of 371 strategy bundles identified, of which 226 were unique. Three of these bundles (0.008%) contained less than four strategies; five bundles (0.013%) contained five strategies, submitted by 6 unique participants. However, in the online surveys, a total of 468 bundles were identified. Sixty-four bundles (14.7%) contained less than 4 strategies; 83 bundles (17.7%) contained five or more strategies. These were submitted by 73 unique participants. Additionally, 1 participant did not complete any strategy bundles. Five participants selected multiple identical packages, only one occurrence of which was included in this analysis. Another ten participants grouped all the available strategies into a single bundle; these results were also excluded from analysis.

While completing the strategy bundling exercise, participants were given the option to explain why they selected these strategy bundles in open answer text boxes. These qualitative responses from participants highlighted a variety of motivations for strategy bundle selection, including saving time for provider and mothers, motivating clients to start and maintain PrEP use, reduce provider workload, and avoid missed opportunities to initiate clients on PrEP. Most responses focused on the impact of the individual strategies, rather than describing how the strategies might synergistically work together.

Ranking Spread:

The ranking spread for each strategy across the past experience surveys, pre/post-workshop rankings, and go-zone plots is depicted in Figure 2. The highest and lowest ranked strategies had the least spread with an overall difference of only two ranked positions. However, the middle ranked 12 strategies had a much higher degree of heterogeneity in the rankings across the four methodologies. Several strategies had very disparate rankings between the pre- and post-workshop ranks and the go-zone plot ranks. For example, "Task shifting PrEP counseling" was ranked 4th and 2nd in the pre- and post-workshop rankings, respectively, while it was ranked 10th in the go-zone plots. Similarly, "Fast tracking in MCH clinics" was ranked 1st and 3rd in the pre- and post-workshop rankings while it dipped to 9th in the go-zone plot rankings. When discussed in small groups, the content of the discussion for these two strategies revealed feasibility concerns (Supplementary Table 2). In these reports, facilitators noted broad discussions about the perceived cons of feasibility for both of the aforementioned strategies, despite the fact that there were strong feelings of perceived effectiveness for each. It was noted that both of these strategies required additional staff, may infringe on the rights on non-PrEP clients at the clinics, and may conflict with partner priorities.

Discussion

In this study, we compared 4 strategy prioritization methods and 2 strategy bundling methods. We observed the strongest correlation between the pre- and post-workshop rankings, demonstrating that stakeholders' rankings were not substantially changed by small group discussion. Small group discussions had a mild effect on participants' rankings as there was weak correlation between the overall go-zone plot rankings and the pre-workshop rankings, but a moderate degree of correlation between the overall go-zone plot rankings and the post-workshop rankings. Individuals who completed the strategy bundling exercise were likely to create bundles with sequential strategies from the overall list provided. The strategy bundling exercise did not yield consensus about the bundles of strategies that should be tested together; individuals who completed the survey over the phone with study staff were much more likely to choose the correct number of strategies per bundle than those who completed the survey independently online.

The goal of stakeholder engagement is prioritizing medical decisions and policies that are relevant and acceptable to all concerned parties;[65] however, power imbalances between patients, providers, and policymakers can result in conversations dominated by the powerful, obscuring the input and needs of those who are perceived to have lesser decision-making power. The nominal group technique (NGT) encourages democratic participation, is designed to quickly reach consensus, and has been increasingly used in medical and health services research.[51,66–70] In this study, we elected to use NGT during the stakeholder workshop to reduce potential power imbalances between participants and to facilitate group consensus given the time constraints of a one-day workshop. The small groups for discussions were constructed so that participants worked in groups with similar cadre individuals to reduce power imbalances and align stakeholders' relevant experience to potential strategies. The lack of substantial ranking change after the use of go-zone plots and small group discussions may be attributed to the knowledge concentration in cadre groups as participants who were less experienced with a particular strategy may have had different perceptions of its feasibility and effectiveness. Furthermore, each individual workshop participant only assessed 3-5 strategies' feasibility and effectiveness, eliminating the consideration of the remaining 10-12 strategies and making it more difficult for participants to place strategies in a relative ranking scale during the post-workshop rankings.

Feasibility seemed to be the major driving consideration in all prioritization approaches. All workshop rankings correlated more closely to past experience survey rankings where strategies had been tested in practice rather than those that improved delivery after testing. It is likely that the previously tested strategies, regardless of their ability to improve delivery, were perceived as more feasible to implement. Although these comparisons are drawn across two different population groups, this also highlights the tendency for confirmation bias to impact decision-making. Cognitive research has shown that when new evidence is presented that aligns with an individual's initial choice, that evidence is processed more efficiently.[71] Furthermore, we observed a differential relationship when overall go-zone plot rankings were calculated separately based on strategies' feasibility and effectiveness scores. Go-zone plot feasibility rankings were more highly correlated with the past experience surveys, pre-, and post-workshop rankings whereas go-zone plot effectiveness rankings had much lower correlation. As workshop stakeholders were familiar with

which strategies had been tested rather than those that actually improved delivery, there may have been stronger preference to align their rankings with what they knew had been tried. There was moderate correlation between the past experience surveys across both measures and the pre-workshop rankings, indicating a baseline level of agreement between the two populations of participants regarding which strategies would best improve PrEP delivery in Kenyan MCH clinics. It is particularly interesting that feasibility rankings have higher correlation with pre- and post-workshop rankings compared to the effectiveness rankings because participants were specifically asked to conduct the pre- and post-workshop rankings by evaluating which strategies would be most to least effective. Future research should explore why feasibility, rather than effectiveness, may be more top of mind for HCW in prioritization activities.

Finally, the fact that there were 16 items being assessed in the pre- and post-workshop rankings may have impacted the correlation between each of these methodologies. Ranking tasks are more difficult to complete with a larger list of items; participants are able to clearly identify the highest and lowest ranked items, but there is often less distinction between the relative rankings of items in the middle of the list.[72] Order effect may also play a role here as workshop participants may have become fatigued by the third ranking exercise. Previous research has shown that unexplained variance in ranking choices increases over time as the rankings become lower and as the number of ranking choices increase.[73]

Strategy Bundling Exercise:

The strategy bundling exercise was an opportunity to test a practical way to conduct stakeholder-engaged prioritization that required less time and resources compared to concept mapping. However, this strategy bundle exercise was not effective. Nearly all of the most frequently identified strategy bundles in both the online and phone surveys included subsequent strategies from the ordered list provided to participants. This may be partially attributable to the fact that the overall strategy list was compiled by themes determined prior to study initiation (e.g. fast tracking, task shifting, etc.), prompting participants to select strategies thematically rather than creating synergistic bundles.

In looking at the accuracy of collecting healthcare worker responses, the phone surveys have more consistent data collection compared to online surveys. During phone surveys, respondents were guided by study staff towards selecting the correct number of strategies in each bundle. Conversely, the online surveys which were independently completed by participants demonstrated much higher variability in the number of strategies selected in each bundle. More rigid data collection strategies, such as programming to restrict to 4 items per group, may be useful when researchers are seeking to group items. While the strategy bundling exercise was able to be aggregated to identify common strategy bundles among participants, concept mapping uses a participatory group process to conceptualize complex issues and incorporate a variety of stakeholders' expertise.[29,74] The highly structured nature of concept mapping removes the possibility of incorrectly including or excluding particular strategies. One study conducted a pooled analysis of 69 concept mapping studies and found that, across studies, concept mapping methodologies yield high internal representational validity and reliability, suggesting that concept mapping may be a more useful method of identifying strategy bundles despite its higher time and resource complexity.[75]

The qualitative responses participants provided explaining why they chose each strategy bundle demonstrated a variety of motivations for bundle selection, including saving time for providers and patients and a desire to influence PrEP uptake. However, none of the responses took a health systems view such as addressing particular barriers to PrEP initiation or anticipated bottlenecks in clinic flow. One study among Australian healthcare professionals found that motivations for healthcare strategy prioritization varied, including need to improve access to services and balance between service supply and demand with the resources needed for appropriate delivery.[76] As healthcare workers are more familiar with the individual and provider level determinants of healthcare delivery, it is intuitive that these aspects would be prioritized in their selection of PrEP delivery strategies; future work in this area should consider additional prompting and targeted questions to address facility and program determinants of intervention implementation, particularly among healthcare workers. 'Saving time' likely emerged as a prominent theme in the qualitative responses because the strategy bundle exercise preamble in the survey included unintentional prompting to highlight speed by explaining that strategy combinations can work synergistically to "make clinic flow

work even better.;" The example of two strategies that work well together noted that they could, "save time for women and save time for healthcare workers." This wording in the survey may have unintentionally steered participants towards focusing on strategy bundles that would improve clinic efficiency.

Ranking Spread:

Highly disparate workshop rankings were observed for strategies such as "Task shifting PrEP counseling" and "Fast tracking in MCH clinics." This may be due to the particular emphasis on feasibility during the go-zone plot discussions where facilitators completed structured debrief reports, (Chapter 1). The emphasis of the feasibility cons from this discussion may have down-weighted the go-zone plot rankings across these strategies whereas the strong perceived effectiveness left participants feeling that these two strategies may still be viable options for best improving PrEP delivery in MCH clinics. Participants discussed how both of these strategies would ultimately improve uptake of PrEP and retention of PrEP clients which was a recurring theme across the highly rated strategies in the go-zone plot discussions.

Strengths and Limitations:

This study has several key strengths including the diversity of stakeholder perspectives that were incorporated into the ranking activities and the evaluation of modified strategy prioritization methodologies. Few studies have had the ability to draw comparisons between ranking methodologies within the same study. The iterative nature of the ranking exercises used in this study enable this analysis to evaluate the effectiveness of ranking and rating methods across different populations in real time.

Several of the limitations of the PrEPARE study have been previously described, including potential recall bias in healthcare worker responses, power differentials in the stakeholder workshop small groups, and the use of purposive sampling (Chapter 1). The primary limitation of this analysis is that the PrEPARE study was not designed to directly assess the effectiveness of the strategy prioritization methodologies. However, there is still value in assessing the feasibility and effectiveness of these methodologies as they were applied in practice.

Future Considerations:

This study has several implications for future implementation science work. First, this study informs best practices around strategy and intervention prioritization methodologies. Use of the nominal group technique and go-zone plots in consensus prioritization requires that each group evaluates all of the strategies under consideration. There will likely be a greater impact in overall rankings from go-zone plots when all strategies are given equal time for consideration across participants. In addition, the small group discussions using the go-zone plots were more correlated with the post-workshop rankings rather than pre-workshop rankings (Table 2), indicating small group discussions did have an effect on participants' strategy rankings. However, the go-zone plot rankings did not eliminate further strategies from the overall list beyond those eliminated by the post-workshop rankings (Chapter 1), demonstrating that while small group discussions may be helpful in strategy consideration, creation of go-zone plots is not required to identify a final set of strategies for implementation. In future strategy prioritization endeavors with multiple stakeholders, a short list of strategies should be provided to all stakeholders, and small group discussions should be utilized wherein each group discusses the pros and cons of each strategy. After small group discussions, participants should complete a relative ranking exercise to determine the final set of strategies for implementation.

Additionally, listing strategies and asking participants to group them is not an effective means to identify strategy bundles for implementation and more time- and resource-intensive methods such as traditional concept mapping may be required to provide more meaningful results. While the strategy bundling exercise used in this study demonstrated improved data collection in phone surveys, the results still tended to be consecutive groupings of strategies from the initial list of strategies provided to participants. Future studies should randomize strategy order as well as highlight the types of strategy bundles they are looking for. For example, it may be helpful to have participants generate specific systems gaps that are seen in intervention delivery and then group strategies to address those gaps.

This study also enables more targeted implementation and testing of PrEP delivery strategies in Kenyan MCH clinics. The diverse stakeholder perspectives that were considered during this study ensured that strategy selection and prioritization was not limited to the particular expertise of one cadre of stakeholders.

Incorporating the viewpoints and experiences of stakeholders at multiple levels of the healthcare system ensures the selection of strategies that will impact provider, facility, and program determinants of implementation as well as increase stakeholder buy-in and commitment to the changes. Additionally, this study offers the unique perspective of building on prior knowledge of PrEP-experienced healthcare workers which may not be found directly in the scientific literature. Asking healthcare workers which strategies had been organically tested and improved PrEP delivery offered a solid starting point to build on and ensured that our work was not unnecessarily repeating the implementation of strategies that had been proven ineffective in real world contexts.

In future research, there is need for studies to evaluate the effectiveness of methodologies to prioritize implementation strategies. The original study was designed to assess prioritization of PrEP delivery strategies, so the methods utilized were not designed to evaluate ranking methods. However, there are still lessons to be learned from the use of these prioritization methodologies in practice.

Conclusion

In this nested study, we sought to evaluate the use of five implementation science strategy prioritization methods. We found that participants were more likely to prioritize familiar strategies and that the nominal group technique may be more effective with a smaller number of strategies to evaluate. Use of a small group discussion wherein each group evaluates all potential strategies, followed by a complete relative ranking exercise is sufficient to determine a set of stakeholder-prioritized strategies for implementation. Furthermore, a reduced time- and resource-intensive strategy bundling exercise was not effective in identifying meaningful strategy bundles for implementation. Future work should utilize more rigorous bundling exercises such as concept mapping and provide greater detail in the instructions if looking to address health disparities at the systems level. While this study provides valuable insight into the application of these strategies in practice, there is a great need for studies that are designed to evaluate these implementation science methodologies. Future work must also pay attention to the cultural context in which these methodologies are used to understand their effectiveness in new settings.

Tables and Figures

Table 1: Summary of data collection

Study Activity	Study Participants	Data collection
Past Experience Surveys	HCWs at MCH/FP facility involved in at least 2 prior PrEP delivery projects/studies; ≥18 years	3-point, categorical Likert scale (Tested but did not improve; Did not test; Tested and improved); N = 182
Strategy Bundling Exercise		Three strategy bundles of four strategies per bundle
Pre- and Post-Workshop Rankings	PrEP policymakers and implementers, HCWs involved in PrEP delivery; ≥18 years	Sequential strategy rankings from 1 (least effective) to 16 (most effective); N = 44
Go-Zone Plots		5-point Likert scale for strategies' perceived feasibility and effectiveness; N = 44

Table 2 – Kendall's correlation coefficient analyses among four strategy prioritization methods

		Pre-Workshop Rankings Tau (p-value)	Post-Workshop Rankings Tau (p-value)	Go-Zone Plots Tau (p-value)		
				Overall Rank	Feasibility Rank	Effectiveness Rank
Past Experiences Survey	Strategies that tested and improved delivery	0.429 (0.036)	0.385 (0.062)	0.143 (0.518)	0.231 (0.279)	0.033 (0.915)
	Strategies tested overall	0.495 (0.014)	0.451 (0.026)	0.165 (0.451)	0.253 (0.233)	0.055 (0.830)
Pre-Workshop Rankings		-	0.648 (<0.001)	0.143 (0.518)	0.231 (0.279)	0.121 (0.591)
Post-Workshop Rankings		-	-	0.363 (0.079)	0.398 (0.055)‡	0.341 (0.101)

**P-value is testing alternative hypothesis true Tau ≠ 0*

***All values rounded to 3 decimal places.*

‡*Not an exact p-value; Unless ties are very extensive and/or the data is very short, this approximation is adequate.*[77]

Table 3 – Most commonly identified strategy bundles from PrEP experienced healthcare workers

Frequency	Phone Survey (N=130)	Frequency	e-Survey (N=185)
38	Task shifting any PrEP counseling from nurses to HIV testing services/HTS providers (1)	20	Fast tracking PrEP clients to reduce waiting time within MCH (5)
	Task shifting any PrEP risk assessment, including RAST, from nurses to HIV testing services/HTS providers (2)		Fast tracking PrEP clients to reduce waiting time within lab (6)
	Task shifting documentation or data entry from nurses to a different cadre (3)		Fast tracking PrEP clients to reduce waiting time within pharmacy (7)
	Task shifting any other component of PrEP counseling, assessment, or dispensing (4)		Fast tracking PrEP clients in some other way (8)
31	Fast tracking PrEP clients to reduce waiting time within MCH (5)	6	Task shifting any PrEP counseling from nurses to HIV testing services/HTS providers (1)
	Fast tracking PrEP clients to reduce waiting time within lab (6)		Task shifting any PrEP risk assessment, including RAST, from nurses to HIV testing services/HTS providers (2)
	Fast tracking PrEP clients to reduce waiting time within pharmacy (7)		Task shifting documentation or data entry from nurses to a different cadre (3)
	Fast tracking PrEP clients in some other way (8)		Task shifting any other component of PrEP counseling, assessment, or dispensing (4)
9	Delivering PrEP related health talks in waiting bays (9)		Fast tracking PrEP clients to reduce waiting times within MCH (5)
	Conducting patient education in a different format than waiting bays (10)	5	Fast tracking PrEP clients to reduce waiting time within MCH (5)
	Retraining providers (11)		Fast tracking PrEP clients to reduce waiting time within lab (6)
	Training different providers (12)		Fast tracking PrEP clients to reduce waiting time within pharmacy (7)
			Delivering PrEP related health talks in waiting bays (9)
		5	Delivering PrEP related health talks in waiting bays (9)
			Conducting patient education in a different format than waiting bays (10)
			Provision of communication aids (15)
			Coordination with adolescent friendly services (16)

Figure 1 – Number of strategies per bundle selected by online and phone past experience survey respondents

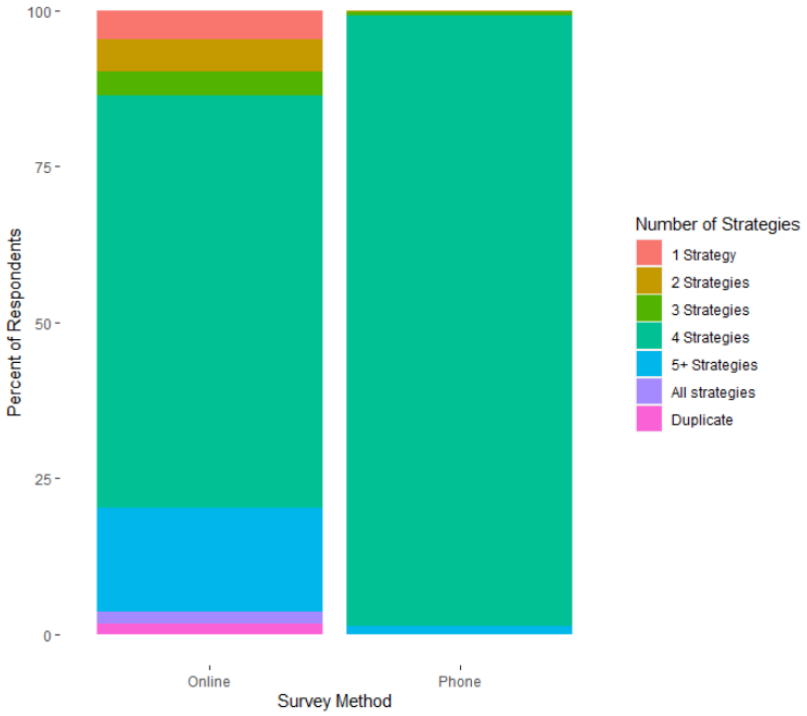
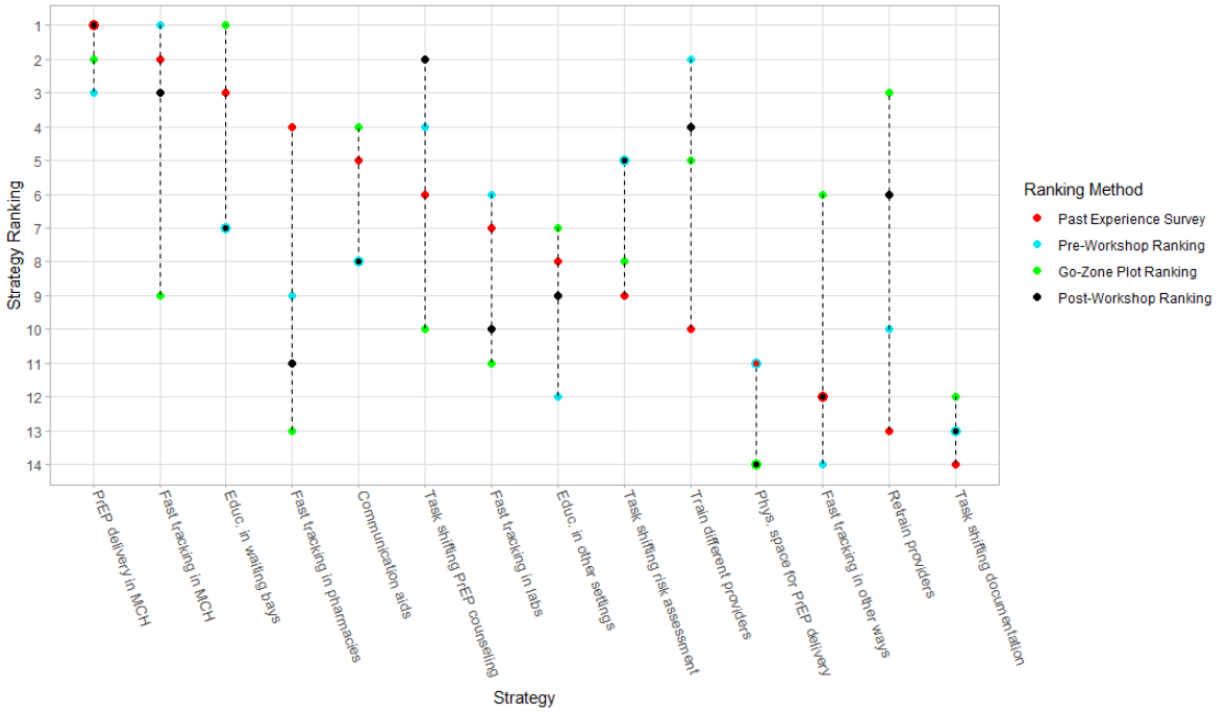


Figure 2 – Ranking spread among past experience surveys, pre/post-workshop rankings, and go-zone plots



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Supplementary materials

Supplementary Table 1: Summary of study designs, settings, subjects, and data collection across data sources

	Surveys with PrEP-Experienced HCWs		Stakeholder Workshop		
	Past Experience Rankings	**Strategy Bundling Exercise**	**Pre-Workshop Rankings**	**Go-Zone Plots**	**Post-Workshop Rankings**
Study design	Quantitative cross-sectional design		Quantitative cross-sectional design	Qualitative and quantitative cross-sectional design	Quantitative cross-sectional design
Study setting	55 facilities in Kisumu, Homa Bay, and Siaya Counties		One, in-person workshop at Grand Royal Swiss Hotel, Kisumu		
Study subjects	Healthcare workers (HCWs) working at a facility involved in 2 prior PrEP delivery projects/studies; ≥18 years		PrEP policymakers, PrEP implementers, frontline healthcare workers involved in PrEP delivery and decision-making; ≥18 years		
Data collection	Online surveys		Online surveys	Facilitated discussions; online surveys	Online surveys
Ranking/rating approach	3-point, categorical Likert scale (Tested but did not improve; Did not test; Tested and improved); N = 182	Concept mapping groupings; N = 182	Sequential strategy rankings from 1 (least effective) to 16 (most effective); N = 44	5-point Likert scale for strategies' perceived feasibility and effectiveness; N = 44	Sequential strategy rankings from 1 (least effective) to 16 (most effective); N = 40

Supplementary Table 2: Facilitator Notes from the PrEPARE Stakeholder Workshop

Strategy (Rank 1-14)	FEASIBILITY		EFFECTIVENESS		Overall Group Reflections	Additional Thoughts on Implementation
	PROS	CONS	PROS	CONS		
Waiting bays (1)	-Addresses many clients at same time -Easy to include PrEP health education in normal routine health talks that are done at MCH -Once trained, everyone in MCH can provide health information to clients	-Needs to be done at the right time to reach most people -Needs structure, otherwise people will pick the information they like -Requires training for mentor mothers and CHVs -Cannot be in every waiting bay	-Creates PrEP demand -Increases sensitization -Increase knowledge, uptake, and adherence -Could use brochures/voucher system to invite male partners to the clinics -Decrease stigma	-May spread misinformation if talk is not structured	- All the members agreed that this is feasible in most of our facility set ups	-Focus on times with high client flow -Can use the services of CHVs and CHWs who understand PrEP -Have structured format or flip charts already filled with main points to standardize delivery of health talk -Ensure capacity building of staff so they have PrEP knowledge -Include HIV self-testing kits at the waiting bays as uptake of HIVST and PrEP go together -Start from the basics and use simple language

		-Late comers will miss health talks if it's only offered during morning hours				-Use HTS providers/clinical team to give talks (not peer educators)
Dispensing PrEP in MCH (2)	-Reduce waiting time -One stop shop system	-Difficult documentation of dispensed drugs -Increase MCH nurse workload	-Reduces drop-outs through improved follow-up -Enhances discussions between service provider and clients receiving other services -Improve PrEP uptake -Increase client satisfaction -Reduce stigma -Minimize back-and-forth movement of clients	- Increase MCH nurse workload -Varied waiting time between clients who are and are not seeking PrEP -May compromise quality	- The group agreed that it was very feasible and effective	-Need to pilot this strategy in some periphery and mid-level facilities -Integrate or merge MCH clinic appointment date with PrEP visit -Task share (e.g. with mentor mother)
Re-train providers (3)	-Can use electronic models -Efficiency of service delivery based on most recent knowledge	-Lack of trained personnel -No time for training	-Could be skills based -Lead to quality service delivery		- Easy to implement with a huge impact	-The trainings should be skill based and use more of experience sharing and electronic models including Benchmarking. -Avoid classroom-like training -Include CHVs in risk assessment and champions of demand creation -Target the us of in-service training, CMEs, and webinars with award certificates to encourage attendance
Communication aids (4)	-Materials available on NASCOP website (cost effective) -Standardized coming from	-Resources for IEC dissemination are limited -Difficult to maintain as adolescents are transitory	-Create knowledge/ awareness -Dispel myths and misconceptions -Can bring youth together but not	-Massive resource requirement for personnel to produce comm. Aids, offer services, and	- One of the best strategies that majority of the members feel that is easy to implement and may have enormous impact in	-Create boards and wall hangings with various information and messages -Use social media and other modern applications that are more accessible to youth (Google Apps)

	national materials -Available in local languages -More feasible in high resource settings -Saves time by equipping clients with necessary PrEP information -Already on-going though with minimal intensity		for PrEP service delivery	engage adolescents	the population especially the youth	-Engage the Ministry in developing policy papers for Adolescent Reproductive health service delivery with retaining of HCWs
Train different providers (5)	-Can incorporate into on-the-job training -Decrease client wait time -Enhance staff capacity building -Encourage ownership of services/ideas by all HCWs -Can be implemented through on-job trainings/ mentorship -Facility sensitizations and CMEs are existing avenues to utilize -Easily engage MCH clinic peer educators, mentor mothers,	-Needs financial inputs -Lack of trained personnel -Low funds to facilitate training -Sustainability is a challenge -Limited privacy with lack of working space in some facilities -Stigma may increase in case other clients realize the purpose of the visit	-Could make PrEP 24-hour service -Facilitates demand creation -Increase staff knowledge/service provision -Increases coverage when most providers have required knowledge -Improve commodity management -Low cadre staff availability in facilities -Effective training modalities -Proper linkage to care for specialized needs	-Lack of trained personnel -Lack of space -Confidentiality breach may be more likely if using low cadre staff	- Majority of the members agreed that the strategy will be feasible to implement and will have positive impact	-PrEP should not be made a healthcare issue therefore all cadres should be trained including in advocacy by schoolteachers and churches. -Train target groups for specific training areas -Promote/facilitate on-the-job training -Facilitate training by the county in collaboration with implementing partners to enhance sustainability -Encourage exchange visits for bench marking to areas where this has worked for replication

	and youth advocates					
Fast tracking other (6)	-Reduces wait time for clients (including through integration of PrEP services) -Integrates PrEP services to reduce lost clients	-Limited human resources (registration needs to escort clients to PrEP service delivery point) -Requires additional training -Not feasible with current resources -May result in lack of documentation (missing indicators in registers)	-Works best for follow-up clients or those who know they are at risk and need PrEP -Reduce stigma	-Non-PrEP clients will be discouraged -Reduce sense of responsibility by healthcare workers		-Use PrEP cards to help identify clients easily -Use community ART/PrEP refill groups -Link PrEP clients to support groups -Link PrEP clients to CHVs to help follow-up with PrEP clients in the community
Patient education in a format other than waiting bays (7)	-Good for high volume hospitals -Saves time by educating clients -Can use CHVs during home visits -Could be done as task shifting where each healthcare worker at every service delivery point offers health talks about PrEP to the clients	-Requires more space and time -Requires human resources and training -Involving CHVs would require more financial incentives	-Increase uptake/retention (especially for mothers who opted to take PrEP) -Reduce stigma	-Client may not feel comfortable with 1:1 communication	- Members agreed that it was very feasible and effective - Will improve PrEP Uptake and retention but not to a bigger /larger extent	-Identify potential PrEP clients and have group education session with them -Introduce phone counseling and education programs -Introduce one-on-one education with mothers at healthcare delivery points -Health talks are more acceptable when given in waiting bays
Task shifting RAST from nurses to HTS providers (8)	-HTS already doing this -Alignment of PrEP/HIV assessment tools	-Requires training -HTS have other targets from partners -Loss of PrEP-eligible clients between	-Save time for patients (PrEP delivery and HIV testing services) -Improve client retention/ confidentiality	-Role conflicts with clinician assessments -HTS providers may feel they are not meeting stipulated	- Majority agreed that the strategy is very feasible and will be very effective in the MCH - feasible however will have minimal	- Should be handled well to avoid role conflict. -Encourage task sharing in facilities with inadequate staffing of HTS providers

	-Enhance rapport and confidentiality assurance -No replication of assessment	ANC/PNC and HTS rooms -Inadequate HTS providers currently -HTS providers cannot carry out physical/lab tests to determine PrEP-eligibility -Conflict with partners and employers' targets	-Establishing rapport between client and HTS improves uptake -Reduces workload -Improve client retention because services will be provided by one person (easier tracking/follow-up)	partners/employers set targets	impact and not very easy to implement because the HTS providers are employed by partners and have different priorities and targets therefore might lead to missed opportunities.	-Train and facilitate HTS providers with necessary tools to effectively RAST clients -Counseling and RAST should be done together
Fast tracking MCH (9)	-Works well with DSD (differentiated service delivery) since they have a leader who picks the drugs on behalf of the clients and distributes them -Helps MCH staff work as team -Link PrEP clients more easily	-Differs from 'first come, first served' model clients know -May reduce time keeping of PrEP clients since they know they will be served first -May require extra labor force	-Improve uptake and retention -Reduced wait time for clients	-Increase workload for those working at reception -HCW conflict because waiting time is too long for other clients who are not on PrEP	- Members agreed the that it would be very feasible and effective	
Task shift prep counseling from nurses to HTS providers (10)	-HTS already involved -Solves staff shortage -Reduce nurse workload -Reduce client waiting time in MCH -Less financial burden with current HTS involvement	- Extra work for HTS - Partners control staff roles -Nurse/clinician roles are not well defined -Inadequate HTS providers in most facilities -May interfere with MCH service delivery integration	-Reduce client wait time -Reduce nurse workload -Increase uptake screening services/PrEP	-Requires training for HTS -May miss some clients if nurses assume HTS will screen them	- Majority of the team agreed that the strategy is feasible and will bring positive impact in PrEP service provision in the MCH -Has a high impact if implemented but not easy to implement.	- This strategy should not be called task shifting because the counsellors will see this as somebody else's activities added to them. It should be christened 'counsellor expanded mandate' to avoid this. -Focus on task sharing rather than shifting to ensure continuity of service delivery -Task shift both risk assessment and counseling rather than separating the two -Define the specific activities that the nurses/clinicians will be

		-Sustainability when partners withdraw is a challenge				required to undertake with regards to PrEP services -Train/capacity building for the HTS providers on PrEP services delivery/ counseling -Recruitment of more HTS providers in the health facilities
Fast tracking lab (11)	-Reduced turnaround time of investigations -Reduced stigma as clients don't know why a person visited the lab	-Several queuing sessions before delivery -Requires more financial resources -Reagents are costly -Difficult to maintain ISO standards and commodities -Basic tests we use are usually not done -Few facilities currently offer lab services -No guarantee of commodity security	-Requires additional personnel	-Lack of available personnel -No space for additional lab staff -Could increase stigma when labs are segregated and labeled -Confidentiality may decrease if more people interact with a client -Most clients don't go through labs -Increase waiting time for other clients -Ensuring sample collection is within our control, but receipt of results is out of our control		-Engage partners fully to operationalize the service delivery -HIV testing/urinalysis can be fast tracked, but other tests like creatine are more difficult
Task shifting documentation (12)	-Reduce documentation workload	-May create errors; person who performs procedures should document -Lack of personnel and partner priorities -General documentation (monthly reports for routine services) is	-Effective data collection	-Teamwork needed is hard to achieve -Reduce data quality more so in FP and MCH clinics. -Collected data not currently used in decision making	-Feasible however will have minimal impact and not very easy to implement because the HTS providers are employed by partners and have different priorities and targets therefore might lead to missed opportunities.	-The advent of electronic documentation will also pose a challenge to this strategy if implemented. -Awareness creation on data collection use and planning to enhance partner participation in documentation -Review of the registers to ensure no missed opportunities or double entries.

		already challenging -May lead to disintegrated paperwork and blanks in registers				
Fast tracking pharmacy (13)	-Saves time (prepacks can be prepared in advance) -May work better in mini pharmacies (eg MCH pharmacies) -One stop shop at MCH -Fast tracking of ARVs done in CCC, so we can use the same model	-All clients still need pharmacy services -Requires extra manpower to escort clients -Increase wait time for non-prep clients		-Increase stigma -Confusion as stable patients are prioritized over sick patients -Increased defaulters' discontinuation and loss to follow-up	-The impact will be high but this strategy cannot be applied with ease. - Members agreed that this strategy is feasible but had reservation on its effectiveness as other clients may know why these clients are served first. This may lead to stigma.	-Drugs could be prepacked -Should apply this strategy in MCH pharmacies, not main pharmacies. -Use model for fast tracking of ARVs done in CCC -Efficient delivery requires task shifting of PrEP from pharmacy to MCH -Sensitize pharmacists to identify PrEP clients -Modify MOH protocols (ie first come first serve)
Dedicating physical spaces as PrEP delivery rooms (14)	-Ensure privacy -Decongest MCH clinics -Capacity building opportunity with CHVs	-Increase stigma -Not feasible due to staffing shortages -Lead to missed opportunities with clients -Expensive -Facilities prefer other services to get new rooms	-Ensures privacy -Could increase PrEP uptake/adherence in facilities with sufficient resources for a special room	-Not effective in achieving eMTCT targets -Increase stigma -Lower adherence and PrEP linkages	- Majority agreed that the strategy will not be feasible to implement and may have negative impact on the PrEP service provision in the MCH - General view among all members were that this strategy is less feasible. - Members agreed that having a special room won't have a bigger positive impact due to the reason that patient will feel stigmatized to be seen going to the "PrEP room".	- Integration of PrEP services within the MCH. This could be done by partitioning rooms to provide privacy -Would not work unless using a post-natal room that is not labeled -When creating a special room or tent for PrEP delivery, that facility should give it a unique name and not just label is as "PrEP Room" as a way of reducing stigma

General Recommendations across strategies:

- Need to empower CHV's through trainings on PrEP in order for them to make referrals and educate at the community level
- Need to include the community to improve PrEP initiation
- Integration should be done rather than task shifting.
- Have partners also prioritize PrEP delivery service package
- Local government should consider employing HTS providers or absorbing those employed to ensure sustainability of services