

## PROJECT SUMMARY

**Parent Grant:** Pregnant women are at substantial risk of contracting HIV in high HIV prevalence settings. Pre-exposure prophylaxis (PrEP) has the potential to further reduce the risk of HIV acquisition and complement existing prevention efforts in antenatal care (ANC) programs. The "Delivering PrEP in Pregnancy" aims to compare and qualitatively assess the barriers and facilitators of two models of PrEP delivery in pregnant women in a cluster-randomized trial: universal PrEP (women self-select) or targeted PrEP (offer to women with high risk score). **Proposed Diversity Supplement:** One of the challenges to optimizing uptake of PrEP among pregnant women is that few women who present for ANC do so within the first trimester. This is a lost opportunity for early access to PrEP. Informal and formal retail pharmacies ['drug shops'] could potentially serve as accessible sites at the community level for distributing pregnancy tests and encouraging women, if they are pregnant, to get ANC, HIV testing and PrEP early. In this Diversity Supplement, we propose a mixed-methods study to determine whether it is feasible to engage drug shop providers in the distribution of pregnancy tests and promotion of early access to ANC and PrEP among pregnant women. In Aim 1, we will conduct a cross-sectional survey among women attending maternal and child health (MCH) clinics, which are the sites of the parent R01, to determine the strategies and sources of care that women use to confirm and manage early pregnancy. The objective of this aim is to determine the extent to which women access drug shops to purchase pregnancy tests and manage early pregnancy needs. In Aim 2, we will conduct qualitative interviews among women attending MCH clinics to identify the factors and motivations that influence how women select sources of care in early pregnancy. In Aim 3, we will conduct qualitative interviews among potential users (women of childbearing age), providers (drug shop providers, community health workers, nurses) and decision-makers (policy-makers, regulators, program managers) to identify the perceptions of ANC and PrEP referral strategies via drug shops. The proposed research is innovative, in our opinion, because it represents a new and substantive departure from the status quo by exploring how to accelerate early access to both ANC and PrEP via drug shop providers, which are not normally considered within the cadre of community health workers. We will use the data generated from this study to design and test an intervention to close gaps in early access to ANC, accelerate PrEP access and uptake among pregnant women at substantial risk for HIV and strengthen the preventive impact of PrEP. With 2-year Diversity Supplement proposed support, the candidate will gain skills in qualitative research and aim to submit a K application building on findings from the Supplement.

## NARRATIVE

Delayed access to antenatal care in high HIV prevalence settings is a gap that limits opportunities for timely identification and delivery of PrEP among pregnant women at high-risk for HIV infection. In this study, we aim to determine whether it is feasible to engage formal and informal retail pharmacy ['drug shop'] providers in the distribution of pregnancy tests and subsequent counseling of pregnant women in order to promote early access to ANC and PrEP. Our hypothesis is that drug shops are an important healthcare access point for pregnant women in their first trimester and can be used in providing pregnancy tests as well as ANC and PrEP referral services in order to promote early access to ANC and PrEP.

## **CANDIDATE STATEMENT**

My long-term career goal is to become an independent implementation research scientist and to design, implement and evaluate health technologies and service delivery models to improve antenatal care (ANC) in low-and-middle income countries. To continue my progress toward this goal, I am proposing a mixed methods study to determine whether it is feasible to engage formal and informal retail pharmacies ('drug shops') in the distribution of pregnancy tests and the promotion of early access to ANC and HIV preventive services among pregnant women. Specifically, I am interested in studying 1) care seeking behavior among women in early pregnancy and the extent to which women use drug shops to address pregnancy-related needs 2) the factors and motivations that influence how women select sources of care in early pregnancy, and 3) stakeholder perceptions on ANC and HIV prevention referral strategies via drug shops. Along with the studies proposed in the parent grant, which focus on facility-based, nurse-initiated PrEP delivery, I hope that this study will generate information that can be used to design interventions to optimize referral and linkage to PrEP services for pregnant women. The knowledge and experience gained from this proposal will allow me to successfully compete for K01 funding to pilot the intervention.

Specific research and career development objectives and activities that will help me achieve my goals during the diversity supplement award are:

- 1. To become proficient in intervention design and qualitative research methods through coursework and hands-on training in:**
  - a. Planning, design, and evaluation of interventions using qualitative research procedures.
  - b. Qualitative data management, analysis, interpretation, and presentation.
  - c. Social marketing and user-centered design techniques that can inform intervention design.
  
- 2. To develop content expertise in key areas related to promoting early access to antenatal care and pre-exposure prophylaxis and among pregnant women:**
  - a. Understand the demand, availability and use of pregnancy testing services in the Kenyan market.
  - b. Understand the role that formal and informal private sector retail pharmacies play in delivering basic health services, including antenatal care, in low-and-middle income countries.
  - c. Understand the recommendations and dynamics of using PrEP in pregnancy in low-resource settings.
  
- 3. To further develop my scientific writing skills through first-author peer-reviewed publications and oral presentations, and to gain proficiency in grant writing:**
  - a. Publish at least 2 first author publications per year
  - b. Attend and present in at least 1 scientific conference per year
  - c. Develop and submit K01 career development award

I am fortunate to continue to benefit from intensive mentorship. My mentorship committee has a wealth of expertise in pertinent research areas including maternal health and HIV, HIV prevention and PrEP, primary care and health systems strengthening, implementation science and cost-effectiveness of health technology interventions in low-and-middle income countries. My primary mentor, Dr. \_\_\_\_\_ has successfully mentored fellows based both in the US and Kenya; we regularly discuss the proposed project and I also participate in weekly phone conferences with the parent grant project team. For these reasons, my mentorship environment provides an excellent opportunity to accomplish my short-and long-term goals.

Signed \_\_\_\_\_

## CAREER DEVELOPMENT PLAN

**Overview.** We propose a 24-month research and career development plan for Dr. [redacted] an Assistant Professor in the [redacted]

Dr. [redacted]

Dr. [redacted] is an outstanding candidate for a diversity supplement on the NIAID-funded R01 award led by Dr. [redacted] and Dr. [redacted]. With this diversity supplement award, Dr. [redacted] will build her expertise in implementation science, specifically, intervention design and qualitative research methods through relevant educational activities and research projects (Table 3). The educational plan includes didactic training in qualitative research methods through coursework, research seminars and study team meetings at the University of Washington. Her research aims will provide compelling preliminary data to enable a successful NIH K01 career development grant submission during this award. Her aims seek to determine whether it is feasible to engage drug shop providers in the distribution of pregnancy tests and promotion of early access to ANC and HIV preventive services among pregnant women in Western Kenya. To ensure continued close guidance and the greatest likelihood of successful career development, structured one-hour mentoring sessions will occur weekly in-person or via phone throughout the course of this award with Dr. [redacted]. Coursework and field experience will provide Dr. [redacted] the skillset and support that she needs for successful career development. During the course of the grant, she will submit at least two first-author manuscripts per year to high-impact journals in the field of implementation science and maternal health research and present at least one oral abstract at a major scientific meeting.

Her specific career goals and research objectives are 1) to become proficient in intervention design and qualitative research methods through coursework and hands-on training, 2) to develop content expertise in key areas related to promoting early access to antenatal care and pre-exposure prophylaxis and among pregnant women, and 3) to further develop her scientific writing skills through first-author peer-reviewed publications and oral presentations, and to gain proficiency in grant writing.

### Development and mentorship plan:

We will schedule regular one-on-one meetings between Dr. [redacted] and Dr. [redacted] to ensure her continued progress in the objectives outlined in this research study. Further emphasis will be placed on ensuring that she can carry out the research projects independently and also begin to mentor students who might be involved in similar aspects of the work. In addition, she will have access to key collaborators on the parent grant to assist with study design, planning and on-site mentorship for the research in Kenya.

Dr. [redacted], is a qualitative and health evaluation expert and an Associate Professor in the [redacted]. She will work alongside Dr. [redacted] and the qualitative study team, under the parent grant, to gain in-depth training in qualitative study design and analysis. Specifically, she will attend weekly meetings with the team and support the qualitative study efforts outlined in Aim 3 of the parent grant – assessing the barriers and facilitators to adherence, acceptability, and feasibility of PrEP in pregnancy.

Dr. [redacted] is [redacted], and has led several HIV research studies in Kenya including on HIV incidence in pregnancy and postpartum. The parent grant also holds weekly group meetings where she can discuss her research findings and progress to date and obtain additional advice and guidance.

Furthermore, the University of Washington Department of Global Health holds a number of meetings and events (see conferences and seminars below), which will be another excellent opportunity for her to meet other researchers and colleagues who can act as additional mentors.

**Evidence of mentorship experience and success:**

Dr. [redacted], is a Professor in the [redacted] at the University of Washington, who has >20 years of experience conducting HIV research in pregnant women and their children in studies throughout Kenya. Dr. [redacted] is Director of the [redacted]. She leads several studies of HIV in women, adolescents and children, including implementation research studies and Dr. [redacted] was a Site PI for the Nairobi site of the Partners PrEP study led by Dr. [redacted]. Dr. [redacted] is PI of the parent R01 grant "Delivering PrEP in Pregnancy" (MPI [redacted]). Over the past 20 years, Dr. [redacted] has successfully mentored >100 research trainees including providing primary mentorship for 7 K award recipients and mentorship for 2 diversity supplement recipients (please refer to Table 1 for the outcomes of the supplements including the diversity candidate's current status). Dr. [redacted] has received a K24 mentorship award and UW School of Medicine mentorship award, as further evidence of her success as a mentor. Several mentees have advanced to faculty, including to Associate and Professor level.

<b>Parent Grant Title</b>	<b>Administering Institute</b>	<b>Diversity Candidate Information</b>	<b>Supplement Outcomes</b>
Optimizing Pediatric HIV-1 Therapy	NICHHD	Time period: 2007 – 2011 Status during award period: Post-doctoral Fellow Current Status: Acting Assistant Professor, University of Washington	10 Publications (see last page of career development plan)
Urgent Versus Post-Stabilization ART in HIV+ Children with Severe Co-infections	NICHHD	Time period: 2014 - 2016 Status during award period: Program Assistant, University of Washington Current Status: Research Assistant, University of Washington	4 Abstracts and Publications (see last page of career development plan)

**Co-mentoring team:** Dr. [redacted] will have four co-mentors during the research period.

**Table 2: Team Members, Roles, Expertise, and Frequency of Meetings**

Team Member	Role	Expertise	Meeting Frequency
[redacted]	Primary Mentor	pregnant	Weekly in person or via phone
[redacted]	Co-Mentor	ch and PrEP	Quarterly in person
[redacted]	Co-Mentor	science; fitness	Monthly in person
[redacted]	Co-Mentor	Health economics	As needed in person
[redacted]	Co-Mentor	Primary health care and health systems strengthening	As needed in person

[redacted] is the [redacted] Department of Global Health, and a [redacted], who has >20 years of experience in HIV clinical research, including studies in Kenya. Dr. [redacted] led the multi-site Partners PrEP study which demonstrated PrEP efficacy in serodiscordant couples and is a globally recognized authority on PrEP and leads several other trials and demonstration projects on PrEP. He will mentor her in designing PrEP delivery models and she will meet with him quarterly to discuss her progress as a junior faculty member. Dr. [redacted] has also linked her to an online forum comprising a dynamic group of scientists from the University of Washington and the Kenya Medical Research Institute (KEMRI) who have been engaged with PrEP since its beginning, are leading rollout in Kenya and are exploring PrEP in delivery on the private sector and pharmacies. The group will be useful in sharing insights and guidance to inform study design and planning.

[redacted] is a Professor, [redacted], at the University of Washington. Dr. [redacted] research focuses on the adoption, implementation, and sustainability of innovations and evidence-based practices in health care delivery and other organizational settings. He will mentor her in applying implementation science frameworks to intervention design, manuscript writing and developing future research proposals.

[redacted] is an [redacted]. He has worked on improving access to safe and cost-effective diagnostic technologies, medicines, and healthcare delivery platforms in low-income countries. His deep understanding of health economics and decision-making will be helpful in designing an economically sustainable intervention.

[redacted] is an [redacted] at the University of Washington, and [redacted]. Dr. [redacted] has worked the majority of the past 20 years in the public and NGO sectors in Mozambique, Uganda, and Bolivia. He brings a deep understanding of identifying and testing practical solutions to support service integration into the Primary Health Care frameworks as a means of improving health system efficiency, coverage and quality.

**Didactic Coursework:** Early in the research period, Dr. [redacted] will develop her understanding of qualitative research methods by taking courses in qualitative research methods offered at the University of Washington:

- Qualitative Research Methods: An Introduction (HSERV 517). Introduction to planning, design, evaluation, using qualitative research procedures.
- Advanced Qualitative Methods in Anthropology and Public Health (HSERV 521). Provides theoretical training in qualitative research and in-depth training in qualitative data management, analysis, interpretation, and presentation.

Dr. [redacted] will also take courses offered by the University of Washington in social marketing and human centered design, which are instrumental to designing user-friendly behavioral interventions such as:

- Health Promotion and Behavior Change Communication (HSERV 504). Overview of the theory and practice of designing, producing, and evaluating public health communication campaigns, including the use of mass media.
- Health Communication and Marketing for Health Promotion: Theory and Practice (HSERV 507). Examines marketing principles for health promotion.

- Introduction to User-Centered Design (HCDE 318). Explores the user-centered design paradigm from a broad perspective, with an emphasis on the importance of developing and applying design processes and strategies.

**Seminars and Conferences:** Dr. [redacted] will attend regularly held meetings at the University of Washington such as the weekly discussion group held by the Kizazi mentorship group. The group uses a peer mentorship model in which attendees provide and receive mentorship during an informal discussion, generally focused on analyses in progress, grant proposals, and draft manuscripts. Dr. [redacted] will also seek out opportunities to present and network with expert researchers at local meetings focused on maternal health and primary health care delivery models, by engaging Seattle's vibrant global health organization such as the Bill and Melinda Gates Foundation and PATH. Finally, Dr. [redacted] will attend at least 1 national or international conference per year that is aligned with her research scope such as the Global Symposium on Health Systems Research, Global Maternal Newborn Health Conference and the International AIDS Conference.

**Timeline for training and research activities.** Dr. [redacted] intends to spend 75% of her effort on training and research activities. A synopsis of the activities is provided in Table 3.

		Year 1				Year 2			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Coursework</b>	Qualitative research methods								
	Advanced qualitative methods								
	Health Promotion and Behavior Change								
	Introduction to User-Centered Design								
<b>Research</b>	Study protocol development								
	IRB review								
	Staff hiring and training								
	Recruitment and interviews								
	Data analysis								
<b>Manuscripts</b>	Submit at least 2 first author articles per year								
<b>Grants</b>	K award development and submission								

**Impact of research and career development experiences on the research capabilities of the candidate:**

This supplemental award will enable Dr. [redacted] to gain intervention design and qualitative research skills, exposure to maternal health research, and strong mentorship. Combined with her health services research doctoral level training [redacted] I have the tools and support needed to realize her vision of successfully applying for a K01 career development award. Additionally, the diversity supplement award will enable her to make progress toward her career goal of becoming an independent implementation research scientist and implementing health technologies and service delivery models to improve antenatal care in low-and-middle income countries.

## **SPECIFIC AIMS OF FUNDED GRANT**

### **Title: Delivering PrEP in Pregnancy**

**AIM 1a.** In a cluster-RCT, to compare universal PrEP (offer to all; women self-select PrEP) to targeted PrEP (offer to women with a high-risk score incorporating partner HIV self-test data) for outcomes reflecting the balance of PrEP effectiveness and safety: HIV incidence at 9 months postpartum among all women (including those who did and did not receive PrEP) and proportion of women exposed to PrEP.

**AIM 1b.** To compare trial arms for proportion of women 'appropriately' on PrEP (risk factors), PrEP adherence (drug levels) and duration, partners with known HIV status, partners on ART; infant outcomes (growth, birth outcomes).

**AIM 2.** To estimate the incremental cost-effectiveness of targeted PrEP compared to universal PrEP for women during pregnancy and postpartum, per HIV infection and disability-adjusted life-year (DALY) averted.

**AIM 3.** To qualitatively assess barriers and facilitators to adherence, acceptability, and feasibility in universal and targeted PrEP models at the organizational, provider, and individual woman level. Optimized PrEP delivery in pregnancy will contribute to HIV eradication as highly accessed MCH systems can efficiently deliver PrEP to women in a defined limited risk period and expedite male diagnosis and treatment.

## **SPECIFIC AIMS OF PROPOSED DIVERSITY SUPPLEMENT**

One of the challenges to optimizing uptake of PrEP among pregnant women is that few women (estimated <20%) who present for antenatal care (ANC) do so within the first trimester. This is a lost opportunity for early access to HIV prevention services including PrEP(1). Early intervention is critical because studies suggest that the risk of HIV-acquisition among pregnant women is high in early pregnancy(2, 3). However, there are few evidence-based strategies to improve early access to antenatal care services(4). Emerging data suggest that:

- 1) Formal and informal retail pharmacies ['drug shops'] are frequently accessed in both urban and rural areas and can provide basic health services(5). Compared to health facilities, drug shops have been found to be more accessible, save time, provide information on how to use health products, and sell a variety of products that the women might need(6).
- 2) Drug shop providers can play an important role in educating and referring pregnant women for ANC in early pregnancy(7).
- 3) Women who have access to pregnancy testing are more likely to present to ANC earlier in pregnancy(8).

Drug shops could therefore serve as accessible sites at the community level for distributing pregnancy tests and encouraging women, if they are pregnant, to get ANC, HIV testing and PrEP. What is not known is the extent to which women access drug shops to purchase pregnancy tests and manage early pregnancy needs, the characteristics and motivations of women who use drug shops, and whether it is feasible for drug shops to offer ANC and PrEP referral services. Dr. [redacted]

's long-term goal is to design, implement and evaluate health technologies and service delivery models to improve ANC in low-and-middle income countries. The overall objective of this application is to determine whether it is feasible to engage drug shop providers in the distribution of pregnancy tests and subsequent counseling of pregnant women in order to promote early access to ANC and PrEP. Along with the studies proposed in the parent grant, which focus on facility-based, nurse-initiated PrEP delivery, we hope that this study will generate information that can be used to design interventions to optimize referral and linkage to PrEP services for pregnant women. Dr. [redacted]

's central hypothesis is that drug shops are an important healthcare access point for pregnant women in their first trimester and can be used in providing pregnancy tests as well as ANC and PrEP referral services in order to promote early access to ANC and PrEP. However, these services will need to be adapted to the context and carefully integrated within the broader health system. We plan to assess the feasibility of this approach by pursuing the following Specific Aims:

**Aim 1: To determine the strategies and sources of care that women use to confirm and manage early pregnancy through a cross-sectional survey.**

**Aim 2: To qualitatively identify the factors and motivations that influence how women select sources of care in early pregnancy through in-depth interviews with women of childbearing age.**

**Aim 3: To qualitatively identify the perceptions of antenatal care and PrEP referral strategies via drug shops among potential users, providers and decision-makers through in-depth interviews.**

We will use the data generated from this research to design and test an intervention that will recruit the involvement of drug shops in the catchment area to facilitate earlier access to ANC and promote PrEP engagement and uptake. These specific aims set the stage for a K01 career developmental award to pilot the intervention.



## **RESEARCH STRATEGY**

### **SIGNIFICANCE**

#### **Overall Scientific Premise**

The World Health Organization (WHO) recommends that ANC should begin in the first trimester of pregnancy in order to allow timely access to preventive interventions. However, *less than 20% of women are estimated to initially present for ANC during their first trimester in Kenya(1)*. Solving this problem is a major priority for NIMH and NIAID (the sponsor of the parent grant), because delayed access to ANC in high HIV prevalence settings is a gap that limits opportunities for timely identification and delivery of PrEP among pregnant women at high-risk for HIV infection. There is an *urgent need* to close this gap because the risk of mother-to-child-transmission is 2 – 3 times higher among women who acquire HIV during pregnancy than those with chronic infection(2).

Our approach to evaluate the access gap and explore the feasibility of closing it is based on the COM-B (capability, opportunity, motivation and behavior) model(3). The COM-B model can be used to describe the factors that are likely to prevent women from accessing ANC early. A woman's *capability* to act is impacted when she is uncertain about her pregnancy status and does not know the importance and type of ANC services that are offered(4). Improving access to pregnancy testing and educating a woman about how the timing and nature of ANC services can positively influence the outcome of her pregnancy and that of her child can change a woman's capability to act(5). High transportation costs limit *opportunities* for a woman to seek care early(4). Bringing care closer to her community can create opportunities for a woman to seek care early. Community-based delivery models might provide better access to pregnancy testing services and appropriate ANC guidance that can enhance a woman's psychological capability and *motivation* to seek care early. One delivery model might involve training drug shop providers to educate and counsel pregnant women in the community about pregnancy identification and the need for prompt ANC services(6).

#### **Significance of the Expected Research Contribution**

Upon successful completion of the proposed research, we expect our contribution to be the identification of key requirements that will be useful in designing a community-based delivery model that leverages drug shop providers in promoting early access to ANC and PrEP. *The contribution will be significant because it is expected to have broad translational importance on the timely prevention and treatment of diseases during pregnancy.* It is also expected to strengthen HIV prevention efforts by reducing gaps in the PrEP care continuum. There is limited research that has tested how to successfully engage pregnant women that are at substantial risk for HIV infection in PrEP care. Implementation science interventions designed to close gaps in early access to ANC and to accelerate PrEP access and uptake among pregnant women at substantial risk for HIV will also strengthen the preventive impact of PrEP (Funding Opportunity Announcement PA-17-103). In addition, the research will contribute to broader understanding of how to better engage drug shop providers and pregnant women and improve ANC service delivery.

#### **Innovation**

To our knowledge, there are currently no community-delivery models that are specifically designed to optimize ANC access and PrEP delivery among pregnant women. Recent WHO guidelines suggest that the use of community health workers to encourage uptake and utilization of ANC services might be beneficial in some areas although there is insufficient evidence supporting this approach(7). A performance evaluation study in Tanzania suggests that community health workers that provided home-based ANC counseling services might have contributed to a decrease in the average gestational age at which pregnant women presented for their first ANC visit(8). However, the affordability, cost-effectiveness, scalability, and sustainability of such programs remain unclear(9). There is a growing interest in leveraging drug shops as a community delivery model to encourage early ANC attendance(6). Theory-informed interventions are needed to determine how to engage pregnant women and drug shop providers in both ANC and PrEP.

The proposed research is innovative, in our opinion, because it represents a new and substantive departure from the status quo by exploring how to accelerate early access to both ANC and PrEP via drug shop providers, which are not normally considered within the cadre of community health workers.

## APPROACH

### Overall strategy

Ensuring early PrEP engagement and uptake among pregnant women in high HIV prevalence settings will require service delivery models that address two barriers to early ANC (lack of knowledge about one's pregnancy status and distance from the health facility) and promote PrEP awareness. We hypothesize that drug shops are used by a significant number of pregnant women and that there are perceived values and benefits of promoting a component of ANC services and PrEP referral services at this level. We plan to conduct an exploratory study using mixed-methods, to inform an intervention designed to facilitate early access to ANC and early PrEP engagement and uptake by addressing barriers to ANC through promotion of pregnancy testing at community-based drug shops.

Aim	Objective	Approach	Outcomes	Relevance
Aim 1	Determine the strategies and sources of care that women use to confirm and manage early pregnancy	Cross-sectional survey among pregnant women attending ANC in parent study clinics	Sources of care used to confirm and manage early pregnancy; proportion of and characteristics of pregnant women using drug shops	Estimate impact of the intervention; better tailor intervention to the type of women who are likely to use drug shops;
Aim 2	Identify the factors and motivations that influence how women select sources of care in early pregnancy.	Focus group discussions with pregnant women attending ANC in parent study clinics	Understanding of what women value in seeking different sources of care including drug shop services; understanding of perceived benefits and drawbacks of sources of care	To design an intervention that is aligned with women's values; to identify potential messaging elements that can be used to promote the intervention ...
Aim 3	Identify the perceptions of ANC and PrEP delivery or referral strategies via drug shops among potential users, providers and decision-makers	Focus group discussions among women of childbearing age and health facility providers; Semi-structured interviews with drug shop providers and select decision-makers.	Desired attributes of ANC and PrEP referral strategies; understanding of perceived benefits and drawbacks of proposed ANC and PrEP referral strategies	To design an intervention that addresses the drawbacks and leverages benefits expressed by key stakeholders.

### **Aim 1: To determine the strategies and sources of care that women use to confirm and manage early pregnancy through a cross-sectional survey**

**Introduction.** The objective of this aim is to determine the extent to which women access drug shops to purchase pregnancy tests and manage early pregnancy needs and the characteristics of these women. Findings from this aim will be useful in estimating the impact of the intervention and better tailoring the intervention to the type of women who are likely to use drug shops.

**Research design and data collection.** We will conduct a cross-sectional survey among women presenting for ANC in MCH clinics participating in the parent study. In the study area, 97% of women are estimated to have at least 1 ANC visit during pregnancy(1). We will initially conduct 10 semi-structured interviews with key informants including community health workers, health providers and researchers familiar with the study population to define how women confirm pregnancy, needs during early pregnancy and sources of care used among women in the study area. Key informants will be selected based on consultations with personnel from the parent study and a review of authors of relevant peer-reviewed publications. Findings from these interviews will be used to design the survey questions. Survey questions will be piloted among a small sample of women outside the research area, revised, and then incorporated into the screening Case Report Forms used as part of the parent grant. Survey questions will center on how women confirm pregnancy status, pregnancy-related needs in early

pregnancy, the strategies and sources of care used to confirm and manage early pregnancy, timing of first ANC visit, and individual characteristics (age, parity, marital status, educational level, occupation).

**Study setting and sample.** The parent study is being conducted in 20 health care facilities in Homa Bay and Siaya counties in Kenya. Facilities selected for inclusion are located in high HIV seroprevalence regions (HIV prevalences 15 – 20%), have approximately 500+ HIV negative clients receiving ANC at the facility per year and offer postnatal care services including infant HIV testing and immunizations. All pregnant women, who are HIV negative and who provide informed consent will be eligible to participate in the study. **Statistical and data analyses.** Differences in strategies used to confirm pregnancy and sources of care among pregnant women will be summarized. We will use logistic regression to estimate associations between individual characteristics and sources of care. We will account for potential differences among women from different health facilities by including health facility type as an independent variable.

**Aim 2: To qualitatively identify the factors and motivations that influence how women select sources of care in early pregnancy through in-depth interviews with women of childbearing age.**

**Introduction.** The objective of this aim is to understand why women value the sources of care identified in Aim 1 to manage their needs in early pregnancy. Findings from this aim will be useful in designing an intervention that is aligned with women's values and in identifying potential messaging elements that can be used to promote the intervention.

**Overview.** We will conduct focus group discussions to identify (1) the attributes that women value among the different sources of care, (2) how these attributes affect their experiences receiving care, and (3) the underlying reasons for which these types of experiences are important to women. Our approach is drawn from Gutman's Means-End theory, designed to understand the underlying personal values or goals that motivate individuals to use a particular service(10). The theory suggests that features of a service (e.g. operating hours), are linked to how the service is experienced - functional benefits (e.g. saves time) or drawbacks; how the service is experienced is then linked to a personal value or goal (e.g. personal empowerment).

**Research design and data collection.** We will conduct 4 focus group discussions with women of childbearing age who use drug shops. We will select 5 – 10 participants for each focus group by engaging community health workers from 4 of the parent study clinics to invite women of childbearing age to participate in the focus group discussions. Focus groups will be stratified by age (15 – 24 years vs. > 24 years) and gravidity (first-time vs. later pregnancy). We will leverage relevant findings from Aim 1 to further structure the focus groups as needed. We will use the laddering interview technique to understand the underlying personal values or goals that motivate women to seek care at drug shops. The laddering interview technique uses a series of questions to elicit how individuals link service features to functional benefits and personal values by probing why each element is important(11). Interviews will be recorded in Swahili, transcribed and translated into English and entered into ATLAS.ti software for analysis. Responses derived using laddering interview techniques will be analyzed using content analysis. In order to develop a set of summary codes, we will categorize the responses by attributes, consequences and values(12). Similar responses will be summarized to create individual summary codes and a codebook developed(13). At least two researchers will independently code the transcripts. Intercoder reliability will be assessed using Cohen's kappa(14). Attribute, consequence and value relationships will be summarized in an implication matrix table and used to develop a hierarchical value map that graphically illustrates how the elements are related(12).

**Aim 3: To qualitatively identify the perceptions of antenatal care and PrEP referral strategies via drug shops among potential users, providers and decision-makers through in-depth interviews.**

**Introduction.** The objective of Aim 3 is to obtain data on perceptions of ANC and PrEP referral strategies so as to inform the design requirements for a community-based delivery model via drug shops to encourage early ANC attendance and PrEP uptake.

**Research design, data collection and analysis.** Prior to the study, the parent grant team will provide input on the development of semi-structured questionnaires to be used in the data collection process. We will collect data

on perceived benefits and barriers of potential ANC and PrEP referral strategies from the perspective of key stakeholders. We will conduct 4 focus group discussions with women of childbearing age who are likely to use drug shops. We will select 5 – 10 participants for each focus group by engaging community health workers from 4 of the parent study clinics to invite women of childbearing age to participate in the focus group discussions. While we plan to structure the focus groups as previously indicated in Aim 2, we will leverage relevant findings from both Aims 1 and 2 to further structure the focus groups as needed. We will also conduct 4 focus group discussions among health facility providers from 2 study sites that are involved in providing ANC services and offering PrEP to understand the potential benefits and barriers to proposed community-based ANC and PrEP referral strategies. We will select 5 – 10 participants for each focus group stratified by provider type - community health workers and nurses - who are involved in providing ANC and PrEP services. Study site selection will be informed by accessibility to a variety of types of health providers involved in ANC and by recommendations from the parent grant team. We will conduct semi-structured interviews with drug shop providers (n = 10), and decision-makers e.g. policy-makers, regulators, and program managers (n = 10). We will seek permission to gain access to and select a sample of drug shop providers from an existing census of registered and unregistered drug shops in Western Kenya(15, 16). Drug shop providers will be selected using a stratified purposeful approach so as to include providers from different types of drugs shops (general shops, informal drug shops, registered pharmacies) and settings (urban, rural, peri-urban)(17, 18). Decision-makers will be purposively selected to include key leaders in maternal health, HIV prevention, and health pharmacy as well as county-level leaders. **Overall, we plan to conduct 4 focus group discussions with women of childbearing age, 4 focus group discussions with health providers (community health workers and nurses), 10 semi-structured interviews with drug shop providers, and 10 semi-structured interviews with decision-makers. Prior research suggests that this sample size should be sufficient to reach thematic saturation(19).**

Interviews will be analyzed using the framework method(20). Interviews will be recorded, transcribed verbatim, and translated into English. Analytic memos that describe the communication and behavior among participants in the research settings and the interviewers' reflections during the data collection process will be prepared. We will carefully review the transcripts to identify important concepts or 'codes'. We will make every effort to ensure that at least two researchers independently code the transcripts(13). In order to develop the codebook, initial transcripts will be compared to ensure that an agreed upon set of codes are categorized, defined and used in subsequent transcripts. We will use a framework matrix to chart data that identifies the benefits and barriers to different ANC and PrEP referral strategies from the perspective of each stakeholder type. We will use ATLAS.ti software to support review and coding of the transcripts(21).

**Pitfalls and Alternative Approaches:** The study will be conducted in sites that are involved in the parent grant in Western Kenya and will provide initial insights into patterns of health and care seeking during pregnancy in this region. Some aspects of our findings may not generalize to other regions. In the future, as we share data from this study, we anticipate getting further insights on drug shop usage and potential intervention strategies from national stakeholders that can add to generalizable strategies for drug shop interventions.

**Timeline:** We anticipate preparatory activities including protocol development and ethical approvals during the first 6 months, implementation of qualitative studies and survey in months 6-18, analysis and dissemination in months 18-24.

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