STUDY PROTOCOL

Reaching Adolescent Girls and Young Women (AGYW) Through Girl-Friendly Drug Vendors

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2. List of Abbreviations

ADDO…….Accredited Drug Dispensing Outlet

AGYW……Adolescent girls and young women

HCD……Human-centered design

HIVST…….HIV self-testing

H-PON.....Health for a Prosperous Nation

SRH…….Sexual and reproductive health

PMTCT……Prevention of mother-to-child transmission

TSH.....Tanzanian Shillings

3. Protocol Summary

Title	Reaching Adolescent Girls and Young Women (AGYW) Through Girl-Friendly Drug Vendors
Study Objective	Pilot the intervention to deliver AGYW-friendly SRH services at ADDOs and determine the intervention's acceptability, feasibility, and preliminary impact on AGYW patronage and SRH product distribution.
Study Design	We will implement a 4-month randomized pilot study of the intervention (the Queen Club) to deliver AGYW-friendly SRH services, including HIVST and contraception, at ADDOs. We will compare mediating outcomes (AGYW patronage, SRH product distribution) between ►10 intervention and 10 comparison ADDOs, randomized into study arms. Our proposed data collection strategy involves three main activities: 1. Surveys with ADDO owners and/or employees 2. Time-location surveys of ADDO customers 3. Shop records kept by ADDO owners and/or employees◄
Study Site	This study will take place in Shinyanga Region, Tanzania.
Study Populations	►Participants in the randomized trial will meet the following criteria: a. Owner or employee of a registered ADDO in Shinyanga, Tanzania b. At least 18 years old c. Provides informed consent◄
Sample Size	►20 ADDO owners/employees◄
Duration	►Data collection for the randomized trial will take place over a 6-month period, including 4 months of intervention implementation.◄

4. Background and Rationale

Adolescent girls and young women (AGYW; ages 15-24) in sub-Saharan Africa face the dual threats of HIV infection and unintended pregnancy that severely undermine their long-term well-being. AGYW comprise 25% of new adult infections in SSA, are more than twice as likely to acquire HIV as their male peers in many countries, and disproportionately bear 44% of all reported unintended births.[1–4] Reasons for prevention failures are multi-faceted, including stigma, lack of perceived risk, and challenges accessing available health services.[5–10] In particular, biases against sexuality among AGYW by many health providers greatly discourages care-seeking.[11–15] *Thus, despite the urgent need to reach AGYW with sexual and reproductive health (SRH) services, health systems are ill-equipped to overcome myriad access barriers alone.*

Our ultimate goal is to reduce HIV incidence and unintended pregnancies by creating a sustainable, easily accessible, community-based platform for delivering HIV prevention and SRH services to AGYW. We hypothesize that this can be achieved through privately owned drug shops where AGYW already go to buy contraception and other hygiene/beauty products. This implementation science-focused R34 proposal will develop and pilot mechanisms to increase demand for the mediating outcomes of HIV self-testing (HIVST) and contraception at community drug shops in Tanzania, in preparation for a future study of effectiveness and sustainability (e.g., pricing, quality). Privately owned drug shops, such as Accredited Drug Dispensing Outlets (ADDOs) in Tanzania, can promote beneficial health behaviors and bridge gaps in health services, but are often underutilized in health systems.[16–22] ADDOs (mostly operated by women) are often women's first point of access for drugs, contraceptives, pregnancy tests, and informal counseling and referral.[23–25] AGYW are twice as likely as older women to obtain contraception from ADDOs[26], but demand remains suboptimal, partly due to discriminatory attitudes toward AGYW sexuality among some shop owners.[24] Thus, reducing stigma and stimulating demand at drug shops is an untapped opportunity to amplify distribution of SRH services, including HIV prevention, to AGYW.

Building on our team's experience with human-centered design (HCD) methods and behavioral economics theories, we will develop an intervention to develop AGYW-friendly drug shops where we will introduce HIVST alongside contraceptives and linkages to care. We hypothesize that creative strategies led by ADDO owners (e.g., selling AGYW-relevant products, creating AGYW-welcoming environments) can attract more AGYW and bolster uptake of SRH services/products, including HIV testing, the gateway to HIV prevention and care services. Our study will be the first to examine HIVST distribution targeting AGYW in Tanzania, doing so with special permission from the Ministry of Health (MOH) to add HIVST kits (recommended by WHO[27,28]) to the ADDO inventory. Working closely with the existing health system, we will conduct the study in Shinyanga, a region with high (23%) unmet need for contraception[26] and a generalized HIV epidemic (7.4% overall prevalence, 5.1% among AGYW).[29] We will identify ways to stimulate AGYW demand at ADDOs using HCD methods[30], a creative and empathetic intervention design approach, combined with insights from behavioral economics theoretical constructs. Our multidisciplinary team will leverage our collective experiences in health service delivery through drug shops; HIVST and uptake among adolescents; and designing and evaluating creative, theoretically-driven interventions for priority public health problems.

Our past studies on drug shops in sub-Saharan Africa show that these providers can effectively increase broad access to basic health services. Numerous studies on drug shops in Nigeria led by Dr. Liu show that they are often the first point of care, give treatment and care advice if requested (e.g., prescribe antibiotics, give injections), stock essential health commodities for common conditions (i.e., diarrhea, malaria, pneumonia, contraceptives), are owned and run by respected members of the community (in some areas, up to 75% were health professionals, e.g., nurses/midwives, community

health workers), and view themselves as fulfilling an essential public service role.[22,31–33] Moreover, drug shops vastly outnumber health facilities (up to 4:1), offering unparalleled reach of health services to underserved populations[22,34], including AGYW. Several previous studies led by our team show that introducing new products at drug shops can substantially improve access to and proper use of products.[21] For example, similar to the successful malaria initiative at ADDOs[35,36], we found that introducing malaria rapid diagnostic tests to customers seeking antimalarials in Nigeria increased appropriate treatment by over 60%[37–40], evidence that led to nationwide allowance of such testing at all licensed drug shops. We are also examining the delivery of Sayana Press, the hormonal contraceptive formulated for self-injection, through community-based distribution points, including drug shops, in efforts to reduce unmet need. Initial results suggest that specific AGYW-focused outreach strategies, including specific training on counseling for AGYW, led to higher contraceptive uptake among AGYW. Together, our past studies underpin our central hypothesis that ADDOs can be an effective platform for reaching AGYW with HIV and SRH services, provided they are supported with training, commodities, and tools for demand-creation.

Our studies also show that interest in HIVST among AGYW is high, suggesting that distributing HIVST kits at ADDOs may successfully increase testing and linkage to care. Our research on barriers and facilitators to HIV testing and linkage among AGYW in sub-Saharan Africa and the U.S. has shown that clinic access issues, lack of youth-friendly services, and provider bias against AGYW sexuality are significant barriers to seeking services.[41] In contrast, being offered HIV testing while engaging in other health services (e.g., antenatal care) motivated testing access in other settings.[41] Dr. Mavedzenge's extensive research on HIVST has shown acceptability and demand for HIVST using oral fluid across a range of populations and settings, including AGYW in sub-Saharan Africa[41–44], and that HIVST in the hands of lay users can be highly accurate.[43,45] Study participants also report that self-testing would reduce stigma around HIV testing and increase convenience and confidentiality, critically important factors for AGYW.[41,44,45] Recent Tanzania policy allows HIVST[46] but there is no evidence on how best to deploy HIVST so as to ensure access and support for vulnerable individuals, such as AGYW. We hypothesize that uptake of HIVST by AGYW can be enhanced if made available at more AGYW-friendly community-based locations, such as ADDOs—a strategy that has never been tried but that has excellent potential for meeting the needs of this population. In this study, we will take the critical first step and focus on demand, in preparation for a later study of effectiveness and sustainability.

However, merely making new health services available will not engender uptake; rather, our studies show that interventions designed with HCD methods and built on theoretical principles from behavioral economics can effectively complement product introduction to spur demand. We have a track record of developing and evaluating innovative interventions to stimulate demand, including those developed with HCD methods and incorporating constructs from behavioral economics, several of which were conducted in Tanzania. Drs. McCoy, Njau, and Ms. Rao recently used HCD to create and evaluate an intervention using the behavioral economics constructs of priming and social influence to address poor retention in HIV primary care among PLHIV in Tanzania. The novel, low cost-intervention bolstered social support at the clinic, provided patients with useful items (e.g., a discreet pillbox to aid their adherence), and resulted in increased retention in care at 6 months (87% vs. 79%, adjusted odds ratio = 1.73, 95% CI: 1.08, 2.78, $p<0.05$).[47–49] In addition, our team has evaluated the effectiveness of cash and in-kind incentives to stimulate demand for ART adherence and HIV testing in Tanzania and the U.S. (McCoy, Njau, Padian)[50,51], cash incentives for preventing mother-to-child HIV transmission in Nigeria (Liu, Padian)[52,53], non-financial incentives delivered in game-like environment for HIV/STI screening (McCoy)[54], non-financial incentives for increasing couples HIV testing and counseling in Zimbabwe (McCoy, Mavedzenge, Padian)[55], financial and non-financial incentives for improving oral health behaviors (Liu; UH2/UH3DE025514), and text message reminders for increasing antimalarial drug adherence (Liu)[39,40]. Thus, across a number of health behaviors and contexts, we are

observing that behavioral economics constructs of incentives, priming, social norms, and saliency can effectively overcome barriers to uptake for both one-time actions (e.g., HIV testing, clinic visits) and those requiring longer fidelity (e.g. drug adherence, PMTCT care). We will leverage this collective insight on how to effectively change behavior by applying these behavioral economics tools to increase demand for HIVST and contraception at drug shops.

To develop acceptable and applicable interventions for demand-creation, our past experiences suggest that the HCD methodological process yields solutions that are highly-tailored and thus effective. From a life course perspective, we have found that AGYW are particularly motivated to achieve important milestones in the transition to adulthood (e.g., schooling, marriage, family formation), but may under-invest in the routes to success due to immediate influences and risks faced everyday.[48,56] Rapidly changing social relations, including premarital sex, make contraception and HIV prevention imperative[57–60], but fears, misconceptions, and stigma[61], among other barriers, obstruct their uptake. Thus, services need to address the specific day-to-day interests and concerns of girls in order to effectively reach AGYW. Our team has experience addressing complex public health problems by in-depth learning about the subject population: In our study of ART adherence in Tanzania, we employed HCD to identify patient segments and insights, map patient "health journeys" from diagnosis to long-term adherence, and develop and iteratively test potential solutions.[47,48,56] Similarly, in an ongoing study in Zambia, Dr. Padian and colleagues are directly soliciting user and patient feedback to shape HIV service delivery across the continuum of community- to clinic-based care, for which the resulting models of care will be evaluated.[62] Both of these experiences revealed the limitations of narrow research approaches that ignore an individual's lived experience, and highlight the potential for private-sector design strategies to tap into novel and unexpected strategies to improve health and well-being.

5. Study Objectives

The overarching goal of the proposed study is to create a sustainable, community-based platform to deliver HIV prevention and other reproductive health services to adolescent girls and young women (AGYW) in Tanzania through drug shops.

►In the previous phase of research (Phase 1), we conducted diverse formative research activities (i.e., ADDO observations; AGYW shadowing; interviews with AGYW, ADDO staff, and stakeholders) and followed the established, iterative HCD process to develop intervention components informed by behavioral economics tenets (e.g., messenger, defaults) and iteratively test them for acceptability, feasibility, and cultural sensitivity in focus groups with AGYW. Now, in Phase 2, we will pilot the resulting intervention at ADDOs in Shinyanga.◄

Based on our team's formative work using HCD methods and behavioral economics theories in Phase 1, we have designed a thoughtful, focused pilot study to supply contraception and free HIVST in Shinyanga ADDOs to maximize learning about which demand-creation strategies resonate with AGYW. Our objective in Phase 2 is to pilot the intervention to deliver AGYW-friendly SRH services at ADDOs and determine the intervention's acceptability, feasibility, and preliminary impact on AGYW patronage and SRH product distribution.

This strategy has a high potential for impact because it is increasingly recognized that "drug shops", such as Accredited Drug Dispensing Outlets (ADDOs) in Tanzania, can promote beneficial health behaviors, bridge gaps in health services, and mitigate health workforce shortages.

M6. Methodology

6.1 Study Setting

This study will be conducted in Shinyanga Region, Tanzania.

6.2 Study Design

During Phase 2, we will pilot the intervention designed in Phase 1 (entitled the "Queen Club") to create AGYW-friendly drug shops where we will introduce HIVST alongside contraception and linkages to care. The components of the intervention are described in detail in Section 6.7.

In a 4-month randomized pilot study, we will introduce the intervention in ADDOs and determine its preliminary impact on the mediating outcomes of AGYW patronage and distribution of HIVST kits and contraception to AGYW. We will compare mediating outcomes between ►10 intervention and 10 comparison ADDOs, randomized into study arms and included in primary analyses.

Our proposed data collection strategy involves three main activities:

1. Surveys with ADDO owners and/or employees
2. Time-location surveys of ADDO customers
3. Shop records kept by ADDO owners and/or employees◄

6.3 Study Population and Sample Size

Given the pilot nature of this study, we have not conducted formal power calculations. The sample size of ►randomized ADDOs (n=20)◄ was selected to ensure we had a diversity of ADDO shops in the study, including various geographic areas, shop sizes, and types of owner.

6.4 Eligibility and Screening

With the Regional and Municipal Pharmacists and using their established communication channels with ADDOs and local pharmacies, we will identify ►20 new ADDO owners who meet the eligibility criteria:

- Accredited ADDO shop in Shinyanga Region
- Owner is ≥18 years of age
- Interested in participating in the pilot program, and thereby willing to distribute HIVST and, if randomized to the intervention arm, willing to implement the intervention in their shops.◄

Eligibility of ADDO owners/shops for the study will be verified when H-PON makes the initial visit to the ADDO (after the ADDO owner has expressed initial interest). At that time, the H-PON team will verify that the shop is accredited and that the owner is at least 18 years of age. (Operation of the shop in Shinyanga Region will be determined based on physical location of the shop.) Should any ADDO employees fill out the baseline survey (i.e., at the owner's suggestion), eligibility (≥18 years) will be verified at the beginning of the survey.

6.5 Recruitment

►Recruitment will be conducted by the local implementing partner, H-PON.

We will randomly select drug shops from four administrative wards in the Shinyanga Region using a registry of ADDOs provided by the Municipal Pharmacist. The Municipal Pharmacist will contact shop

owners using phone numbers from the registry and inform them that they are invited to participate in a study. After this first contact, trained staff members from H-PON will call drug shop owners to provide information about the study and, if interested, arrange to meet to obtain informed consent. H-PON staff members will meet one-on-one with every interested ADDO owner to discuss the study, to answer questions, and if the ADOO owner is interested, to obtain informed consent to participate as a study shop. Shop owners who sign informed consent will be invited to a future 2-day training event and asked to complete a short baseline survey about their background and shop operations. If the shop owner has limited involvement in the daily operations of the shop, an employee suggested by the owner may instead be invited to complete the baseline survey after providing informed consent.◄

6.6 Informed Consent

In a one-on-one meeting with interested ADDOs owners at the ADDO shop or at another location selected by the owner, a trained member of the research staff who is hired by the research team through H-PON specifically for this research study will outline the overall purpose of the study, as well as risks and benefits of study participation. This will include a discussion about:

- Their willingness to learn about and distribute HIVST, and to instruct customers about its use when appropriate;
- The possibility of the ADDO being randomly assigned to the intervention group, in which case the owner would be asked to implement the intervention (described above);
- Their willingness to participate in a survey about daily operations and products and services available at their shop;
- Their willingness to allow ADDO shop observations in the future; and
- Maintenance of paper records of product distribution and referrals.

The ADDO owner will be told that s/he can choose to leave the study at any point without penalty, including no implications on their role as an accredited ADDO in the community. After the research staff member thoroughly explains the consent form and answers any questions related to the study or participation, ADDO owners will be given the opportunity to join the study by signing the informed consent form. The informed consent form includes consent for participation in the baseline survey. Study staff will sign the two copies of the consent form, noting that they have obtained written informed consent. A copy of the signed informed consent form will be provided to participants who wish to have a copy.

If the ADDO owner has limited involvement in the daily operations of the shop, an employee suggested by the owner may instead be invited to complete the baseline survey, after the employee completes informed consent procedures (described in the previous paragraph).

6.7 Intervention Procedures

We will use stratified randomization by ward to assign 20 ADDOs 1:1 into the study groups, an intervention arm and a comparison arm. ►We will do this through a participatory randomization process at the HIVST training that representatives of all participating shops will attend. Specifically, shopkeepers will draw colored balls from an opaque bag in front of all attendees to obtain their study arm assignment.◄

Regardless of intervention arm, we will conduct the following activities in all ADDOs:

1. **HIVST Trainings and HIVST Supply:** In-person trainings of ADDO owners and staff on HIVST kits will involve: 1) hands-on demonstrations of the FDA-approved Orasure Oraquick ADVANCE

rapid HIV ½ oral fluid test, 2) review of the Kiswahili package insert, 3) review of the Orasure instructional video in Kiswahili which can be sent via SMS or Whatsapp to interested customers, 4) a comprehension quiz, and 5) a certificate of competency for public display.

Each ADDO (regardless of study arm) will be given a starting supply of approximately 30 HIVST kits, with resupply conditional on presentation of satisfactory distribution records. Adolescents at least 16 years of age and those <16 who are sexually active can legally consent to an HIV test in Tanzania.

We will instruct all ADDO owners and staff that HIVST kits will be provided free to all AGYW who request the kit; we will measure the relative distribution of AGYW HIVST recipients versus non-AGYW as a mediating outcome. Half of each bundle of kits distributed to the ADDOs will be explicitly earmarked for AGYW only; supplies will be verified against tallies of distribution to various age and sex groups (no names will be collected, only tallies within approximate age groups collected on a paper record keeping form). However, ADDOs will be told that kits for adults and other groups (young men) can be sold to those groups. (We will measure whether ADDOs sold the kit to other groups and for how much at the conclusion of the study.)

Every HIVST will be pre-packaged with cards with referral information for HIV confirmatory testing and HIV care affixed to the HIVST kit. For the kits designated for AGYW (with a specific color), this referral card will include the specific contact information for a referral facility staff member designated as the local youth-friendly contact for HIVST customers at a local hospital.

2. **An HIV Care Referral Plan:** Given that one of the benefits of HIV self-testing is its anonymous nature, we do not expect that many people will share the results of their HIVST kit with ADDO owners and staff; we have nevertheless prepared for this possibility with a plan to make referrals to local facilities for free confirmatory testing and HIV care. In addition to the pre-packaged referral card presented above, all ADOO shops will be given the contact information and procedures for confidential referral of individuals with a reactive HIVST result to the HIV care and treatment facility for confirmatory testing at a local hospital. ADDOs will track referrals on a standardized form, including age of the patron.

3. **Shop Record Tracking:** At the initial meeting with the ADDO owner and after informed consent, we will introduce a simple paper record system for participating ADDOs in order to collect data on the following outcomes:
    a. AGYW patronage: number of visits by AGYW, collected in a simple tally system (no names or contact information collected);
    b. Contraceptive distribution: number and types of contraceptives (i.e., condoms, oral pills, emergency contraceptive pills) distributed to AGYW per month;
    c. Health facility referrals: number of referrals for AGYW made for ►family planning, pregnancy, or HIV-related services;◄
    d. HIVST kit distribution: number and proportion of kits distributed to AGYW per month.

    ADDOs in the intervention arm will also track customers' engagement with intervention activities, described below.

    Monthly reviews of inventory by the local team will include review of shop records to determine AGYW patronage (for any service) and the volume and types of contraception and HIVST kits distributed to AGYW.

ADDOs in the intervention arm will be trained to implement the "Queen Club" intervention. The Queen Club intervention was developed through a year-long human-centered design process with AGYW and

other stakeholders and is informed by behavioral economic theory and game-design. It is intended to partially mitigate to the physical, economic, and social constraints faced by AGYW in Shinyanga, as revealed in the formative research, and motivate them to discreetly seek HIVST and contraceptives at local drug shops, while in a context of fun.

The Queen Club is a loyalty program that builds on multiple formative research insights, including that AGYW often make purchases at ADDOs throughout the course of their day, often at the behest of parents and other adults, but rarely feel empowered or comfortable asking for contraception given a perceived lack of privacy and expectation of judgment by ADDO owners and staff. In addition, we found that while HIVST was perceived as exciting and useful to AGYW, there were information gaps about how to use the product. The Queen Club ties these insights together, in a fun program that has been developed in close consultation with stakeholders and the Youth Advisory Board.

<u>We will conduct the following activities in ADDOs assigned to the intervention arm:</u>

1. **Loyalty Program:** In brief, the Queen Club involves distribution of membership cards to AGYW who would like to join. The card includes a space for the AGYW's name but no other identifying information and no text that could reveal what the program is about. A simple "road" displays spaces where AGYW will receive a stamp/punch each time they visit the ADDO and make any purchase. This is intended to build loyalty and trust with an ADDO shop, and also build the customer base for the ADDO owner. After every one to two spaces on the card are complete, the AGYW will have the option to select an item from the mystery box. Mystery boxes are intended to be fun rewards for loyalty and include a variety of items of interest for AGYW, including inexpensive (<2,000 TSH) beauty items, pads, apparel, school supplies, and snacks. Girls who 'complete' their card before the end of the study can turn their completed card into the ADDO shop and can re-start with a fresh card.

   Note that because only tallies of products distributed will be kept that are not tied to individuals, and the loyalty program contains no personal data, we will not be requesting informed consent from club members.

2. **Symbol Card:** While the Queen Club loyalty program motivates AGYW to attend the shop, there are several elements of the program to increase the likelihood that AGYW will be access to HIVST and contraception. First, the back of the Queen Club card includes symbols, selected by AGYW, that represent the following health products: oral contraceptives, HIVST, emergency contraception, condoms and pregnancy tests. These are products routinely available at ADDOs but which AGYW do not feel comfortable asking for, especially in busy shops. With the symbol portion of the card, AGYW can discreetly point to their desired product and receive it (for free) without questioning.

3. **SRH Product Supply:** In addition to HIVST, we will reimburse intervention ADDOs for the oral contraception, condoms, emergency contraception, and pregnancy tests provided to AGYW customers for free upon request (e.g., when using the symbol card).

4. **HIVST Display and Instruction:** At every intervention ADDO, we will provide a wall display with a HIVST for demonstration (if desired by any customer) including a tablet computer with the pre-loaded Oraquick Kiswahili video and videos about various contraceptive products (videos developed by PSI or other local organizations). We will also provide headphones for discreet listening to the videos. Note that the Oraquick HIVST has been distributed in numerous countries, including to AGYW in eastern Africa, and the package insert is intended to contain all

necessary information to successfully perform the test. Nevertheless, we will provide additional opportunities to learn about the test via the in-store displays and videos to ensure that AGYW have numerous ways to answer all of their questions.

5. **Refresher ADDO Training on Contraceptive Counseling and Girl-Friendly Services:** In a one-day training with ADDO owners and/or employees, we will review contraceptive methods and counseling techniques using training materials adapted from the Ministry of Health, Community Development, Gender, Elderly, and Children. This will ensure that AGYW are given a choice of methods available at the ADDO as well as referral for longer-acting methods (e.g., intrauterine devices, implants) at nearby facilities. Training will focus on communicating information in ways that AGYW can understand using tailored job aids that have been used previously by the Government of Tanzania and adapted from our current study on injectable contraceptives.

6.8 Data Collection

We will monitor mediating outcomes and assess acceptability and feasibility of the intervention using the data collection activities detailed below.

1. Surveys with ADDO Owners and/or Employees (up to ►20◄)
Immediately after informed consent, a short in-person survey will be conducted with the owner or a designated employee at the shop about their background (e.g., age, education, experience with AGYW) and shop (e.g., size, location, years of operation, products and services offered).

2. Time-location Surveys of ADDO Customers
We will discreetly observe ADDOs, with their permission, during randomly selected ►3-hour◄ intervals to document the number of customers, their sex, and approximate age and products and services received. These data are complimentary to the paper-based records collected by ADDO staff. ►We will select observation day/time blocks at baseline (0-4 weeks prior to intervention), midline (after 2-3 months), and endline (after 3-4 months). We will randomly select 5 blocks per shop per time point, corresponding to up to 15 time-location surveys per ADDO.◄

3. Shop Records
At the initial meeting with the ADDO owner and after informed consent, we will introduce a simple paper record system for participating ADDOs in order to collect data on AGYW patronage, HIVST and contraceptive distribution, and health facility referrals (previously described in detail in Section 6.7). ADDOs in the intervention arm will also track engagement with intervention components (e.g., participation in the Queen Club).

6.9 Study Compensation

ADDO owners and employees will not be directly compensated for their shop's participation in the intervention, including their completion of the baseline survey and shop records. However, as part of the intervention procedures, we will provide ADDOs in both study arms with a four-month supply of HIV self-test kits for free (~30 kits per month, each valued at $4 USD), and ADDO owners will be able to sell half of these kits to shop customers and keep the profits.

6.10 Data Analysis

We will compare AGYW patronage, referrals to health facilities, and ►HIVST kit and contraception provision between the 20 randomized intervention and comparison ADDOs over the 4-month pilot period using: (1) statistical tests of means (t-tests) and medians (Kruskal-Wallis tests) and (2) a negative binomial regression model (for counts of AGYW customers)◄ to estimate rate ratios and confidence intervals controlling for baseline levels of AGYW patronage using a "difference-in-differences" approach. Results will be used to understand the potential effectiveness of AGYW-friendly ADDO environments on AGYW visits and demand generation for HIV prevention and SRH services, a basis for power calculations to determine the sample size needed for the future study of effectiveness and sustainability.

6.11 Data Management

Our research team has considerable institutional expertise and well-established systems for data collection and management. In addition, H-PON has established a research site and has hired and trained study personnel in Shinyanga who also adhere to these systems. A key policy of our collaborative research group is that the fewer individuals handling sensitive information, the greater the protection. Thus, project files and databases will only be available to research personnel through the authorization of the PIs (Dr. Liu & Dr. McCoy (UCB)). All staff with access to the data or who interact with participants must sign confidentiality agreements and will be informed of their responsibility to maintain confidentiality once they have left the study or the study has ended. Staff will be trained on the policies and procedures for data management and transmission and will also receive instructions on how to report any violations of those policies and procedures. All staff will be appropriately trained in the handling of sensitive study data through their employment training and annual completion of training in the ethical conduct of research (UCSF and UC Berkeley staff and students). The PIs will review all procedures for protecting confidentiality with study staff on a bi-monthly basis, including storing the data, consents, and questionnaires in secure databases and locked file cabinets in locked offices, password protection, and procedures for transferring study data to the secure password-protected cloud-based folder. In addition, the team has a standard operating procedure in place to conduct quality control spot checks and ensure the privacy and confidentiality of study participants, data collection forms, and electronic data. Additional protections against risks specific to each data collection activity are outlined in Section 7.2 and 7.3.

All study forms, including the signed informed consent forms and field notes from the shadowing exercise, will be placed in a locked file cabinet in the locked study office and will be available only to study investigators and key study personnel.

7. Ethical Considerations

7.1 Alternatives to Participation

ADDO shops, owners, and employees and referral facility staff who decline to participate as a site can do so without consequence. The identities of ADDO shops and their participation status will not be revealed publicly in this phase of the research to preclude any impact on their business or reputation.

7.2 Risks and Benefits

There are no physical risks associated with this study. This research presents no risks of harm greater than the probability and magnitude encountered in daily life.

A year-long formative research process with AGYW and numerous community stakeholder groups (e.g., parents, community leaders, ADDO owners) led to the development of the Queen Club intervention, which is intended to leverage known motivational strategies from behavioral economics to motivate AGYW to visit ADDO shops – a behavior they already engage in – in order to receive fun rewards. The symbol portion of the club is intended to protect their privacy and allow them to obtain sensitive products like HIVST and contraception in a discreet way. Contraception is already legally allowed for AGYW in Tanzania but social mores prohibit them from accessing it in a way where they feel safe and comfortable.

HIVST is a new product in Tanzania but country-wide rollout of HIV self-testing globally, including elsewhere in the region (e.g., Kenya) indicate that this product can be safely used by a variety of vulnerable groups, including AGYW. We have a robust training plan for ADDO staff and a referral plan for confidential confirmatory HIV testing and linkage to care. The HIVST involves an oral swab and no blood draws, and is intended to be self-administered.

In the surveys, the primary risks are psychological distress or loss of confidentiality. For example, participants may experience discomfort or anxiety when discussing their perspectives on adolescent sexuality, HIV self-testing, access to health services, HIV-related risk behavior, gender biases, and/or HIV/AIDS in their community. However, it is very unlikely that sharing their viewpoints and opinions or answering survey questions about these issues will result in long-term or severe distress. In addition, loss of confidentiality resulting from personal information inadvertently being shared with outside individuals may have repercussions, including anger from family members or friends. All participants will be informed that the surveys and observations are confidential (as stated in the informed consent process) prior to their agreement to participate. We have outlined our plan to minimize any risk of loss of confidentiality in Section 7.3. The consent process will also inform participants that they may refuse to answer any question or leave the survey or study at any time.

We believe that the benefits of the study warrant the relatively low risks posed to subjects in the study. Customers at ADDOs, including AGYW, may benefit from the product and services offered at ADDOs as part of the pilot study. The ADDO program in Tanzania is already widely recognized as a model for building a lower-skilled cadre of health providers, and the successful introduction of malaria services at ADDOs suggests that population-wide access to other basic health services can similarly be achieved. Thus, by providing HIVST at trained ADDOs, customers may gain knowledge about their HIV status and (if needed) be referred to confirmatory testing and treatment during this study. Moreover, the intervention may increase access to contraception and SRH services among AGYW customers through several targeted components of the intervention (i.e., free contraceptive provision, informational videos, the loyalty/symbol card, training of ADDOs), with potential impacts on their health and health behaviors.

ADDO owners/employees who participate in the pilot study may benefit from their participation in several ways. ADDOs will be able to sell for a profit half of the HIVST which we distribute to them for free during the study period. Additionally, by providing ADDOs with HIVST and (in the intervention arm) girl-friendly marketing strategies, this study may increase profitability by driving business to participating shops.

We believe that ADDOs are well positioned within local communities and health systems to offer girl-friendly services to AGYW that simultaneously achieve public health goals. In Tanzania, ADDOs are located in nearly every community and are tasked with improving access to quality-assured pharmaceuticals, including oral contraceptives, pregnancy tests, and malaria testing and treatment. It is possible that the addition of HIV prevention services, including HIV self-test kits per the WHO guidelines, could greatly benefit AGYW who often face barriers to services in more traditional clinic-

based environments. ADDOs therefore are a prime opportunity to target AGYW with underutilized HIV prevention services. We hypothesize that creative strategies led by ADDO owners can attract more AGYW and will bolster uptake of HIV self-test kits and contraception. In this way, the current study to develop the ADDO platform to focus on AGYW-specific challenges could pave the way for more efficient community-based delivery of other high priority AGYW health initiatives. The results from the study will add to generalizable knowledge about how to deliver HIV prevention services to AGYW through an existing network of community-based drug shops. Young women elsewhere in Tanzania and in sub-Saharan Africa more broadly could potentially benefit if the strategy of reaching AGYW with HIV prevention services at ADDOs proves effective.

7.3 Confidentiality of Study Participants

All HPON staff who will have contact with human subjects will be trained on data collection instruments, confidentiality, and informed consent procedures in English and Swahili. Therefore, consistent translation during survey administration will be emphasized during training. All interviewers hired will be bilingual. All data collection activities will be conducted in a private location that preserves the confidentiality of the participant. Study participants will be provided with local study contact phone number that they can contact with any questions or concerns. The study protocol and all instruments will be submitted for approval to the Committee for Protection of Human Subjects to ensure compliance with local ethical standards.

As described in Section 6.11, a key policy of our collaborative research group is that the fewer individuals handling sensitive information, the greater the protection. Thus, project files and databases will only be available to research personnel through the authorization of the PIs (Dr. Liu & Dr. McCoy (UCB)). We will also implement the following measures:

- All staff with access to the data or who interact with participants must sign confidentiality agreements and will be informed of their responsibility to maintain confidentiality once they have left the study or the study has ended.
- Staff will be trained on the policies and procedures for data management and transmission and will also receive instructions on how to report any violations of those policies and procedures.
- All staff will be appropriately trained in the handling of sensitive study data through their employment training and annual completion of training in the ethical conduct of research (UCSF and UC Berkeley staff and students).
- All data collected will be anonymized prior to sharing with the PIs and the research team, except for video files from video shadowing which may potentially contain identifying content. The de-identified data cannot be linked back to individual participants; identifiable video files will be securely stored in an encrypted and protected cloud-based server.
- The data will be housed in a secure password-protected cloud-based folder. Only the PIs can grant access to the folder and access is limited to key personnel only. During data analysis, a local copy of the de-identified data may be housed on the PI's computer which is securely stored and password protected at all times.
- Access to any of the data is limited to the PI and other key personnel and requires a password at all times.
- No subjects will be identified in any report or publication of the study or its results.
- The PIs will review all procedures for protecting confidentiality with study staff on a bi-monthly basis, including storing the data, consents, and questionnaires in secure databases and locked file cabinets in locked offices, password protection, and procedures for transferring study data to the secure password-protected cloud-based folder.

- In addition, the team has a standard operating procedure in place to conduct quality control spot checks and ensure the privacy and confidentiality of study participants, data collection forms, and electronic data.

Additional protections against risk specific to certain data collection activities are outlined below.

Time-location surveys:
Observations of ADDO customers will be conducted by trained local researchers who speak Kiswahili and English. Observations will be recorded following a structured form and identified only by a unique ID for the ADDO shop. All collected forms will be stored in locked file cabinets and transcribed into electronic files housed in the same secure password-protected cloud-based storage folder described above.

Shop records and referral records:
ADDO owners/employees and referral facility staff will keep records following a structured form. The forms do not ask for any identifying information about ADDO customers and/or facility patients, and we will explicitly instruct those who complete these forms not to record identifying information. The ADDO shop record forms will identify ADDOs only by a unique ID for the ADDO shop, and the referral record forms will identify referral facility staff only by a unique ID. All collected forms will be stored in locked file cabinets and transcribed into electronic files housed in the same secure password-protected cloud-based storage folder described above.

7.4 Vulnerable Populations

Some of the women in various target groups (e.g., AGYW, ADDO owners and employees, referral facility staff) may be pregnant at the time of the study, and if they meet the inclusion criteria, they will eligible for inclusion. It is likely that we will have pregnant women in our study considering the age range of participants (≥18 years for ADDO owners and employees and referral facility staff) and the high fertility rate in Tanzania. This study involves only minimal risk and our study team can make appropriate referrals to antenatal care at nearby healthcare facilities, if necessary. The research team has substantial experience conducting research on sensitive topics such as sexual risk behavior among young women and men; this experience is reflected in our plans to minimize research participation-related risks.

All research members who will interact with potential subjects will be bilingual (Swahili and English) and will be trained on consistent translation of data collection instruments and informed consent documents during training. They will be instructed to read the consent form out loud to the potential participant. After discussing the consent form with study staff, participants will be quizzed about the nature of participation to ensure that they have adequately understood the information.

8. Qualifications of Key Study Personnel

Prosper Njau, MD
Local Principal Investigator
Health for a Prosperous Nation

- Responsibilities: Oversees the implementation of the intervention and evaluation data collection in Tanzania through H-PON.
- Qualifications: Dr. Njau has collaborated and locally lead more than five research projects, providing leadership and technical oversight as part of my role as Executive Secretary of the

Tanzanian NGO Health for a Prosperous Nation. He has focused his research on HIV and the intersection between HIV and sexual and reproductive health through programing for the prevention of mother-to-child transmission (PMTCT) of HIV infection.

Jenny Liu, PhD
Co-Principal Investigator
University of California, San Francisco

- Responsibilities: Oversees all aspects of the proposed study, including design, data collection, analysis, recruitment, informed consent, and reporting of results.
- Qualifications: Dr. Liu is a health economist and Assistant Professor at the University of California, San Francisco's School of Nursing. She has been conducting research in Sub-Saharan Africa for over 8 years, studying market penetration and uptake of health commodities for priority global health initiatives.

Sandra McCoy, PhD
Co-Principal Investigator
University of California, Berkeley

- Responsibilities: As Co-Principal Investigator, oversee all aspects of the proposed study, including design, data collection, analysis, recruitment, informed consent, and reporting of results.
- Qualifications: Dr. McCoy is an Associate Professor in Residence in Epidemiology at the University of California, Berkeley School of Public Health with expertise in HIV prevention and care, including the use of incentives, the intersection of food insecurity and HIV, family planning and HIV, and impact evaluation and implementation science. This study builds off of her ongoing research program in Shinyanga, Tanzania.

Sue Mavedzenge, PhD
Co-Investigator
RTI International

- Responsibilities: Advise on the implementation of HIVST kits.
- Qualifications: Dr Mavdzenge is a Research Scientist at RTI International. She has conducted HIV/STI and reproductive health research among high risk AGYW and other populations disproportionately affected by health disparities. She has been at the forefront of research on HIV self-testing since 2008, exploring the feasibility, accuracy, and acceptability of HIV self-testing, strategies to promote linkage to onward services, potential cost-effectiveness, and shaping the policy environment around self-testing.

Aarthi Rao, MBA
Independent Consultant
CVS Pharmacy

- Responsibilities: Advise on the application of human-centered design methods to develop the intervention being piloted.
- Qualifications: Ms. Rao completed her MBA at the University of California, Berkeley Haas School of Business concentrating on how to use tools from design thinking and marketing research to drive behavior change. She has a background in global health and development with the Results for Development Institute and has collaborated with the University of California, Berkeley School of Public Health on adherence programs in Tanzania.

Lauren Hunter, MPH
Project Manager

University of California, Berkeley

- Responsibilities: On behalf of the UCSF/UCB PIs, manage the project and coordinate activities with Tanzanian collaborators, and contribute to research data collection and analysis.
- Qualifications: Ms. Hunter is a doctoral student in Epidemiology at the University of California, Berkeley School of Public Health, studying under the direction of Co-Principal Investigator, Dr. McCoy. She has been leading the formative research data collection work under this project, and will assist in all aspects of the pilot study and evaluation.

Agatha Mnyippembe, BA
Project Manager
Health for a Prosperous Nation

- Responsibilities: Oversee the field activities in Shinyanga, Tanzania and manage the field team operations.
- Qualifications: Ms. Mnyippembe has over 8 years of experience managing research projects in Shinyanga as part of Dr. McCoy's Tanzania research program. She has been trained in human subjects research, qualitative research methods, and human-centered design, and has managed large-scale randomized controlled trials.

Kassim Hassan, BA
Project Staff
Health for a Prosperous Nation

- Responsibilities: Implement study activities and participate in research synthesis under the direction of the project managers.
- Qualifications: Mr. Hassan has over 4 years of experience carrying out research projects in Shinyanga as part of Dr. McCoy's Tanzania research program. He has been trained in human subjects research, qualitative research methods, and human-centered design.

Moza Chitela, BA
Project Staff
Health for a Prosperous Nation

- Responsibilities: Implement study activities and participate in research synthesis under the direction of the project managers.
- Qualifications: Ms. Chitela has previous experience implementing research projects in Tanzania. She has been trained in human subjects research, qualitative research methods, and human-centered design.

Atuganile Kalinjila, BA
Project Staff
Health for a Prosperous Nation

- Responsibilities: Implement study activities and participate in research synthesis under the direction of the project managers.
- Qualifications: Ms. Kalinjila has previous experience implementing SRH programs in Tanzania, and has been trained in human subjects research and research methods.

9. Study Sponsor and Management

The study is sponsored by the National Institutes of Health.

9.1 Stakeholder Engagement and Dissemination Plan

A strong research collaboration has already been established between H-PON, the University of California, and the Shinyanga Regional Medical Officer. This link will facilitate the incorporation of the study findings into national health policy and HIV care practices. Results from the study will be presented at conferences and in peer-reviewed journals and will be local stakeholders at the end of the study.

10. Limitations

Our intervention to create girl-friendly ADDO shops is designed to build on the extensive network of ADDOs in Tanzania, has government support, and fits into the national HIV, SRH, and task-shifting strategic goals—all of which pave the way for adoption and scale-up should results show it to be feasible, acceptable, and, later, effective. To our knowledge, this is the first time such a community-based program has been developed to address the ultimate goals of reducing AGYW HIV incidence and prevention of unintended pregnancy using innovative HCD methodological approaches to ensure applicability. Although we cannot test the delivery of a comprehensive package of HIV (beyond HIVST kits) and SRH services through ADDOs in this initial phase, we plan to do so in the next study.

11. Future Directions

A fully self-sustaining program through privately owned ADDOs will need to develop a more comprehensive business line for HIV and SRH services to match demand with sufficient supply, including sourcing, to maintain profitability incentives. If we can demonstrate that demand can be effectively generated for AGYW to seek products and services at ADDOs, including for HIVST kits and contraceptives when given for free, then we plan to incorporate several additional intervention features in the future: additional essential health commodities (e.g., PrEP, injectable contraceptives) that similarly can be accessed more easily from a community-based portal; enhanced demand generation capabilities (e.g., technologies to enable direct-to-consumer communications; social networking interfaces and apps) and recognition (e.g., specialized branding for AGYW-friendly shops); pricing schemes to may enable some cost recovery but that do not inhibit AGYW demand; supply-side factors, including more comprehensive training and licensing, mechanisms for monitoring quality assurance, and other non-monetary incentives needed for ADDO continued participation and engagement (e.g. community recognition, legitimacy); and robust linkages between ADDOs and health facilities to enable case management. This may potentially be achieved in partnership with public sector support and collaboration in order to create market structures that enable long-run sustainability.

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