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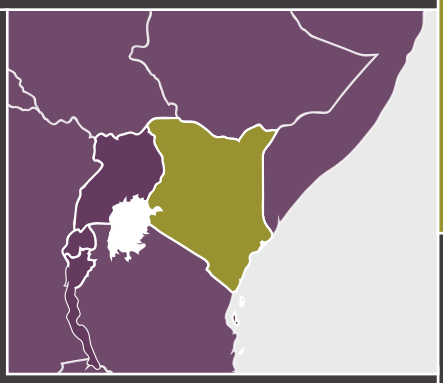
COST OF PROVIDING ORAL PRE-EXPOSURE PROPHYLAXIS TO PREVENT HIV INFECTION AMONG SEX WORKERS IN KENYA



This publication was prepared by Annie Chen, George Kosimbei, Daniel Mwai, and Arin Dutta of the Health Policy Project.

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Cost of Providing Oral Pre-Exposure Prophylaxis to Prevent HIV Infection Among Sex Workers in Kenya

AUGUST 2014

This publication was prepared by Annie Chen,[1] George Kosimbei,[2] Daniel Mwai,[1] and Arin Dutta[1] of the Health Policy Project.

[1] Futures Group, [2] Consultant

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EXECUTIVE SUMMARY

Targeted HIV prevention strategies that address the risk of exposure to HIV among key populations in Kenya are essential to alleviating the HIV epidemic. One identified strategy is the use of oral pre-exposure prophylaxis (PrEP). As defined by the World Health Organization (WHO), oral PrEP is the use of a daily, preventive antiretroviral by "HIV-uninfected people to block the acquisition of HIV infection… [which] have shown evidence of effectiveness" (WHO, 2012, p.3). Although the cost of oral PrEP is high, "in some situations oral PrEP could be cost-saving overall" (WHO, 2012, p. 9).

Given the importance of effective programs for key populations in Kenya, several government entities, donors, and stakeholders expressed the need for country-specific data on the costs of providing oral PrEP. Such data would contribute to the development of evidence-based oral PrEP policies and help ensure that the required resources are made available for appropriate implementation and scale-up. Therefore, in collaboration with the National AIDS and STI Control Program (NASCOP) and the Sex Worker Outreach Program (SWOP), the Health Policy Project conducted a study to address the following questions:

1. How much does it cost to provide oral PrEP to one sex worker for a year?
2. How much would it cost to scale up oral PrEP to all sex workers country-wide?

The study team first estimated the average, annual unit cost of delivering oral PrEP services to one sex worker through four SWOP clinics. The team then used this data to estimate the total cost of scaling up oral PrEP for female sex workers (FSWs) and male sex workers (MSWs) nationally—which along with inputs from other studies could help Kenya determine whether the intervention is feasible. In addition to supplying the first evidence-based cost estimates for PrEP in Kenya, the study results highlight the major cost drivers for oral PrEP services and the cost implications of different coverage scenarios as oral PrEP is brought to scale.

The findings show that the average, annual unit cost of providing oral PrEP to one sex worker is **KSh 48,667** (**US$602**) (see Table 1). Three scenarios of coverage—the number of FSWs and MSWs with HIV-negative serostatus who would access HIV PrEP services in one year—were examined to provide cost estimates for scaling up oral PrEP: 50 percent (Scenario 1), 75 percent (Scenario 2), and 100 percent (Scenario 3). Using the National AIDS Control Council's 2009 *Kenya HIV Prevention Response and Modes of Transmission Analysis,* ranges of upper and lower size populations for FSWs and MSWs in Kenya were used to estimate lower and upper cost estimates for these groups.

Table 1. Summary of Estimated Costs for Provision of Oral PrEP in Kenya

Costs for Oral PrEP	Total (KSh)	Total (US$)
Annual Unit Cost for One Sex Worker	48,667	602
National Annual Cost for FSWs		
Scenario 1: 50% Coverage	1.8 billion	22 million
Scenario 2: 75% Coverage	2.7 billion	33 million
Scenario 3: 1005 Coverage	3.6 billion	44 million
National Annual Cost for MSWs		
Scenario 1: 50% Coverage	146 million	1.8 million
Scenario 2: 75% Coverage	218 million	2.7 million
Scenario 3: 100% Coverage	291 million	4 million

The estimated annual national cost of providing oral PrEP to HIV-negative FSWs is based on population size estimates for all provinces. The cost for MSWs is based on population size estimates for all provinces except the North Eastern Province due to the lack of data. The total cost includes the direct costs for oral PrEP provision and the indirect costs for demand creation, training of providers, and

monitoring and evaluation. The study found that the direct costs of provision constituted the largest cost driver in scaling up oral PrEP and depended on the desired scale and scope of the program.

This study did not assess the cost of providing oral PrEP through other modes of provision, the cost-effectiveness of oral PrEP, the quality of services, or service impact; to fully analyze the scale-up of service delivery for oral PrEP nationally and the advantages and disadvantages of oral PrEP for sex workers, additional studies in these areas are necessary. The study team also assumed that services would be provided without fear of arrest by authorities or stigma and discrimination by healthcare workers.

Recommendations

To effectively provide and scale up oral PrEP nationwide, the Government of Kenya should consider the following recommendations:

- **Build capacity for oral PrEP**—Intervention sites will require significant capacity-building support and training to provide high-quality oral PrEP services and accurately collect high-quality data on service packages. Direct training on new tools, data use for local decision making, and strategies to improve data quality will be necessary.
- **Develop a national operational definition of program reach for oral PrEP services for key populations**—The Government of Kenya should use these study results when updating the costing of the Kenya National Strategic Plan on HIV and AIDS, the MARPs Strategic Framework, and the MARPs Operational Plan; and when budgeting future project proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria and other potential donors. More specifically, the government should develop a national operational definition of program reach for oral PrEP. Once this definition has been established, national data collection and reporting tools, as well as national databases and other data storage architecture, should be updated to reflect these changes and accurately collect the right data on the oral PrEP service package.
- **Support adherence among oral PrEP users**—The 2011 study conducted by the Kenya Medical Research Institute on the safety and adherence to oral PrEP among men who have sex with men and FSWs found that adherence to "fixed doses, and in particular coitally-dependent doses, may be more difficult than adherence to daily dosing" (Mutua et al., 2012, p.1). Since PrEP effectiveness is strongly correlated with daily adherence, there is a need to build on past studies and continue studying patient adherence to oral PrEP in the Kenyan context.
- **Assess the costs for other modes of provision for oral PrEP**—This study determined the costs for providing oral PrEP through SWOP clinics. Since the direct costs of oral PrEP provision constitute the largest cost driver of the intervention, other modes of provision should be costed to provide a comparison and help determine the most suitable one.
- **Assess whether oral PrEP is appropriate, compared to other prevention interventions such as condom use and treatment for sexually transmitted infections (STIs)**—Providing oral PrEP while avoiding the displacement of existing condom use is crucial (WHO, 2012).

Future scale-up of oral PrEP should also account for key points raised by the WHO in its *Guidance on Pre-Exposure Oral Prophylaxis (PrEP) for Serodiscordant Couples, Men and Transgender Women Who Have Sex with Men at High Risk of HIV: Recommendations for use in the context of demonstration projects*. When introducing oral PrEP in national health systems, the WHO recommends that it be considered an addition to existing prevention methods, such as condom use and STI treatment for the uninfected partner. The WHO also recommends that countries first run demonstration projects to ascertain the most appropriate groups for oral PrEP and the best delivery approaches.

ABBREVIATIONS

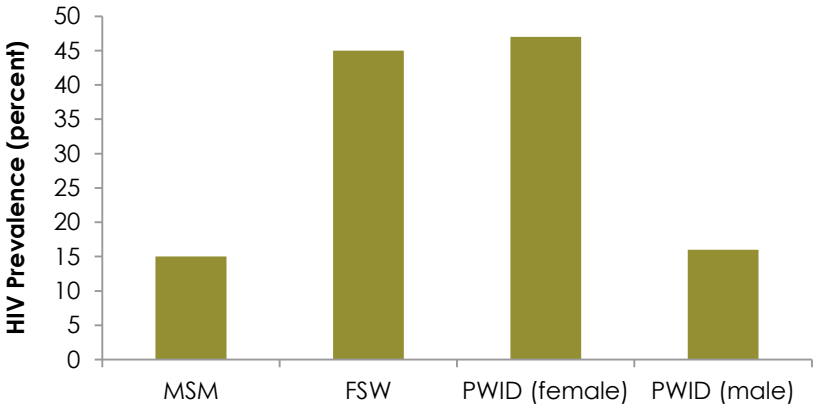
AIDS	acquired immune deficiency syndrome
ART	antiretroviral treatment
CDC	US Centers for Disease Control and Prevention
FSW	female sex worker
FTC	emtricitabine
HIV	human immunodeficiency virus
HPP	Health Policy Project
HTC	HIV testing and counseling
M&E	monitoring and evaluation
MARP	most-at-risk population
MSM	men who have sex with men
MSW	male sex worker
NASCOP	National AIDS and STI Control Program
PrEP	pre-exposure prophylaxis
STI	sexually transmitted infection
SW	sex worker
SWOP	Sex Worker Outreach Program
TDF	tenofovir
UNAIDS	Joint United Nations Program on HIV/AIDS
VOICE	Vaginal and Oral Interventions to Control the Epidemic (study)
WHO	World Health Organization

INTRODUCTION

HIV and AIDS in Kenya

HIV prevalence in Kenya varies significantly across regions and populations. Although HIV prevalence has declined among the general population in Kenya, infection remains high among key populations, such as men who have sex with men (MSM), sex workers (SWs), and people who inject drugs (World Bank, 2011). The 2009 Kenyan Modes of Transmission study found that an estimated 14.1 percent of new national HIV infections are among sex workers and their clients, ranging from 14.7 percent in Nairobi to 23.1 percent in Nyanza (Kenyan National AIDS Control Council, 2009). Studies have also shown that women and key populations experience a disproportionate burden of HIV, with prevalence at approximately 45 percent among female sex workers (FSWs) (see Figure 1) (Kerrigan et al., 2013). In a 2012 study in Nairobi, baseline HIV prevalence among male sex workers (MSWs) was estimated at 40.4 percent (McKinnon et al., 2013).

Figure 1. HIV Prevalence Among Key Populations in Kenya



Sources: Beyrer, 2011; Kerrigan et al., 2013; Dutta et al., 2012

Research has shown that "service coverage levels for HIV prevention services among sex workers are low (generally <50%)" (Kerrigan et al., 2013, p. xxxiii). Compared to the general population, key populations in Kenya face social and structural barriers to accessing life-saving HIV prevention and care services. A 2008 large household study in Kenya found that 75 percent of HIV-positive respondents had experienced "enacted stigma" (i.e., differential treatment because of their HIV status) (Odindo and Mwanthi, 2008). This highlights the importance of providing HIV care and services to sex workers.

Program and Policies for HIV and AIDS

As a response to the HIV epidemic, in 2010, the Kenyan National AIDS & STI Control Program (NASCOP) developed the National Guidelines for HIV/STI Programs for Sex Workers with biomedical, behavioral, and structural components. With "treatment as prevention" becoming one of the key strategies in the fight against HIV, biomedical prevention methods, such as pre-exposure prophylaxis (PrEP), represent a promising new approach to HIV prevention (see Table 2). Several recent clinical trials found that oral PrEP is an efficient and cost-effective intervention for preventing HIV infection in heterosexual serodiscordant couples, MSM, and transgender women (WHO, 2012; Grant et al., 2010). Previous trials found that the intervention is especially effective in instances where participants had high adherence rates (>95%) (Mutua et al., 2012; Gomez et al., 2012; Delva et al., 2012; Granich et al., 2012). Table 2 highlights all the PrEP studies that are completed, ongoing, or planned in Kenya.

Table 2. Pre-Exposure Prophylaxis (PrEP) Studies and Projects in Kenya

Trial/Project	Study Drug/Design	Location	Status
Partners Demonstration Project	1,000 discordant couples Evaluates HIV prevention preferences, adherence to PrEP and antiretroviral treatment (ART), reproductive health priorities, and ART-based prevention	Kenya, Uganda	All four sites open and enrolling as of August 2013; results expected in 2016
LVCT and SWOP	Young women, FSWs, and MSM Aims to introduce PrEP into combination prevention interventions targeting these groups	Kenya	Formative research in planning phase; feasibility study report results likely in December 2013
Partners PrEP Open Label Extension	Serodiscordant couples Daily oral TDF/FTC or daily oral TDF	Eldoret, Nairobi, Thika, Kisumu (also in Uganda)	Placebo arm was discontinued when PrEP showed efficacy in the study population; after July 2011, all participants received active PrEP
Partners PrEP	Serodiscordant couples Daily oral TDF/FTC or daily oral TDF	Eldoret, Nairobi, Thika, Kisumu	Both TDF and TDF/FTC were found effective; trial concluded in late 2012
FEM-PrEP	Heterosexual women Daily oral TDF/FTC		Halted after interim data review found equivalent HIV rates in active and placebo arm
International AIDS Vaccine Initiative E001	Serodiscordant couples and MSM Daily oral TDF/FTC; intermittent oral TDF/FTC (twice weekly + coital dosing)	Kilifi, Nairobi	Found adherence challenges for high-risk populations and with intermittent regimen; completed

Sources: Rossi, 2013; Kenya Pre-Exposure Prophylaxis (PrEP) Profile, 2013

As a result of these findings, the US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have developed international oral PrEP treatment guidelines. The US Food and Drug Administration's Antiviral Drugs Advisory Committee has also recommended expanding existing labelling for specific antiretroviral drugs (tenofovir/emtricitabine or TDF/FTC) to include their use as an HIV prevention intervention (Baeten et al., 2012). See the WHO's guidance on oral PrEP, including for key populations (WHO, 2012).

These developments have increased interest among government, stakeholders, and key populations in the targeted introduction of oral PrEP in Kenya's national health system as a prevention method. The Sex Worker Outreach Program (SWOP) has also observed increasing interest by sex workers in enrolling in treatment programs. Through discussions with stakeholders, it was agreed that SWOP clinics would be a great entry point for introducing oral PrEP to sero-discordant couples. A rollout strategy was developed at a meeting in Nairobi in February 2013, initially targeting sex workers through SWOP clinics.

The SWOP Program

SWOP was initiated in Kenya in 2008 to reduce HIV transmission and infection among sex workers (Gakii-Kimani, 2011). The program is based on a community-led, peer education model that provides comprehensive services including HIV prevention, care, and treatment, as well as sexually transmitted infection (STI) and tuberculosis screening. The SWOP process identifies peer sex workers in the

community who can act as community leaders, who then receive training on outreach and mobilization. These peer leaders act as gatekeepers between the community of sex workers and SWOP clinics. Each peer leader is assigned deliverables and responsibilities to follow up on and provide open communication and training for HIV prevention to their sex worker peers (Gakii-Kimani, 2011).

From 2008 to 2011, SWOP clinics handled approximately 20,717 clinical visits by sex workers, "including 340 male sex workers…6,515 had an HIV test for the first time (with about 28% testing positive), 825 had been initiated on ART and more than 3 million condoms had been distributed" (Kerrigan et al., 2012, p.103). As of 2013, there are nine SWOP clinics in Nairobi, Kenya.

STUDY RATIONALE

Given the importance of including sex workers in Kenya's national HIV response, government entities, donors, and HIV stakeholders expressed the need for country-specific data on the costs of providing oral PrEP to sex workers. Such data could provide needed evidence to inform the development of the third Kenya National AIDS Strategic Plan. The Health Policy Project (HPP) therefore worked with NASCOP, SWOP, and the Kenya Medical Research Institute to obtain accurate cost estimates to inform the implementation and scale-up of oral PrEP services for both the male and female sex worker populations, which vary in size.

A previous study from Pretorius et al. (2010, p. 1) used an "age- and gender-structured model of the generalized HIV epidemic in South Africa to investigate the potential impact of PrEP in averting new infections." That study found the annual unit cost for HIV counseling and testing, serum creatinine tests, and the PrEP regimen to be $150. However, the cost estimate does not include indirect costs for demand creation, monitoring and evaluation, and training. This study was designed to provide Kenya with its first evidence-based cost estimates for delivering oral PrEP to FSWs and MSWs through SWOP clinics, which along with inputs from other studies could help Kenya determine whether this intervention is feasible. The specific objectives were to

- Estimate the average annual cost of reaching one sex worker with a comprehensive package of oral PrEP services through SWOP clinics
- Estimate the annual cost of providing a comprehensive package of oral PrEP services to all sex workers through SWOP clinics
- Establish the variations or cost components driving these costs

METHODOLOGY

Data Collection

The HPP team conducted a mixed methods study, involving both primary and secondary data collection. Data collection was based on the process a client follows to access PrEP services in a typical SWOP clinic (see Figure 3 and Annexes A, B, and C). Using a standard costing tool,[1] the team collected data from existing program documents, interviews, and observations of program staff from four SWOP clinics. The estimated costs included the direct costs for oral PrEP provision (the first visit, four scheduled revisits, and six unscheduled revisits) and indirect costs for demand creation, training of providers, and monitoring and evaluation of the oral PrEP program. The direct costs also included support and supply chain costs. The timeframe for the costs was one year, with adjustments made for resources that incurred costs for more or less than one year.

From January–February 2013, at each SWOP site, data were collected on the time the staff spent with each patient, the different stages of oral PrEP service delivery process, and the resources used. Respondents also provided information on management functions, including time allocation and resources used. Time allocation refers to the time afforded for different tasks and activities, which provides a measure to estimate direct costs of providing oral PrEP to a client. The proportion of time spent on monitoring and evaluation was provided by the SWOP Head Office finance department and direct observations (SWOP, 2013). The dimensions of areas used and descriptions of equipment were recorded. Additional data were collected through a review of financial records at SWOP clinics on prices for specific supplies and commodities and overhead costs. The study team also collected cost data from the Kenya Medical Supplies Agency and the Clinton Health Access Initiative price lists, asset registers from SWOP clinics, and finance officer records from SWOP clinics. The unit cost for information, education, and communication materials was based on the unit cost of a brochure or information pamphlet produced by the National AIDS Control Council. All cost estimations used the nominal exchange rate of KSh 83.7 per US dollar (USD-Kenya Shilling Exchange Rate, 2013).

Data validation was conducted in March 2013. The study team then used three scenarios of coverage—the number of FSWs and MSWs with HIV-negative serostatus who would access HIV PrEP services in one year—to estimate the cost of scaling up oral PrEP: 50 percent (Scenario 1), 75 percent (Scenario 2), and 100 percent (Scenario 3).

Oral PrEP Service Delivery Process

The SWOP clinic provides services specifically for sex workers using peer-led recruitment with an established incentive scheme (KSh 100 per client introduced). This is important because it promotes client retention and uptake of services among sex workers.

To establish the ideal process of providing PrEP within the clinic, a treatment flow process at the SWOP clinics was outlined. The study team categorized the main services offered and interventions implemented into three types of visits: first visit, scheduled revisit, and unscheduled revisit (see Figure 2 and Annexes A, B, and C for more details). First visits mainly involve enrolling and registering new patients. New patients that have an HIV-negative serostatus are also put on a 14-day trial of oral PrEP. Scheduled revisits provide follow-up and support for adherence, and the client receives one month's provision of drugs. Unscheduled revisits are flexible, drop-in visits to clarify questions regarding the drugs.

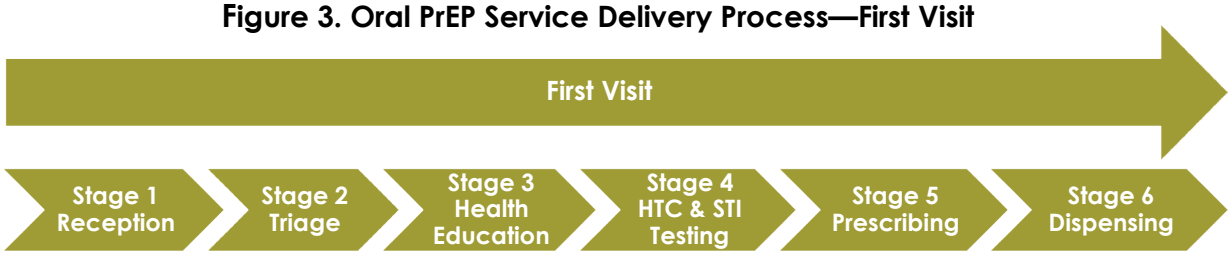
[1] Adapted from the UNAIDS manual for costing HIV facilities and services (UNAIDS, 2011).

Figure 2. Three Different Types of Oral PrEP Visits

The duration of time spent by a client in the clinic during the **first visit** was estimated for all stages of the visit (see Figure 3 and Annex A). This provided the estimate for the direct service costs. Other resources, such as for demand creation, monitoring and evaluation (for improving adherence), and training, were costed separately.

During a first visit for oral PrEP, SWOP providers screen and enrol clients into SWOP. Receptionists screen clients to establish whether they are sex workers, what service they have come for, and to collect bio-data information. The client proceeds through six stages during this first visit.

Figure 3. Oral PrEP Service Delivery Process—First Visit



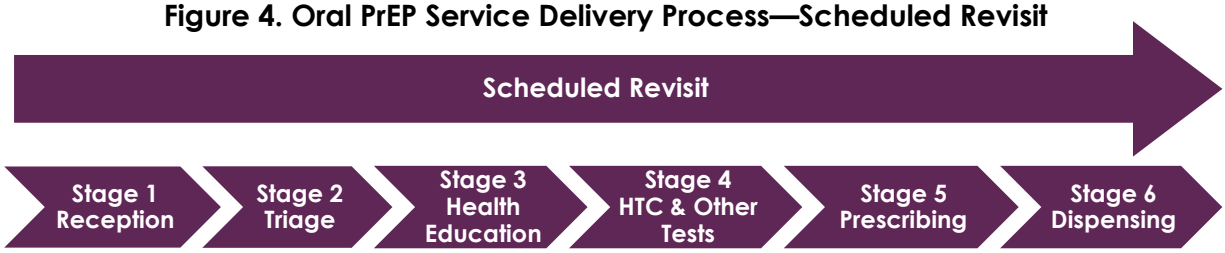
At the second stage, providers take a complete medical history of the client and fill out a baseline questionnaire. The third stage focuses on health education, which is an essential element in the proper use of oral PrEP. The client is counseled on how to use the drugs and on other HIV and STI prevention methods. At the fourth stage, clients receive HIV pre- and post-test testing and counseling (HTC). They also receive more information about the importance of using a condom with oral PrEP. Once HIV-negative serostatus is confirmed, providers introduce oral PrEP to the client after obtaining her/his consent and give further information on how the intervention prevents HIV infection. The clients also receive a prescription for oral PrEP at this time. At the last stage (dispensing), the client receives the drugs. Newly enrolled sex workers receive an initial dose of 14 daily tablets, and their adherence and medical response are evaluated after 14 days during the scheduled revisit.

Research suggests retention and adherence are key elements in the successful implementation of oral PrEP. To encourage adherence, the SWOP clinic uses peers, who are recruited through a snowball methodology[2] and given an incentive of KSh 100 for every client recruited into the program. SWOP clinics collect basic bio-data and use fingerprints to identify their clients to ensure confidentiality and give clients access to any of the nine SWOP clinics in Nairobi.

During follow-up **scheduled revisits,** the clinic receptionist screens the client and uses his/her fingerprints to retrieve medical records files. Once again, the client goes through six stages during which service providers assess the client's adherence and response to the drugs and provide follow-up counseling and support (see Figure 4). The client receives HIV testing and counseling, liver function tests, and a Hepatitis B test to identify adverse events and whether the client has sero-converted, in which case oral PrEP services for him/her would be discontinued. The client is also screened for other health needs. If the HIV test result is positive, the client is assessed for ART eligibility and referred to other services as appropriate. Clients that test negative receive a prescription for another dose of oral PrEP, which they pick up from the pharmacy. The SWOP clinic estimates that, on average, sex workers will have approximately four scheduled revisits per year.

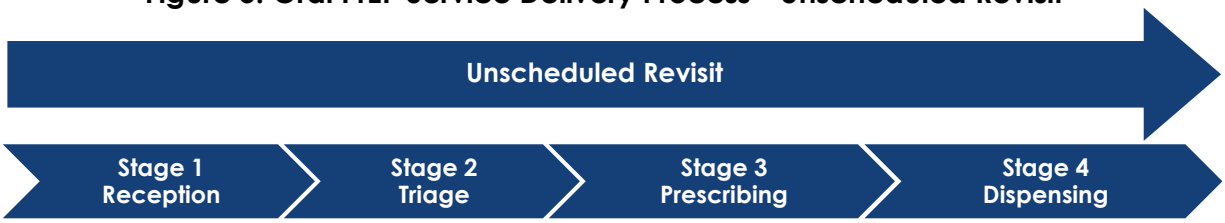
[2] "Snowball methodology" refers to the recruitment of participants via referrals from current participants (Patton, 1990).

Figure 4. Oral PrEP Service Delivery Process—Scheduled Revisit



Unscheduled revisits are flexible, drop-in visits for clients to pick up medication and ask questions about their medication or other issues related to oral PrEP. Clients sometimes come back for an unscheduled to discuss negative experiences with the drugs or to seek treatment for STIs. The SWOP clinic estimates that, on average, sex workers will have approximately six unscheduled revisits per year. These visits are typically shorter and only require four stages: reception, triage, prescription, and dispensing (see Figure 5). Providers use the client's thumbprint to access his/her medical history. Before prescribing oral PrEP, providers also offer screening for any other health issues or complaints the client might have.

Figure 5. Oral PrEP Service Delivery Process—Unscheduled Revisit



Study Assumptions

Clinic operation was estimated to be 5 days a week for 8 eight hours (8 a.m. to 5 p.m.) for approximately 50 weeks per year (excluding holidays) for a total of 120,000 operation hours. Usage of a clinic vehicle was estimated to be approximately 5 days a week for 5 hours for approximately 50 weeks for a total of 75,000 total operation hours. While not all sex workers with HIV-negative serostatus in Kenya may access services from the SWOP oral PrEP program, the program requested estimated costs for offering oral PrEP services to 50 percent, 75 percent, and 100 percent of FSWs and MSWs countrywide. This may have caused the resulting cost estimates to be higher, because average unit costs can decline as "returns to scale" for oral PrEP increase over time.[3]

[3] Returns to scale "occur when a proportional increase in all inputs results in the same proportional increase in output" (OECD, 2001, p. 89).

RESULTS

Cost of the First Visit

As indicated in earlier sections, the study estimated the average costs of providing services to one sex worker during three types of visits (first visit, scheduled revisit, and unscheduled revisit) and six stages in the service delivery chain (see Annexes A, B, and C). Table 3 summarizes the costs of providing oral PrEP during the first sex worker visit to a SWOP clinic.

Table 3. Cost of One Client's First PrEP Visit

Stages	Cost per SW (KSh)	Cost per SW (US$)
Stage 1—Reception	779	9.31
Stage 2—Triage	596	7.12
Stage 3—Health Education	1,188	14.19
Stage 4—HIV Testing and Counseling	576	6.88
Stage 5—Prescribing	3,587	42.85
Stage 6—Dispensing	1,702	20.34
Total	**8,429**	**100.70**

Source: Calculation based on SWOP Clinics Data Analysis.

The estimated total average cost for the **first visit** is **KSh 8,429** (**US$100.70**), with the largest cost being incurred at the prescribing stage (KSh 3,587 or US$42.85) because of the extra time spent with clients. The client spends approximately one hour at the pharmacy, during which the provider draws up a risk profile and explains oral PrEP. This is an essential step to ensure that the client has a proper understanding of and adheres to the regimen, which enhances the efficacy of the intervention.

Cost of a Scheduled Revisit

The first scheduled revisit for sex workers enrolled to receive oral PrEP occurs monthly, beginning 14 days after the initial visit. During this visit, clients that return with an HIV-negative serostatus and who show signs of good adherence and no negative medical reactions receive one month (30 days) worth of oral PrEP. The scheduled revisit also includes six stages but requires less time because the client does not have to participate in the risk profiling. Clients also receive interactive health education on HIV and STIs, condom use, lubricants, etc. HIV-negative clients then obtain a prescription and proceed to the pharmacy to receive the medication. Table 4 shows the estimated costs for a scheduled revisit.

Table 4. Cost of One Client's Scheduled Revisit

Stages	Cost per SW (KSh)	Cost per SW (US$)
Stage 1—Reception	490	5.85
Stage 2—Triage	477	5.70
Stage 3—Health Education	716	8.56
Stage 4—HIV Testing and Counseling	1,673	19.99
Stage 5—Prescribing	2,267	27.08
Stage 6—Dispensing	1,702	20.34
Total	**7,326**	**87.53**

Source: Calculation Based on SWOP Clinics Data Analysis

The estimated average cost for the **scheduled revisit** is **KSh 7,326** (**US$87.53**). This visit is less expensive than the estimated cost of enrolment (first) visit because it takes a shorter time at every stage of the process. Increased investment in HIV testing and counseling is provided to monitor client health in reaction to oral PrEP.

Cost of an Unscheduled Revisit

During most unscheduled revisits, the clients return for either clarification or further advice on oral PrEP. Unscheduled revisits have a different process flow to cater to the client's needs. The process includes only four stages (see Table 5).

Table 5. Cost of One Client's Unscheduled Revisit

Stages	Cost per SW (KSh)	Cost per SW (US$)
Stage 1—Reception	382	4.57
Stage 2—Triage	449	5.37
Stage 3—Prescribing	322	3.84
Stage 4—Dispensing	147	1.75
Total	**1,300**	**15.53**

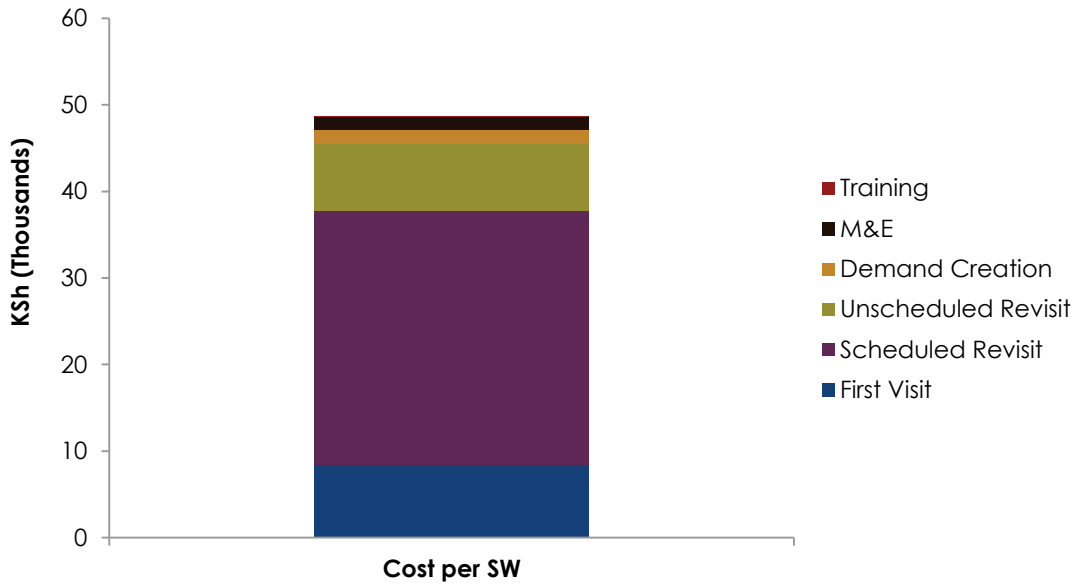
Source: Calculation Based on SWOP Clinics Data Analysis

This visit requires fewer stages and less time with the patient. The estimated average cost for the unscheduled revisit is **KSh 1,300** (**US$15.53**), with the largest cost being incurred at the triage stage.

Annual Cost of Providing Oral PrEP to One Sex Worker

Based on the estimated costs, the average annual total cost of providing oral PrEP to one sex worker through SWOP clinics is **KSh 48,667** (**US$602**), which includes both the direct costs (first visit, scheduled revisits, and unscheduled revisits) and indirect costs (demand creation, monitoring and evaluation, and training). Figure 6 provides a breakdown of the total cost by type.

Figure 6. Annual Unit Costs for Oral PrEP, by Type



Direct costs for PrEP (one first visit, four scheduled revisits, and six unscheduled revisits)—Using unit costs calculated by type of visit, the estimated annual direct cost of oral PrEP provision per sex worker is **KSh 45,531** (**US$544**).

Demand creation for PrEP services—Creating demand for oral PrEP through health education via mass media or outreach and mobilization is an important element in scaling up the intervention. This unit cost is relatively high because oral PrEP is a new intervention and there is a need for public education and awareness raising. The demand creation cost per sex worker is approximately **KSh 1,621** (**US$19**). SWOP clinics estimate that costs for demand creation would include salaries of the mobilizer and the HIV prevention project officer, incentives provided to sex worker peer leaders, and costs related to information, education, and communication materials.

Monitoring and evaluation—Monitoring and evaluation (M&E) systems are essential for the successful implementation of oral PrEP. The annual cost of providing monitoring and evaluation per sex worker is approximately **KSh 1,502** (**US$39**). The cost includes the proportion time allocated toward M&E of the prevention project officer, data manager, nurse/mobilizer, data clerk, and receptionist.

Training for providers—Since oral PrEP is a new intervention in Kenya, nurses and clinicians will need training. Assuming that all nine SWOP clinics train 30 providers (nurses and doctors) to provide oral PrEP, with an estimated total of 29,000 sex workers served per year by all SWOP clinics, the estimated annual cost per sex worker of training providers would be **KSh 12** (**US$0.32**) (Kimani, 2013). Eighty-three percent of this cost is the facilitator's compensation for SWOP training.

Annual Cost of Scaling Up Oral PrEP to All Sex Workers

To estimate the annual costs to scale up oral PrEP provision nationwide, the study team had to first estimate the total number of HIV-negative sex workers (male and female) in Kenya, using data from the NASCOP report, *Kenya Most-at-Risk-Populations Size Estimate Consensus Report 2013*. The size estimate incorporates lower and upper approximates for HIV-negative FSWs and MSWs (Kenya National AIDS Control Council, 2009). However, it did not include MSWs in the North Eastern Province, so this sub-population is not reflected in the national cost estimate of scaling up oral PrEP for MSWs.

The study team used the same three coverage scenarios to estimate the annual costs of scaling up oral PrEP for these groups (see Tables 6 and 7). These totals include the direct costs for oral PrEP provision and the indirect costs for demand creation, monitoring and evaluation, and training of providers.

Table 6. Annual Cost of Oral PrEP for FSWs, by Scenario

Total Cost for FSWs	Scenario 1: 50%	Scenario 2: 75%	Scenario 3: 100%
KSh in millions	1,789	2,684	3,578
US$ in millions	22	33	44

Table 7. Annual Cost of Oral PrEP for MSWs, by Scenario

Total Cost for MSWs	Scenario 1: 50%	Scenario 2: 75%	Scenario 3: 100%
KSh in millions	146	218	291
US$ in millions	1.8	2.7	3.6

RECOMMENDATIONS

To effectively provide and scale up oral PrEP nationwide, the Government of Kenya should consider the following recommendations:

- **Build capacity for oral PrEP**—Intervention sites will require significant capacity-building support and training to provide high-quality oral PrEP services and accurately collect high-quality data on service packages. Direct training on new tools, data use for local decision making, and strategies to improve data quality will be necessary.
- **Develop a national operational definition of program reach for oral PrEP services for key populations**—The Government of Kenya should use these study results when updating the costing of the Kenya National Strategic Plan on HIV and AIDS, the MARPs Strategic Framework, and the MARPs Operational Plan; and when budgeting future project proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria and other potential donors. More specifically, the government should develop a national operational definition of program reach for oral PrEP. Once this definition has been established, national data collection and reporting tools, as well as national databases and other data storage architecture, should be updated to reflect these changes and accurately collect the right data on the oral PrEP service package.
- **Support adherence among oral PrEP users**—The 2011 study conducted by the Kenya Medical Research Institute on the safety and adherence to oral PrEP among men who have sex with men and FSWs found that adherence to "fixed doses, and in particular coitally-dependent doses, may be more difficult than adherence to daily dosing" (Mutua et al., 2012, p.1). Since PrEP effectiveness is strongly correlated with daily adherence, there is a need to build on past studies and continue studying patient adherence to oral PrEP in the Kenyan context.
- **Assess the costs for other modes of provision for oral PrEP**—This study determined the costs for providing oral PrEP through SWOP clinics. Since the direct costs of oral PrEP provision constitute the largest cost driver of the intervention, other modes of provision should be costed to provide a comparison and help determine the most suitable one.
- **Assess whether oral PrEP is appropriate, compared to other prevention interventions such as condom use and treatment for STIs**—Providing oral PrEP while avoiding the displacement of existing condom use is crucial (WHO, 2012).

Future scale-up of oral PrEP should also account for key points raised by the WHO in its *Guidance on Pre-Exposure Oral Prophylaxis (PrEP) for Serodiscordant Couples, Men and Transgender Women Who Have Sex with Men at High Risk of HIV: Recommendations for use in the context of demonstration projects* (see Box 1). When introducing oral PrEP in national health systems, the WHO recommends that it be considered an addition to existing prevention methods, such as condom use and STI treatment for the uninfected partner. The WHO also recommends that countries first run demonstration projects to ascertain the most appropriate groups for oral PrEP and the best delivery approaches.

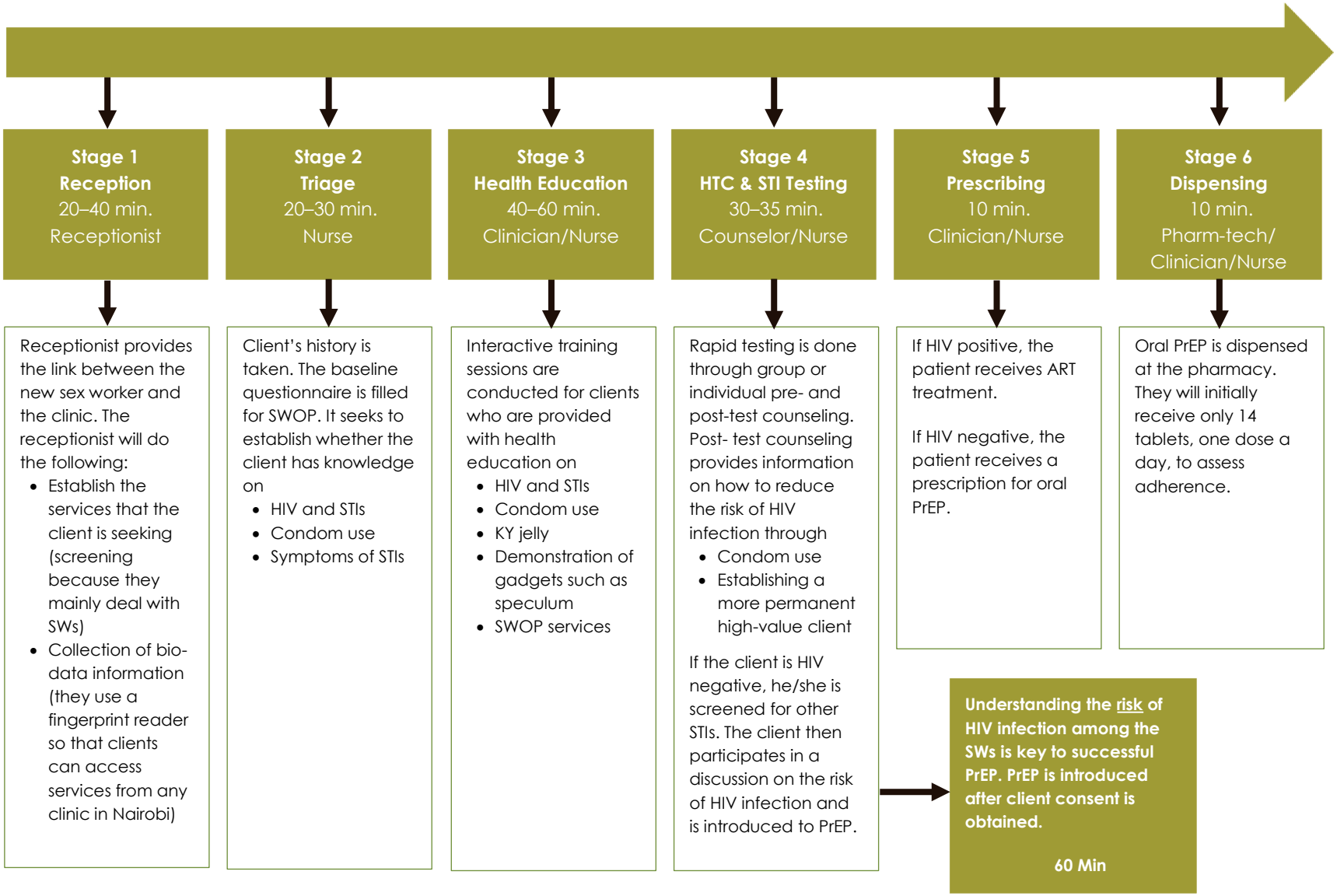
Box 1. Key Points in WHO's Guidance on Oral PrEP

Evidence of the effectiveness of oral PrEP for the prevention of HIV transmission among HIV-negative individuals is strong. To ensure that PrEP may best be implemented and scaled up in settings where its use might be most beneficial, the WHO recommends

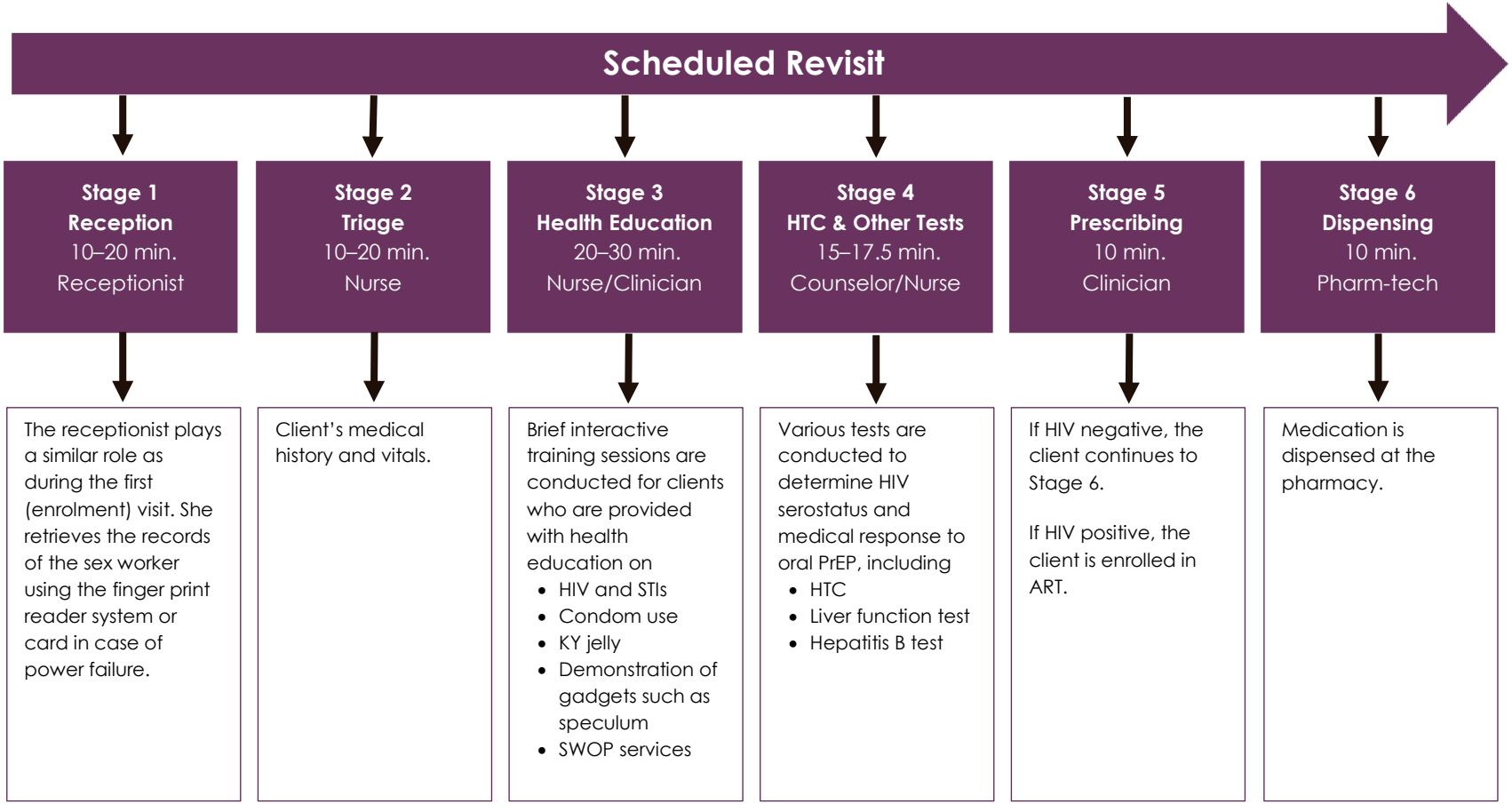
1. Confirming HIV-negative status before initiation of PrEP
2. Assessing clinical contraindications and monitoring safety among oral PrEP users, specifically screening for adverse events
3. Fostering and supporting adherence to oral PrEP
4. Identifying most suitable points for oral PrEP delivery and resupply
5. Periodic HIV retesting of oral PrEP users to detect any breakthrough infections in a timely manner
6. Developing bridging procedures for testing those who become infected while taking PrEP and referring them to appropriate services
7. Developing transition mechanisms for those who need to stop taking oral PrEP
8. Assessing how to best allocate available resources for HIV prevention, considering the cost-benefit of oral PrEP

Source: WHO, 2012, pp.12–13

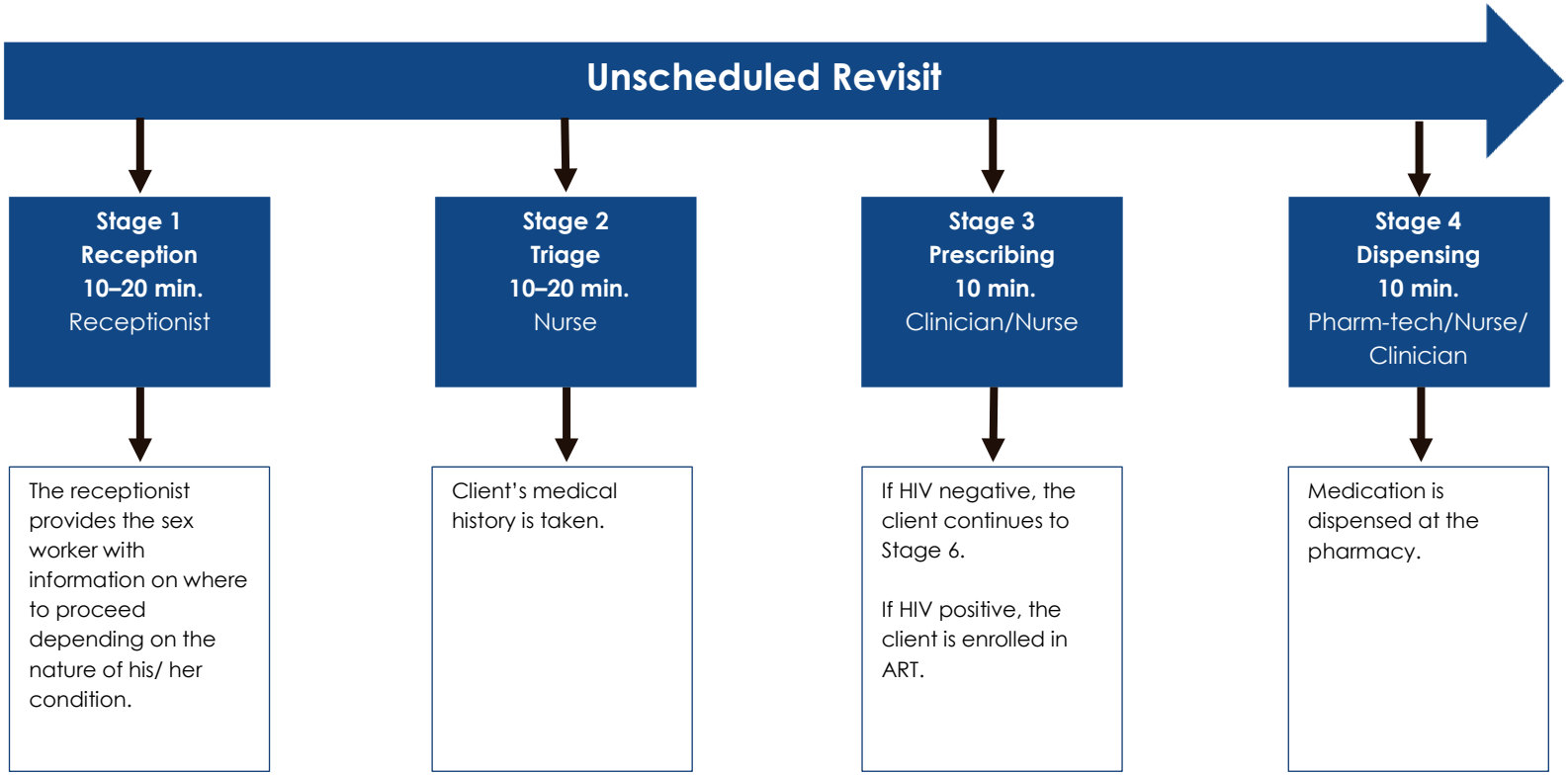
ANNEX A. PrEP SERVICE DELIVERY PROCESS—FIRST VISIT



ANNEX B. PrEP SERVICE DELIVERY PROCESS—SCHEDULED REVISIT



ANNEX C. PrEP SERVICE DELIVERY—UNSCHEDULED REVISIT



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For more information, contact:

Health Policy Project
Futures Group
One Thomas Circle NW, Suite 200
Washington, DC 20005
Tel: (202) 775-9680
Fax: (202) 775-9694
Email: policyinfo@futuresgroup.com
www.healthpolicyproject.com