Acceptability of direct to pharmacy pathway to improve efficiency of PrEP delivery in Kenya

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Abstract

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Background: PrEP is a highly effective and safe medication that reduces the risk of HIV acquisition. Differential service delivery methods, such as direct to pharmacy (DTP) refills and HIV self-testing (HIVST), are promising adaptations to PrEP delivery that could reduce barriers to both patients and providers particularly in resource constrained settings.

Methods: We conducted a cross sectional quantitative survey with PrEP providers at two public health facilities implementing DTP refills and HIVST. We used the implementation outcomes framework developed by Proctor et al. to guide our implementation evaluation. We assessed outcomes of acceptability, appropriateness, and feasibility of the two interventions with a validated questionnaire on a 5-point Likert scale. Means for each outcome were compared across demographic and professional characteristics using one-way analysis of variance (ANOVA).

Results: A total of 145 providers completed the survey, of which 31% were HIV testing counselors, 17.9% were peer educators or other counselors, 11.7% were clinicians, 6.9% were nurses, 1.4% were in-charge administrators, and 31% reported “other” for healthcare worker

cadre. Both DTP and HIVST were found to be widely acceptable with ≥ 86% of all respondents reporting that they agree or completely agree across all three implementation outcomes. The average response for direct to pharmacy refill outcomes were acceptability = 4.21, appropriateness = 4.20, and feasibility = 4.19. The average response value for HIV self-testing outcomes were acceptability = 4.18, appropriateness = 4.20, and feasibility = 4.22. One way ANOVA for each implementation outcome and each key provider characteristic (e.g., sex, provider cadre, clinic location, duration of service years, and history of PrEP delivery) did not show statistically significant differences detected in mean responses to the constructs by individual characteristic.

Conclusion: In this study we found direct to pharmacy refills and HIV self-testing were acceptable forms of differentiated PrEP delivery among healthcare workers in central Kenya. These strategies should be considered when scaling up pharmacy-based PrEP services in resource constrained settings.

Keywords: PrEP, HIV prevention, Pharmacy, Differentiated service delivery, Kenya, Implementation science

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Background and Significance

HIV pre-exposure prophylaxis (PrEP) is a highly effective and safe medication that reduces the risk of HIV acquisition by as much as 99%.[1,2] Kenya, with the fourth largest HIV epidemic in the world, officially launched a PrEP program in May 2017, making it the first national PrEP program in Africa.[3] The Kenyan Ministry of Health guidelines recommend the provision of PrEP to all individuals at ongoing risk of HIV infection.[4] Currently, more than 157,000 people have initiated PrEP in Kenya. While PrEP initiation in Kenya is high, there is an increasing need to focus on retention and different methods of offering PrEP to meet the UNAIDS goal of eliminating all new HIV infections by 2030.[5]

In Kenya and other resource constrained settings, PrEP is being added to an already burdened healthcare system[6] and the ability of the health systems to maximize PrEP access will necessitate finding novel delivery strategies. Lessons for PrEP delivery can be learned from the scale-up of antiretroviral therapy (ART) delivery in similar settings. One key lesson is the importance of differentiated models of service delivery.[7] Individuals who are at risk of infection, but who do not feel ill may be less likely to seek preventive care than those who are seeking treatment, so it is critical that PrEP is made as easily available as possible.

Throughout the PrEP scale-up process, a number of challenges have been identified for both PrEP users and providers. For PrEP users, challenges include long wait times and frequent clinic visits that endanger PrEP continuation because of opportunity costs.[8,9] They also face stigma due to the association with HIV care and treatment.[10] Providers encounter increased workloads, which may be associated with higher rates of healthcare work turnover, which then compound the pressures on the healthcare system.[10] Pharmacy based PrEP delivery may ameliorate these challenges.[11]

The goal of this study was to advance PrEP delivery by aiming for greater efficiency, reduced workload, diminished client burden, and better outcomes– allowing human and financial

resources to be directed to those most in need through the implementation of differentiated PrEP delivery. The primary objective was to evaluate the acceptability, appropriateness, and feasibility of direct to pharmacy (DTP) PrEP refills and client HIV self-testing (HIVST) models among healthcare providers in HIV care clinics in central Kenya. The secondary objective was to assess differences by key provider characteristics including sex, provider cadre, clinic location, duration of service years, and history of PrEP delivery. By gaining a deeper understanding of provider views on the acceptability of differentiated care models, we hope to inform scale-up and support future work on how to efficiently deliver PrEP in public health systems in Kenya and other resource constrained settings.

Methods

Overview of the parent study

The current study is part of the Efficiency Project (R00MH 118134), an ongoing prospective implementation project aiming to define differentiated care models for efficient delivery of PrEP in public health HIV care clinics in central Kenya. The overarching goal of the Efficiency Project is to demonstrate the feasibility and acceptability of direct to pharmacy PrEP refill visits with client HIV self-testing to improve the efficiency of PrEP delivery. Two clinics implemented a differentiated pharmacy-based follow up PrEP care pathway, and an additional two clinics serving as contemporaneous controls implemented current PrEP patient flow without any changes. The core components of the multifaceted implementation strategy included: 1) DTP refill visits, 2) HIVST while waiting for refills, 3) rapid risk assessment for ongoing risk, adherence, side effect, and acute HIV symptoms, 4) provider training, and 5) quarterly debrief meetings. During implementation, all core components of PrEP delivery – including screening for HIV risk, HIV testing, dispensing, and provision of refills – were conducted by existing facility healthcare providers as part of the standard care service package. The goal was to catalyze sustainable scale-up within existing structures beyond the study. PrEP was provided by the Kenya national

stock of antiretrovirals as part of the national PrEP scale-up program; HIV self-test kits were provided by the project. We conducted mixed methods evaluations with healthcare providers and clients to examine early implementation outcomes and document implementation processes.

Design of the current study

The current study was a cross-sectional analysis of a quantitative survey conducted with healthcare providers to assess views on acceptability, appropriateness, and feasibility of direct to pharmacy refills of PrEP in public clinic settings. We used the implementation outcomes framework developed by Proctor et al. to guide our implementation evaluation.[12] The Proctor framework is an operational implementation science model used to organize and define key implementation variables and frame research questions to advance closing the 'know-do' gap. Proctor et al. proposed that implementation outcomes should be distinct from clinical outcomes and identified eight discrete implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability). For this pilot study we focused on the early implementation outcomes of acceptability, feasibility, and appropriateness to understand provider perspectives on direct to pharmacy refills to guide PrEP decision-making and delivery.

Study setting, clinic selection, and participants

We administered validated quantitative surveys to healthcare providers at two health facilities in Central Kenya (i.e., Murang'a and Ruiru) implementing the direct to pharmacy intervention. The two clinics were selected purposively from 12 clinics with established PrEP delivery services integrated in HIV care clinics as part of the Kenya National PrEP program. Clinic selection was based on willingness to pilot the intervention, volume of clients accessing PrEP, and space availability. Both clinics had an average of 10 providers on staff daily from different cadres within their respective comprehensive care centers. Ruiru had an average patient volume of 70 ART clients and 5 PrEP clients per day. Murang'a had an average patient volume of 65 ART

clients and 5 PrEP clients per day. The target study population were all healthcare providers at the participating clinics. Surveys were administered to providers based on the following inclusion criteria: 1) willingness and ability to provide consent to participate in the survey, and 2) currently working at any of the clinics implementing PrEP delivery. Eligible provider's cadre included HIV testing service counselors, nurses, peer counselors, clinicians, social workers, or clinic managers. There was no sample size calculation, however a representative sample of all healthcare worker cadres at participating clinics were targeted and findings can be generalized to these clinical settings.

Human subjects

The study protocol, informed consent forms, and other requested documents and modifications were reviewed and approved by the University of Washington Human Subjects Ethical Committee and the Scientific and Ethics Review (SERU) Committee of the Kenya Medical Research Institute. Subsequent to initial review and approval, the responsible IRBs/ECs reviewed the study at least annually. All participants provided written informed consent.

Outcome definitions and data collection

This study had three primary outcomes of interest - acceptability, appropriateness, and feasibility. Acceptability was defined as the "perception that a given innovation is agreeable, palatable, or satisfactory", appropriateness as the "perceived fit, relevance, or compatibility of the innovation for a given setting", and feasibility as the "extent to which a new innovation can be successfully used or carried out within a given setting." [12]

We used a validated quantitative survey designed by Weiner et al. to assess early implementation outcomes. This tool measures multiscale outcomes that map to the Proctor et al. outcomes of acceptability (Acceptability of Intervention Measure (AIM)), appropriateness (Intervention Appropriateness Measure (IAM)), and feasibility (Feasibility of Intervention Measure (FIM)). These measures have been validated and demonstrate established substantive validity,

structural validity, discriminant validity, known-groups validity, test-retest reliability, and sensitivity to change.[13]

In each construct (AIM, IAM, FIM) there were 4 questions that were each evaluated on a five-point Likert scale (1= Completely disagree, 2= Disagree, 3= Neither agree nor disagree, 4= Agree, 5= Completely agree). The units for analysis of AIM, IAM, and FIM were examined in aggregate for each intervention to evaluate mean response levels for each respective construct. DTP and HIVST were both evaluated separately for outcomes of acceptability (AIM), appropriateness (IAM), and feasibility (FIM). See Appendix 1 for an overview of all questions and associated implementation outcomes.

Surveys were administered to providers in-person on site at Murang'a and Ruiru clinics by study staff following initiation of the interventions. They were completed during facility debrief sessions that were conducted following study initiation. Surveys at Ruiru were proctored one month after initiation and surveys at Murang'a were proctored two months after initiation. Staff entered data using RedCap.[14] Automated legal range checks were used to reduce data entry errors.

Data analysis

The primary outcomes were acceptability, feasibility, and appropriateness of two distinct, but complementary PrEP services – 1) direct to pharmacy PrEP delivery, and 2) client HIV self-testing. Descriptive statistics were generated for each characteristic of the study population (e.g., sex, clinic, healthcare worker cadre, duration of work, and experience with PrEP delivery). Duration of work was collected as a continuous variable and then binned into categories of "Less than 1 year", "1-3 years", and "More than 3 years" based on the distribution of data and cut-off points that were contextually relevant. Due to the similarity of function and small number of respondents, "Clinical Officer" and "Doctor" were consolidated to "Clinician" in healthcare worker cadre. All descriptive categorical variables were summarized as proportions.

The 4 questions for analysis of acceptability, appropriateness, and feasibility for both interventions were aggregated separately to examine mean levels for each construct. Distributions of the aggregate measures were visualized using box plots. Means for each scale (AIM, IAM, FIM) were then compared across demographic and professional characteristics using one-way analysis of variance (ANOVA). All statistical analyses were conducted using R and RStudio software (version 4.0.2). Statistical significance was defined as p-values of less than 0.05.

Results

Descriptive demographic data on all healthcare workers who completed the survey at both clinic sites are provided in Table 1. A total of 145 providers completed the survey with relatively even numbers of providers from both clinical sites (Ruiru (n= 76) and Murang'a (n= 69)). Among participants surveyed, six different healthcare worker cadres were involved– clinicians, HIV testing service counselors, nurses, peer educators/other counselors, in-charge administrators, and those that reported "other". Nearly 60% of all respondents had less than 3 years of work experience, and 39.3% reported having a work duration of less than one year. The majority of respondents were female (68.3%) and nearly all reported having been directly involved in PrEP delivery (82.8%).

For both direct to pharmacy refills and HIV self-testing, acceptability, appropriateness, and feasibility were high among providers with ≥ 86% reporting that they agree or completely agree. Table 2 displays the mean and the interquartile range (IQR) for each of the multiscale outcomes for DTP and HIVST. Across the three outcomes, mean responses were >4 representing agree or completely agree (Table 2 and Figures 1 and 2).

Although responses were generally high, we found small absolute differences in the mean responses by clinic, healthcare worker cadre, and duration of work. The Ruiru clinic reported lower agreement on acceptability and feasibility of DTP compared to Murang'a (mean acceptability =

4.11 vs 4.33; mean feasibility = 4.10 vs 4.30). Overall clinicians, HIV testing service counselors, and peer educators often responded more positively than nurses and “other” healthcare worker cadres to all outcomes regarding DTP refills, but the differences were not statistically significant. For example, nurses responded to the DTP outcomes less favorably than clinicians who responded most favorably to DTP (mean scores: acceptability = 3.93 vs 4.35; appropriateness = 3.83 vs 4.41; feasibility = 4.10 vs 4.43). Lastly, those who had worked for less than 3 years viewed DTP more favorably than those who had worked for more than 3 years. The largest differences were seen in acceptability and feasibility of DTP among those who had worked more than 3 years versus those who had worked less than 1 year (mean acceptability = 4.07 vs. 4.29; mean feasibility = 4.05 vs 4.29).

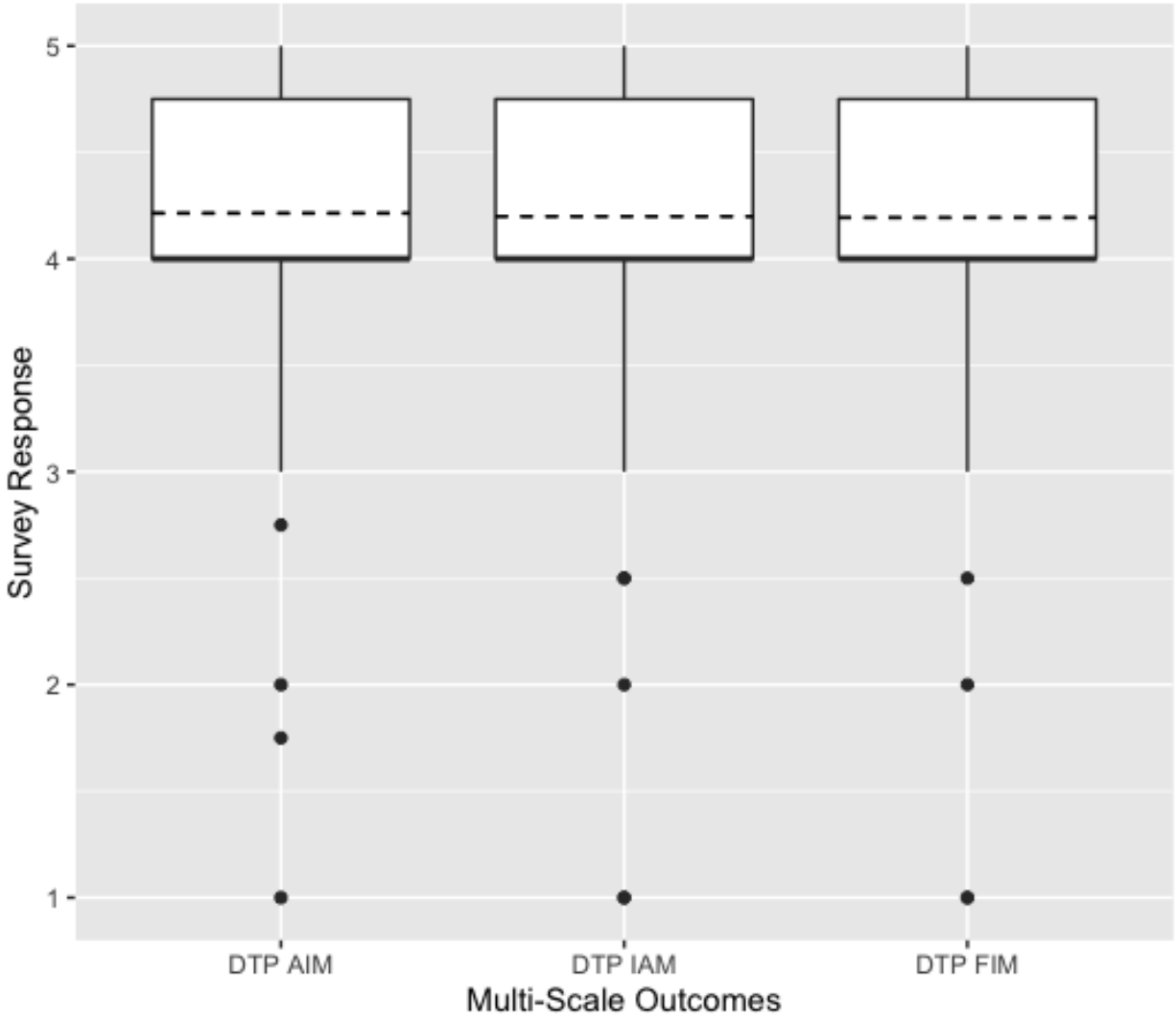
One way analysis of variation (ANOVA) for each implementation outcome and each key provider characteristic (e.g., sex, provider cadre, clinic location, duration of service years, and history of PrEP delivery) did not show statistically significant differences detected in mean responses to the constructs across each characteristic.

Table 1. Participant demographics by clinic

	Murang'a (N=69)	Ruiru (N=76)	Overall (N=145)
Gender			
Female	47 (68.1%)	52 (68.4%)	99 (68.3%)
Male	22 (31.9%)	24 (31.6%)	46 (31.7%)
Healthcare Cadre			
Clinician	7 (10.1%)	10 (13.2%)	17 (11.7%)
HTS Counselor	24 (34.8%)	21 (27.6%)	45 (31.0%)
Nurse	6 (8.7%)	4 (5.3%)	10 (6.9%)
Other	25 (36.2%)	20 (26.3%)	45 (31.0%)
Peer Educator or Other Counselor	7 (10.1%)	19 (25.0%)	26 (17.9%)
In-charge	0 (0%)	2 (2.6%)	2 (1.4%)
Duration of work			
Less than 1 year	43 (62.3%)	14 (18.4%)	57 (39.3%)
1-3 years	16 (23.2%)	15 (19.7%)	31 (21.4%)
More than 3 years	10 (14.5%)	47 (61.8%)	57 (39.3%)
Directly involved in PrEP delivery			
No	5 (7.2%)	20 (26.3%)	25 (17.2%)
Yes	64 (92.8%)	56 (73.7%)	120 (82.8%)

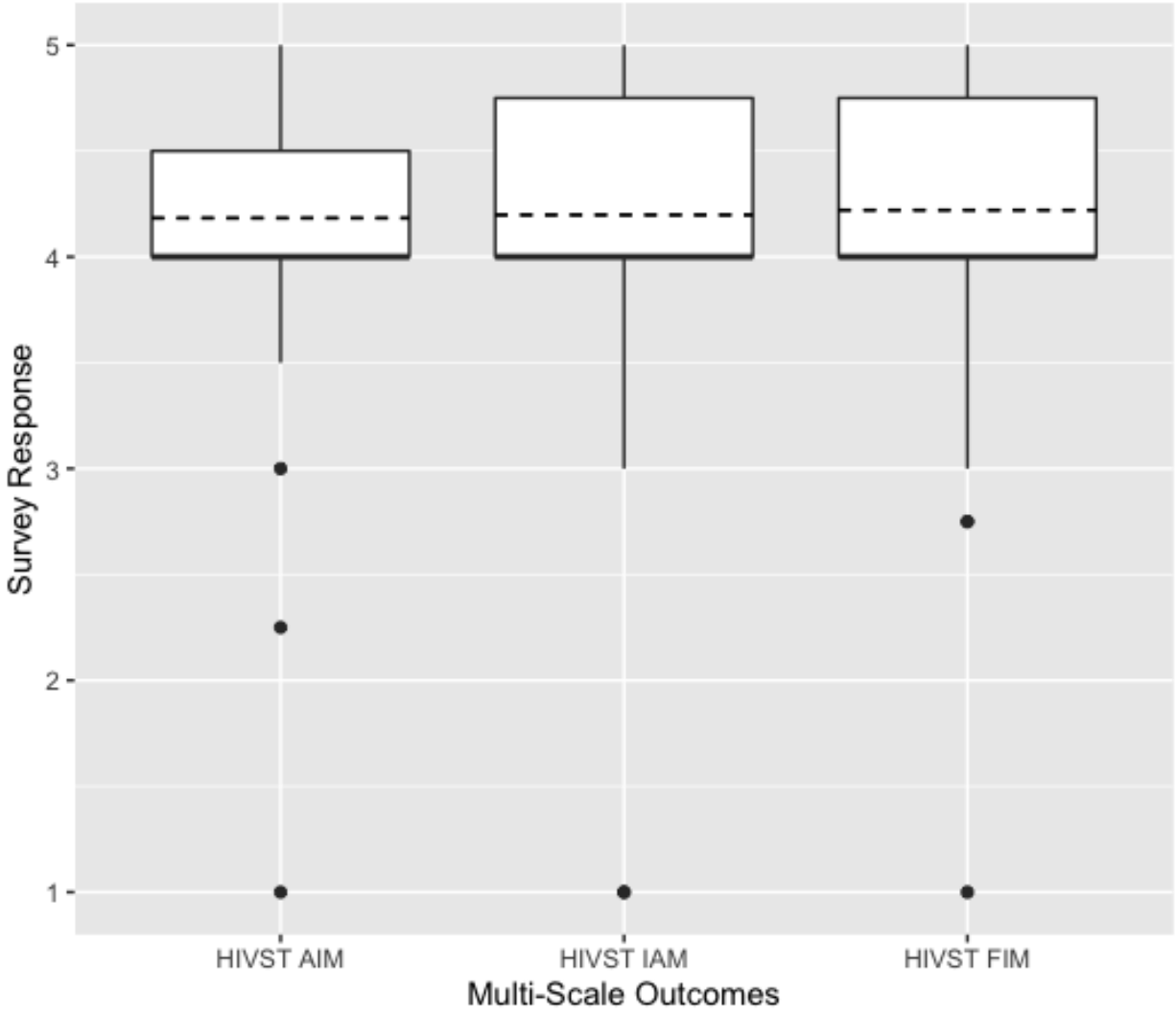
Table 2. Likert responses to AIM, IAM, and FIM		
	Mean	IQR
DTP Acceptability (AIM)	4.21	(4.0-4.75)
DTP Appropriateness (IAM)	4.20	(4.0-4.75)
DTP Feasibility (FIM)	4.19	(4.0-4.75)
HIVST Acceptability (AIM)	4.18	(4.0-4.50)
HIVST Appropriateness (IAM)	4.20	(4.0-4.75)
HIVST Feasibility (FIM)	4.22	(4.0-4.75)
Responses reflect the 5-point Likert scale (1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=completely agree)		

Figure 1. Summary Figures for Acceptability, Appropriatness, and Feasibility of Direct to Pharmacy Delivery



Note: Bounds of the boxes represent the interquartile range (IQR). Dashed line indicates mean.
DTP AIM - Direct to Pharmacy Acceptability Implementation Measure
DTP IAM - Direct to Pharmacy Intervention Appropriateness Measure
DTP FIM - Direct to Pharmacy Feasibility Implementation Measure

Figure 2. Summary Figures for Acceptability, Appropriatness, and Feasibility of HIV Self Testing



Note: Bounds of the boxes represent the interquartile range (IQR). Dashed line indicates mean.
HIVST AIM - HIV Self-testing Acceptability Implementation Measure
HIVST IAM - HIV Self-testing Intervention Appropriateness Measure
HIVST FIM - HIV Self-testing Feasibility Implementation Measure

Discussion

In this cross-sectional study among healthcare providers, we found high levels of acceptability, appropriateness, and feasibility for differentiated service models of PrEP delivery that include direct to pharmacy PrEP refill visits and client HIV self-testing while waiting for refill. While these findings are only specific to these two clinical sites, they may be applicable for those looking to expand delivery of PrEP in similar resource constrained settings. These findings are in line with existing literature that has found high stakeholder approval for PrEP distribution in pharmacy settings.[15-17]

Diverse facility-based differentiated care service models in United States President's Emergency Plan For AIDS Relief (PEPFAR) supported HIV treatment programs – i.e., patient-centered strategies that simplify care for most patients through task shifting, same-day initiation, rapid refills, or multiple month drug dispensing for stable virally suppressed clients – have successfully been implemented in a variety of African settings and have successfully improved retention and adherence to treatment.[18] For PrEP, similar approaches to promote access and continuation need to be defined. For PrEP, the direct to pharmacy PrEP refill is among the first step to define differentiated care pathways for PrEP provision that could promote access and continuation. Direct to pharmacy has the potential to add efficiencies to PrEP systems without undermining outcomes by reducing the burden of PrEP visits in busy clinics, with cost-savings, and due to the highly client-centered nature of care this would translate into improved PrEP continuation. For healthcare providers DTP refills can decongest clinics by reducing the number and duration of visits and subsequently reducing the workload for healthcare workers, but ensuring that providers understand these benefits will likely be an important step for securing their support.[16] Across clinics and healthcare cadre in we found direct to pharmacy visits were an acceptable and appropriate model for PrEP provision in this setting. Our findings suggest that healthcare providers in this setting may be more willing to implement PrEP delivery when the

service model is efficient and person-centered. While these findings only reflect the views of providers, they show that DTP is highly acceptable in clinical settings.

HIV testing is a key component of PrEP delivery necessary to reduce the risk of antiretroviral resistance, thus is required prior to PrEP initiation and for ongoing follow-up while on PrEP. In current HIV testing protocols, HIV testing is conducted by providers, but self-testing conducted by patients while waiting for other services has the potential to advance greater delivery efficiency while still maintaining a core component of PrEP provision. Understanding provider perspectives on a strategy with this potential that would directly impact their role is important. In this study, we found broad acceptability among providers of user HIV self-testing for in-facility PrEP delivery. These findings support the existing research that show high levels of acceptability for HIV self-testing in both patients and providers.[19,20]

Despite widely positive response to these interventions, differences in acceptability by healthcare worker cadre may suggest concerns about task shifting. Nurses and counselors, who are included in the "other" category, have conducted PrEP refill tasks that would be eliminated in this patient flow. Consultation with healthcare workers in these cadres and clear communication prior to implementation of new differentiated care approaches may improve acceptability.[21] Additionally, clinic level differences in acceptability suggest a need to consider organizational readiness for change.[22] Introducing differentiated models of PrEP delivery requires collective, coordinated behavior change that extends beyond the views of an individual.

Strengths of this study include the use of a well validated set of measures to assess provider attitudes. Second, while other studies have used components of the Proctor et al. implementation outcomes framework to evaluate PrEP scale-up, few have used all three constructs for early implementation (acceptability, appropriateness, and feasibility) together. [23] By using all three at an early point in implementation, we have increased the salience of our findings and maximized the external validity to multiple stakeholder groups. In addition, the collection of data on a wide variety of different types of healthcare workers and professional characteristics,

provides a more comprehensive view of the implementation setting which may more accurately reflect site level implementation, not just individual views.

While this study has a number of strengths, there were also limitations. Changes in views on DTP and HIVST were not captured in this analysis given the cross-sectional nature of the survey. Surveys were proctored near the beginning of the intervention and views may have changed over time. Due to the use of a Likert scale, there may have been a central tendency bias to avoid extreme response categories. However, there were relatively few Completely Disagree responses and data skewed heavily towards “Completely Agree” and “Agree” responses which reduces the likelihood that this was a significant factor. Lastly, data was not collected on the age of providers which may be an important attribute of provider acceptability of implementing novel interventions in clinical settings.

Conclusion

In conclusion, direct to pharmacy refills and HIV self-testing were found to be acceptable forms of differentiated PrEP delivery among healthcare workers in central Kenya. These strategies should be considered when scaling up pharmacy PrEP services in resource limited settings. Encouraging adoption of differentiated PrEP delivery into national and county level guidelines may reduce barriers to both clients and providers and help meet the increasing demand for PrEP.[24] Further research should explore the linkages between early implementation outcomes and patient level PrEP initiation and retention.

Appendix

Appendix 1. Early implementation outcomes and survey questions

Implementation Outcomes	Survey Questions
Acceptability of Direct to Pharmacy Visits	1. Direct to pharmacy PrEP visits meets my approval. 2. Direct to pharmacy PrEP visits is appealing to me. 3. I like direct to pharmacy PrEP visits. 4. I welcome direct to pharmacy PrEP visits.
Appropriateness of Direct to Pharmacy Visits	1. Direct to pharmacy PrEP visits seems fitting. 2. Direct to pharmacy PrEP visits seems suitable. 3. Direct to pharmacy PrEP visits seems applicable. 4. Direct to pharmacy PrEP visits seems like a good match.
Feasibility of Direct to Pharmacy Visits	1. Direct to pharmacy PrEP visits seems implementable. 2. Direct to pharmacy PrEP visits seems possible. 3. Direct to pharmacy PrEP visits seems doable. 4. Direct to pharmacy PrEP visits seems easy to use.
Acceptability of patient HIV self-testing for PrEP follow-up	1. Patient HIV self-testing for PrEP meets my approval. 2. Patient HIV self-testing for PrEP is appealing to me. 3. I like direct to pharmacy PrEP visits. 4. I welcome patient HIV self-testing for PrEP.
Appropriateness of patient HIV self-testing for PrEP follow-up	1. Patient HIV self-testing for PrEP seems fitting. 2. Patient HIV self-testing for PrEP seems suitable. 3. Patient HIV self-testing for PrEP seems applicable. 4. Patient HIV self-testing for PrEP seems like a good match.
Feasibility of patient HIV self-testing for PrEP follow-up	1. Patient HIV self-testing for PrEP seems implementable. 2. Patient HIV self-testing for PrEP seems possible. 3. Patient HIV self-testing for PrEP seems doable. 4. Patient HIV self-testing for PrEP seems easy to use.

Note: Response options were consistent across all questions – Completely Disagree, Disagree, Neither Disagree or Agree, Agree, Completely Agree

References

1. Chou R, Evans C, Hoverman A, et al. Preexposure prophylaxis for the prevention of HIV infection: evidence report and systematic review for the US Preventive Services Task Force. *Jama.* 2019;321(22):2214-2230.
2. Masho SW, Wang C-L, Nixon DE. Review of tenofovir-emtricitabine. *Therapeutics and clinical risk management.* 2007;3(6):1097.
3. Masyuko S, Mukui I, Njathi O, et al. Pre-exposure prophylaxis rollout in a national public sector program: the Kenyan case study. *Sex Health.* 2018;15(6):578-586.
4. Framework for the Implementation of Pre-exposure Prophylaxis of HIV in Kenya, Nairobi, Kenya: NASCOP [press release]. 2017.
5. Bavinton BR, Grulich AE. HIV pre-exposure prophylaxis: scaling up for impact now and in the future. *The Lancet Public Health.* 2021;6(7):e528-e533.
6. Mack N, Wong C, McKenna K, Lemons A, Odhiambo J, Agot K. Human resource challenges to integrating HIV pre-exposure prophylaxis (PrEP) into the public health system in Kenya: a qualitative study. *African journal of reproductive health.* 2015;19(1):54-62.
7. O'Malley G, Barnabee G, Mugwanya K. Scaling-up PrEP delivery in sub-Saharan Africa: what can we learn from the scale-up of ART? *Current HIV/AIDS Reports.* 2019;16(2):141-150.
8. Ongolly F, Ngure K, Dolla A, et al. Experiences of accessing PrEP in public HIV clinics: a case of Kenyan HIV-uninfected people in serodiscordant relationships. Paper presented at: AIDS RESEARCH AND HUMAN RETROVIRUSES2018.
9. Irungu E, Ngure K, Mugwanya K, et al. Surmounting PrEP delivery challenges through adaptation of implementation guidelines: Lessons learned from HIV care clinics in Kenya. Paper presented at: JOURNAL OF THE INTERNATIONAL AIDS SOCIETY2019.
10. Ngure K, Ongolly F, Dolla A, et al. Health Care Provider Experiences Delivering PrEP to HIV Serodiscordant Couples in Public HIV Clinics in Kenya. Paper presented at: AIDS RESEARCH AND HUMAN RETROVIRUSES2018.
11. Ortblad KF, Mogere P, Bukusi E, Ngure K, Baeten JM. Pharmacy delivery to expand the reach of PrEP in Africa. *J Int AIDS Soc.* 2020;23(9):e25619-e25619.
12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and policy in mental health and mental health services research.* 2011;38(2):65-76.
13. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implementation Science.* 2017;12(1):108.
14. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics.* 2009;42(2):377-381.
15. Kennedy CE, Yeh PT, Atkins K, Ferguson L, Baggaley R, Narasimhan M. PrEP distribution in pharmacies: a systematic review. *BMJ open.* 2022;12(2):e054121.
16. Ortblad KF, Mogere P, Roche S, et al. Design of a care pathway for pharmacy-based PrEP delivery in Kenya: results from a collaborative stakeholder consultation. *BMC Health Serv Res.* 2020;20(1):1034.
17. Roche SD, Wairimu N, Mogere P, et al. Acceptability and feasibility of Pharmacy-Based delivery of pre-exposure prophylaxis in Kenya: a qualitative study of client and provider perspectives. *AIDS and Behavior.* 2021;25(12):3871-3882.
18. Duncombe C, Rosenblum S, Hellmann N, et al. Reframing HIV care: putting people at the centre of antiretroviral delivery. *Tropical Medicine & International Health.* 2015;20(4):430-447.

19. Ngure K, Heffron R, Mugo N, et al. Feasibility and acceptability of HIV self-testing among pre-exposure prophylaxis users in Kenya. *J Int AIDS Soc.* 2017;20(1):21234.
20. McGuire M, de Waal A, Karellis A, et al. HIV self-testing with digital supports as the new paradigm: A systematic review of global evidence (2010–2021). *EClinicalMedicine.* 2021;39:101059.
21. Zachariah R, Ford N, Philips M, et al. Task shifting in HIV/AIDS: opportunities, challenges and proposed actions for sub-Saharan Africa. *Transactions of the Royal Society of Tropical Medicine and Hygiene.* 2009;103(6):549-558.
22. Weiner BJ. A theory of organizational readiness for change. *Implementation Science.* 2009;4(1):67.
23. Wilson KS, Mugo C, Katz DA, et al. High Acceptance and Completion of HIV Self-testing Among Diverse Populations of Young People in Kenya Using a Community-Based Distribution Strategy. *AIDS and Behavior.* 2022;26(3):964-974.
24. Schaefer R, Schmidt H-MA, Ravasi G, et al. Adoption of guidelines on and use of oral pre-exposure prophylaxis: a global summary and forecasting study. *The Lancet HIV.* 2021;8(8):e502-e510.