



ABC of HIV Pre-Exposure Prophylaxis (PrEP)

GHANA IMPLEMENTATION GUIDE



Second edition • December 2022



ABC OF HIV PRE-EXPOSURE PROPHYLAXIS (PREP)

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SECOND EDITION

December 2022



USAID
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Meeting Targets and
Maintaining Epidemic Control



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DEFINITIONS

ChemSex - sexual activity engaged in while under the influence of stimulant drugs such as methamphetamine or mephedrone, typically involving several participants.

Cisgender woman - someone who had female sex at birth and identifies as a woman

Cisgender man - someone who had male sex at birth and identifies as a man

Gender - an individual's concept of themselves also known as their gender identity. It refers to the socially constructed characteristics of women and men, such as norms, roles, and relationships of and between groups of women and men. It varies from society to society and can be changed (WHO). Sometimes, a person's genetically assigned sex does not line up with their gender identity.

Gender diverse - An umbrella term to describe an ever-evolving array of labels people may apply when their gender identity, expression, or even perception does not conform to the norms and stereotypes others expect.

Transgender male/trans male - someone whose personal identity and gender does not correspond with their female sex at birth.

Transgender female/trans female - someone whose personal identity and gender does not correspond with their male sex at birth.



ACRONYMS AND ABBREVIATIONS

3TC	Lamivudine
ADR	Adverse Drug Reaction
ABYM	Adolescent Boys and Young Men
AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Transaminase
ANC	Antenatal Care
ARVs	Antiretroviral drugs
ART	Anti-Retroviral Therapy
AMC	Average Monthly Consumption
CAB-LA	Long-Acting Cabotegravir
CQI	Continuous Quality Improvement
CMS	Central Medical Store
CrCl	Creatinine Clearance
CSO	Civil Society Organization
CT	Chlamydia trachomatis
DIC	Drop-In-Centre
DNA	Deoxyribonucleic Acid
DPV-VR	Dapivirine Vaginal Ring
DSD	Differentiated Service Delivery



ED-PrEP	Event-driven Pre-Exposure Prophylaxis
eGFR	Estimated Glomerular Filtration Rate
EpiC	Epidemic Control Project
EPT	Expedited Partner Treatment
FBO	Faith-Based Organization
FDA	Food and Drugs Authority
FDC	Fixed-Dose Combination
FIFO	First-In, First-Out
FSW	Female Sex Worker
FTC	Emtricitabine
GAC	Ghana AIDS Commission
GFTAM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	Ghana Health Service
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HMT	Hospital management team
hrM	High risk Men
HPV	Human Papilloma Virus
IBSS	Integrated Biobehavioral Surveillance Survey
IM	Intramuscular
JSI	John Snow, Inc.
KP	Key population
LFT	Liver Function Test
MOH	Ministry of Health
MSF	Monthly Summary Form
MSM	Men who have sex with men



MPSE	Mapping and Population Size Estimation
NG	Neisseria gonorrhoea
OPD	Out-Patient Department
PE	Peer Educator
PEP	Post-Exposure Prophylaxis
PEPFAR	U. S. President’s Emergency Plan for AIDS Relief
PWID	People Who Inject Drugs
NACP	National AIDS/STI Control Programme
NSP	National Strategic Plan
PMTCT	Prevention of Mother-To-Child Transmission of HIV
PrEP	Pre-Exposure Prophylaxis
PLHIV	People Living with HIV
RMS	Regional Medical Stores
RNA	Ribonucleic Acid
SDC	Sero-Discordant Couple
SDP	Service Delivery Point
SSDM	Supplies and Drug Management Division
STI	Sexually Transmitted Infection
TDF	Tenofovir Disoproxil Fumarate
Trans	Transgender
USAID	United States Agency for International Development
WHO	World Health Organization



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The section on PrEP for Adolescent and Young Adults was culled from the WHO PrEP Implementation Tool Module 12.



FOREWORD



Primary prevention of HIV-1 infection among those with ongoing risk may be achieved using antiretroviral drugs (ARVs) either before exposure (pre-exposure prophylaxis [PrEP]) or within 48 hours after exposure (post-exposure prophylaxis [PEP]). Targeting individuals at high risk and providing PrEP as part of a comprehensive set of prevention services alongside regular monitoring contributes to effective and safe HIV prevention. This need has arisen because most biological and behavioral preventive strategies have not decreased HIV acquisition and an effective preventive vaccine is yet to be discovered. Ghana adopted WHO guidance on PrEP and captured it as part of the combination prevention package, which includes HIV testing services (HTS), male and female condom and lubricant promotion, ART for HIV-positive partners in sero-discordant couples, and STI prevention and management.

Multiple studies have shown strong evidence for the efficacy and effectiveness of oral PrEP using tenofovir disoproxil fumarate (TDF) co-formulated with emtricitabine (FTC). These ARVs have demonstrated substantial HIV prevention benefits in clinical trials with TDF having a high genetic barrier to resistance while FTC has a low genetic barrier. Acquired drug resistance (DR) is possible if HIV is transmitted and there is also poor adherence level by the client. However, the overall risk of HIV DR from TDF-based oral PrEP has been shown to be low so benefits of PrEP in preventing HIV infections outweigh the risk of DR. In addition to oral PrEP, WHO has recently recommended the use of Dapivirine vaginal ring (DPV-VR) and long-acting Cabotegravir injection in HIV prevention. Another issue of concern is the potential increase in high-risk sexual behaviour, such as sex without condoms, among clients on PrEP. This possibility though observed in a few settings underlines the need for PrEP to be provided as part of comprehensive and integrated services. It also emphasizes the need for regular client education and monitoring. Behavioural counseling in the form of information sharing and assurance of safety and efficacy are important components of PrEP. Other factors of PrEP implementation that have been suggested include improving access, averting stigma, cost effectiveness, and education on PrEP to improve knowledge and assure people of the efficacy profile of products used for PrEP.

This guideline which forms the basis for planning, organizing, and implementing PrEP at all levels of service delivery in governmental, non-governmental, and private health institutions in Ghana has been updated to this second edition after extensive stakeholder consultations.

To promote the effective use of this guide, only trained and authorized persons in certified health care facilities (public and private) are allowed to prescribe PrEP, and HIV commodities are not to be sold to the public unless authorized by the Ghana Health Service, Ministry of Health.



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INTRODUCTION



In recent years, the Ghana Health Service through the National AIDS/STI Control Programme (NACP) has made strides towards increasing demand for and access to HIV prevention and treatment services through relevant legislation, policies and guidelines such as the PrEP Guidelines. Ghana is broadening approaches to reach the 2025 goal of reducing new HIV infections by 85%. This includes strategies to ensure individuals known to be HIV positive across the 684 ART centers are retained on and adhere to treatment, and to particularly target Key Populations (KPs) and other high-risk groups for a reduction in acquisition of new HIV infections. The strategies included PrEP, HIVST

services and addressing human rights barriers among KPs (MSM, FSWs and TG).

In April 2020, a national PrEP Implementation Committee co-chaired by NACP and the Ghana AIDS Commission (GAC) was set up with financial and technical support from PEPFAR via USAID through its EpiC mechanism implemented by FHI360. Other members of the committee are WHO, UNAIDS, USAID, JSI, WAPCAS, EQUIP Health Ghana and WAAF. The Committee accelerated key components of the implementation plan that led to the jump start of PrEP implementation among KP in three regions, Ashanti, Greater Accra and Western in August 2020. Ghana implemented the jump-start strategy in two phases.

Phase one (jump-start): covered established areas of high HIV prevalence that have relative access to persons with potentially high-risk behavior. PrEP was offered to all members of eligible populations who seek it with a focus on KPs starting from the Greater Accra, Ashanti and Western Regions.

Scope and Key implementation strategies of the Jump Start Strategy

1. Above site support on PrEP and HIVST from the committee to achieve national level scale up
2. Monitoring, mentoring and coaching of health care workers (HCWs) on PrEP & HIVST service delivery
3. In person & online demand creation on PrEP/HIVST and Private sector engagement
4. Referrals and linkages of high-risk HIVST non-reactive KPs for PrEP services.

5. Intimate Partner Violence in PrEP services and index testing
6. Going online: for clients to book appointment for PrEP & HIVST services.
7. Capacity building to provide quality HIVST and PrEP services

Phase two (scale-up): After the jump-start phase, lessons learnt guide the scale-up of PrEP to all eligible populations around the country.

In both phases, PrEP was part of a combination prevention package, a mix of biomedical, behavioral, and structural interventions that decreases risk of HIV acquisition. In the future, combined preventive approaches will produce a greater impact than using a single intervention alone. The elements of combination prevention are shown in Table 1.

Structural	Behavioral	Biomedical
<ul style="list-style-type: none"> • Policies • Laws • Regulatory environment • Culture • Cash transfers 	<ul style="list-style-type: none"> • Education • Counseling • Stigma reduction • Harm reduction • Adherence interventions 	<ul style="list-style-type: none"> • HIV testing • Condoms • PMTCT • STI treatment • ART • PEP • PrEP

EpiC provided technical assistance, and in collaboration with the Committee, developed the National ABC of PrEP Implementation Guide, the national PrEP monitoring tools, trained national PrEP master trainers, created demand for PrEP and implemented the “Going

Online” strategy to book client appointments for HIV services. Lessons learnt from the jump start include the need to provide differentiated PrEP services through:

- Door-to-door community PrEP refills by trained lay counselors
- PrEP initiation & refills through mobile clinic at safe locations in communities & hot spots,
- PrEP users trained as PrEP Champions to support PrEP adherence,
- Provision of technical assistance to local partners on M&E systems to track client’s discontinuation/restart PrEP cycle and strong HIVST-PrEP linkage. The latter ensures that high risk clients testing negative with HIVST are linked to PrEP services.

Lessons shared by implementing partners on PrEP informed the national scale up to the remaining 13 regions by the Government of Ghana (GoG) and GF partners in 2022. At the end of the PrEP pilot, 888 males and 1,246 females had ever been initiated on PrEP comprising 1,004 FSWs, 428MSM, 1 TG, 90 sero-discordant couples (SDC), 108 adolescent girls and young women (AGYW), 127 adolescent boys and young men (ABYM) and 360 other high-risk individuals.

The objective of this guide is to provide a framework for the implementation of Ghana’s PrEP policy, using PrEP as a combination prevention strategy for HIV. It also includes basic knowledge on HIV and the different PrEP modalities.



SUMMARY OF UPDATES

Chapter 1

- Focus on adolescents and young adults as well as considerations for the provision of PrEP services to this population.

Chapter 2

- Eligibility for oral PrEP updated to include people with Hepatitis B or C infection
 - ▶ PrEP services provide an important opportunity to screen for HBV and HCV infection with linkage to care when required
- Updated guidance on safely starting, using and stopping oral PrEP
 - ▶ Avoiding or stopping TDF-based PrEP in persons with estimated glomerular filtration rate (eGFR) less than 60ml/min
 - ▶ Clear guidance for cisgender and trans women taking or using oestrogen/oestradiol hormones
- Event-driven oral PrEP guidance updated
 - ▶ ED-PrEP is only appropriate for the prevention of HIV acquisition from sexual exposure.
 - ▶ All who had male sex at birth who are not using or taking oestrogen/oestradiol hormones are eligible for ED-PrEP.

- Inclusion of long acting cabotegravir (CAB-LA) to the PrEP options
 - ▶ An integrase strand transfer inhibitor (INSTI), has been recommended by WHO as pre-exposure prophylaxis (PrEP) for HIV-1.
- Inclusion of Dapivirine vaginal ring to PrEP options for all females at birth
 - ▶ A non-nucleoside reverse transcriptase inhibitor for prevention of HIV-1
- HIVST added on as part of PrEP service
 - ▶ HIV self-testing (HIVST) complements existing HIV testing strategies for PrEP services and enables DSD approaches for PrEP with reduced clinic visits. DSD makes PrEP and HIVST services more accessible and acceptable which improves uptake and use.
- Measuring kidney function and creatinine clearance
 - ▶ Measuring kidney function is optional for all who are 49 years old and below who have no co-morbidities or any kidney-related morbidities and are requesting PrEP
 - ▶ 50+ and all who have co-morbidities should have it measured within the first 3 months of starting PrEP.

Chapter 3

- Guidance on integrating PrEP and STI services
 - ▶ PrEP services provide an opportunity for addressing other sexually transmitted infections besides HIV and Hepatitis B
 - ▶ The PrEP approach for preventing, identifying, and treating those infected with HIV also provides an appropriate platform for STI prevention, diagnosis, and treatment

- ▶ Integrating STIs services into PrEP services, as well as offering PrEP to people seeking STI and related services has the following advantages:
 - Fosters synergies and efficiencies in the public health response to HIV and STIs.
 - Promotes a people-centred approach to improve sexual health and quality of care
 - Creates opportunities to build the capacity of health care workers to address PrEP and STIs

Chapter 5

- Implementing differentiated PrEP Service Delivery
 - ▶ DSD for PrEP is person-centred and adapts services to the needs and preferences of the people who are interested in and could benefit from PrEP.
 - ▶ The four building blocks of differentiated and person-centred PrEP service delivery are: WHEN, WHERE, WHO, and WHAT to deliver



1. HIV Basics



What you must know about HIV

AIDS (acquired immune deficiency syndrome) is caused by the human immunodeficiency virus (HIV). This virus was first discovered in 1983, and the first case in Ghana was identified in 1986.

HIV belongs to a group of viruses called retroviruses. There are two main strains of HIV; HIV-1 and HIV-2. HIV has numerous varieties and has been shown to mutate, or change, within an individual during the progression of infection. Both HIV-1 and HIV-2 have the same modes of transmission and are associated with similar opportunistic infections, and both can lead to AIDS.

The virus multiplies by replicating in the body at a rate of approximately one billion times per day, but frequently fails to produce identical copies of itself. These nonidentical copies are referred to as mutations and may persist in the infected individual as “subtypes,” which are genetically slightly different from the original (parent) virus.

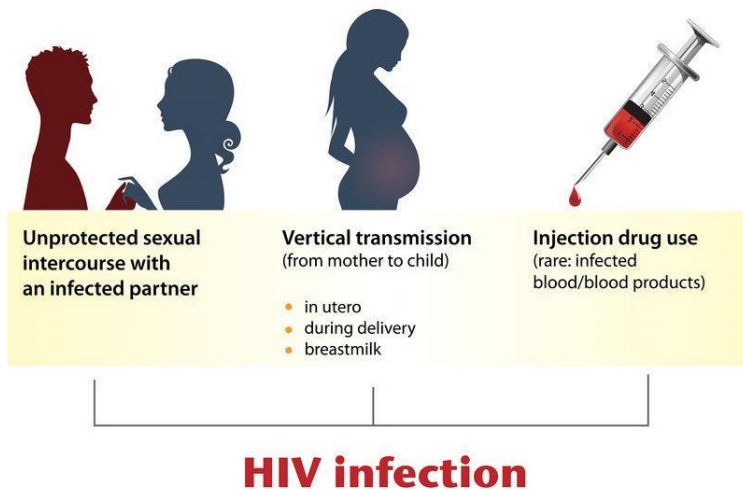
1.1 HIV Transmission

Among adults, HIV is spread mainly through unprotected sexual intercourse with an infected partner. During intercourse, the virus can enter the body through the mucosal linings of the vagina, vulva, penis, rectum, or, rarely, via the mouth and possibly the upper gastrointestinal tract after oral sex. The likelihood of transmission is increased by factors that may damage these linings, especially other sexually transmitted infections (STIs) that cause ulcers and inflammation. Research suggests that immune cells, which live in the mucosal surfaces such as macrophages and dendritic cells, may begin the infection process after sexual exposure by binding to and carrying the virus from the site of infection to the lymph nodes where other immune system cells become infected.

HIV can also be transmitted by contact with infected blood by the sharing of contaminated blades, needles or syringes among people who inject drugs (PWID), after occupational exposure among health workers, and by contaminated blood transfusions.

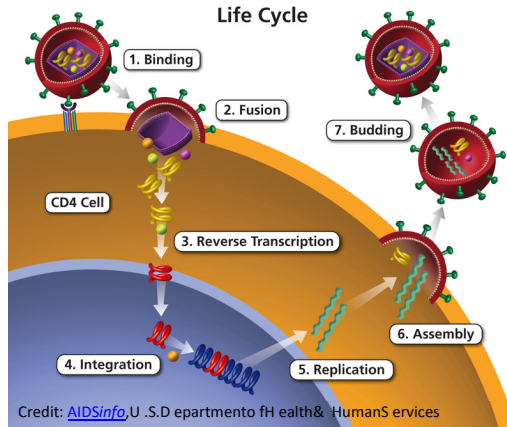
HIV-positive women can transmit HIV to their babies during pregnancy, at birth, and through breastfeeding. Up to 40 percent of untreated pregnant women infected with HIV have a high likelihood of transmitting the infection to their babies.

Figure 1. *HIV transmission*



1.2 Life Cycle of HIV Infection

HIV begins its infection of a susceptible host by binding to receptors on the CD4 lymphocytes, which are a critical part of the body's immune system. Following fusion of the virus with the host cell, HIV enters the cell. The genetic material of the virus, which is RNA, is released and undergoes reverse transcription into DNA facilitated by the reverse transcriptase.

Figure 2: HIV life cycle

Once the genetic material of HIV has been changed into DNA, this viral DNA enters the host nucleus where it can be integrated into the genetic material of the cell. Once this happens, the cell can either become activated or can remain inactive. Activation of the host cells results in the transcription of viral DNA into messenger RNA, which is translated into viral proteins. The new viral RNA forms the genetic material of the next generation of viruses. The viral RNA and viral proteins assemble at the cell membrane into a new virus. Among the viral proteins is HIV protease, which is required to process other HIV proteins into their functional forms. Following assembly at the cell surface, the virus then buds off from the cell and is released to infect another cell. Unless the HIV cycle is interrupted by treatment, the viral infection spreads throughout the body and results in the destruction of the body's immune system. The ARVs used in ART, PEP, and PrEP target different aspects of the HIV life cycle.

Those CD4 cells that remain inactive act as a reservoir for HIV. The virus can persist within the cell for many years in a latent form. Because latent virus is not actively replicating, it cannot be targeted by ARVs. Persistence of virus in latently infected cells is the major barrier to eradication or cure of HIV. For this reason, patients who are started on ART must remain on it for life.

HTS is considered an important entry point to HIV prevention, care, treatment, and support in Ghana, and the National Strategic Plan for HIV 2021–2025 highlight the need to strengthen testing interventions to increase the number of individuals who know their HIV status and are able to access ART, PEP, or PrEP services depending on the indication.

1.3 HIV in Ghana

Ghana has a low-level generalized HIV epidemic with an estimated national prevalence of 1.7% and an estimated 345,599 persons living with HIV (PLHIV).¹ Of these, 68% (233,690) are females in the reproductive age group of 15 to 49 years. The median HIV prevalence in women attending antenatal care in 2021 was 2.0%.² In relation to the UNAIDS 95-95-95 target, 72% of the estimated 345,599 PLHIV know their status, 99% of whom are on lifesaving ART, with 79% of that cohort virally suppressed. The HIV burden in the country is disproportionately distributed across the regions, with the highest in the urban areas of Bono, Bono East, Greater Accra and Ashanti regions.

¹Ghana AIDS Commission. National and Sub-National HIV and AIDS Estimates and Projections 2021 Report.

²National AIDS Control Programme (NACP). HIV Sentinel Survey Report, 2021. Accra: NACP, Ghana Health Service; 2022.

1.4 Key Populations

KPs are groups of individuals who have specific high-risk behaviors that increase their chances of becoming infected with HIV. About 70% of all new infections worldwide occur among KPs and their immediate partners. Available data suggest that the risk of HIV acquisition among gay men and other men who have sex with men (MSM) was 28 times higher in 2021 than it was among all adult men. Similarly, the risk of acquiring HIV for PWID was 35 times higher than for people who do not inject drugs, 30 times higher for female sex workers (FSWs) than adults aged 15–49 years, and 14 times higher for transgender women than adults aged 15–49 years.³

KPs also have a substantially higher HIV prevalence and are a major driver of the HIV epidemic in Ghana. The average HIV prevalence among FSWs is 4.6% while prevalence among MSM is 18.1%. There are about 51,900 FSWs and 54,800 MSM in Ghana. In 2018, an estimated 28 percent⁴ of new infections in Ghana were among KPs. Despite the high HIV risk among KPs, ART coverage remains very low due to structural and environmental factors including laws, policies, cultural myths, and stigma and discrimination that have a huge effect on their ability to confidently access health care. WHO recommends that populations with high vulnerability to HIV, including KP groups, should be assisted to initiate PrEP. Research has shown that PrEP significantly reduces the risk of HIV acquisition by as much as 92% when taken as prescribed. The implementation of PrEP in Ghana is consistent with the objectives of the national strategic plan for KPs.

³UNAIDS. Global HIV and AIDS Statistics – Fact Sheet 2022.

⁴Human Sciences Research Council. Mapping and population size estimation (MPSE) and integrated bio-behavioral surveillance survey (IBBS) among men who have sex with men in Ghana. Accra: Ghana AIDS Commission, National HIV and AIDS Research Conference; 2018.

1.5 Adolescents and Young Adults

The HIV epidemic among adolescents (10 to 19 years) and young people (10 to 24 years) has many faces around the world. According to WHO, each day, 37% of the approximately 4,500 daily new HIV infections occurring beyond childhood, were among youth (15 to 24 years). Adolescent girls and young women make up approximately one in every five of these new infections, and in sub-Saharan Africa where the youth population has expanded by nearly 100 million over the past three decades, infection rates in adolescent girls and young women outpace those in their male counterparts by three to one. HIV in young people often occurs within the context of a range of conditions such as poor mental health, substance use (alcohol and other drugs) and emotional and social issues including gender-based violence. These conditions or comorbidities can place young people at substantial risk of acquiring HIV and other sexually transmitted infections (STIs) and also make health-seeking behaviours more challenging for youth. Another contribution to risk in this population is poor access to and uptake of effective biomedical HIV prevention interventions, such as PrEP.

1.5.1 Factors influencing HIV susceptibility among adolescents and young adults

Factors associated with the risk of the transmission and acquisition of HIV by young people, include biologically conditions and events, compounded by psychosocial, behavioural and structural drivers.

1.5.1.1 Biological factors:

These factors include changes in the balance of the mucosal microbiome and inflammatory responses, which can be the result of early sexual debut in young women. STIs, including herpes simplex virus, human papillomavirus, gonorrhoea, chlamydia and syphilis, which lead to inflammation and disruptions in the mucosal epithelium, increase the risk of HIV acquisition and disproportionately affect young people.

1.5.1.2 Behavioural and psychosocial factors

Behavioural and psychosocial factors experienced by adolescents and young adults may further increase their susceptibility to HIV infection. Beginning with lower levels of overall health literacy, adolescents and young adults ages 15–24 years in 79 countries that contributed data to the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2016 had very low levels of knowledge about HIV risk and prevention, with a median rate of 29% across these countries. Stigmatized behaviours among key populations, such as sex among men, injecting drugs or selling sex, can also lead to increased HIV risk. Furthermore, common behaviours during adolescent development (for example, poor impulse control, risk taking, inadequate planning for safe sex, and mood disorders) place some individuals at risk for HIV infection and correlate with poor health-seeking behaviours and poor adherence to health care. Adolescents who have older partners, difficulty negotiating condom use, rely on transactional sex for basic material needs, experience high rates of sexual violence, or use substances with sex, can have very high rates of STIs. Therefore, adolescents

and young adults attending PrEP programmes need to be routinely screened for STIs and promptly treated. They also need youth-friendly services and strategies to ensure that they adhere to daily PrEP as an HIV prevention tool.

1.5.1.3 Structural factors

Like anyone else, adolescents and young adults have basic needs for food, shelter, education, family and social support and economic security (including work opportunities). They might also desire commodities (for example, fashionable clothes, jewellery, makeup, mobile phones) that enable them to attain a certain lifestyle and an enhanced social network. To meet both these basic needs and desires, adolescents and young adults sometimes engage in behaviours that can increase the risk of HIV acquisition, including engaging in transactional sex or intergenerational/cross-generational sex (i.e. heterosexual sex with a non-marital partner who is 10 or more years older). These behaviours, with their inherent problems such as power imbalance and intimate partner violence, can compound the risk of HIV acquisition.

Considering the above, prioritizing young people at substantial risk of HIV infection who are willing to take PrEP, or who may, with assistance, be motivated to continue PrEP, is important.

1.5.2 Clinical considerations

1.5.2.1 Maximizing continuation on PrEP and minimizing loss to follow up.

Although adherence to PrEP is crucial for protection against HIV infection, many young clients struggle to take the pill daily and after starting PrEP, younger people find it more difficult to take PrEP regularly. PrEP appears to be of interest to young people, but inattention to adherence or inability to continue may reduce its effectiveness, particularly among those who may be most vulnerable to HIV infection. Also, adolescents and young adults (24 years old or less) may benefit from additional monitoring and adherence support, such as more frequent clinic visits or other approaches, to address their changing routines and multiple needs. These may be in the form of text messaging and dispensing larger numbers of pill packs in addition to routine clinical follow-up. Interventions to maximise continuation and minimize loss to follow up are needed at the individual, interpersonal, health facility and community levels.

Summary of reviewed interventions to improve uptake, adherence and continuation of oral contraceptive use among adolescents and young women

COMMUNITY LEVEL

- School-based curriculum and services
- Broad educational and social marketing campaigns
- Decentralized contraception provision

HEALTH-FACILITY LEVEL

- Youth-friendly clinics
- Specially trained counselors

INTERPERSONAL LEVEL

- Peer support
- Peer modeling

INDIVIDUAL LEVEL

- Education and counseling
- Phone reminders
- Quick pill starts
- Increased pill packs

(Source: WHO PrEP Implementation Tool Kit for Adolescents and Young Adults by Velloza et al., Module 12 Fig.6)

Table 2***Ideas that have been used to support adherence counselling for adolescents***

Frequent contact	<p>To maximize PrEP engagement and continuation, adolescents may need to be seen more often.</p> <ul style="list-style-type: none"> • Ask a young person, “When would you like to come back?” and help young people to cope with the need for frequent follow-up. • Offer interim contact between visits if desired, including text messages or phone calls.
Counselling strategies	<ul style="list-style-type: none"> • The relationship between the counsellor and the patient is a critical component of success. Trust has to be earned through genuine and nonjudgmental interactions. • More directive approaches to counselling may work better for adolescents. Counsellors should be active, asking questions and suggesting topics of discussion. • Skills-building activities can be included in counselling with adolescents (for example, role-playing, decisional balance activities, homework).
Additional support	<ul style="list-style-type: none"> • Discuss supportive others in the adolescent’s life: Explore who might be a PrEP ally for them. • Consider peer-support strategies such as adherence buddies, social support groups and adherence clubs. • Provide information on available social media support groups such as Whatsapp, chat forums and others. • Provide adherence tools that are adolescent-friendly, such as attractive bags, pill containers that are key chains, lipstick holders and so forth. • Discuss economic barriers such as transportation costs. • Ask about gender-based violence if indicated. • Refer to other services such as voluntary medical male circumcision, STI diagnosis and treatment, contraception and harm reduction alongside PrEP.

(Source: WHO PrEP Implementation Tool Kit for Adolescents and Young Adults, Module 12 Table 1)

1.5.3 Making PrEP practical, accessible and impactful

1.5.3.1 Creating demand for PrEP

Increasing awareness and uptake of PrEP among young people will require multi-pronged strategies to create demand. When communicating with young people about PrEP, avoiding stigmatization and creating materials that are positive about sex and normalize HIV prevention are key. For young people a “sex-positive” approach is important, especially in communities where adults hold negative attitudes towards sexual activity in young people, particularly young women.

Information, as well as attitudes, is important since youth who are considering PrEP may have concerns about potential side-effects, such as changes in weight or body appearance. It is therefore important to create communication materials that provide information specifically for youth, spelling out how PrEP works, what to expect (or not) and how it should be used. Social media and videos are useful media to explain PrEP efficacy, safety, the importance of adherence for high-level protection and the potential for mild side-effects in the first few weeks of taking PrEP. Using multiple channels to deliver content through these mediums, will increase the chances of reaching youth who would benefit from PrEP.

1.5.3.2 Enabling access to PrEP

Ideally, PrEP should be introduced as part of the package of combination HIV prevention and sexual and reproductive health care for adolescents. While PrEP can prevent HIV infection when used consistently, it cannot prevent other sexually transmitted infections or pregnancy. Young people who are seeking or using PrEP to prevent sexual acquisition of HIV are also at risk for STIs and unplanned pregnancy. Thus, these services should ideally be delivered as part of an integrated package of sexual and reproductive health services. Potential areas to locate PrEP services include family planning clinics, reproductive health clinics, youth clinics, STI clinics, school and university health clinics, clinics serving key populations and mobile outreach services.

1.5.3.3 Counselling young people on risk reduction

Counselling for adolescents needs to consider their developmental stage and needs. Other age-related issues may include privacy about medical decisions, consent to testing and HIV services. Counselling on the need to delay sexual intercourse as a viable protection strategy should be targeted at adolescents and young adults who are not yet sexually active. However, adolescents and young adults who are asking about PrEP will often have already engaged in intercourse or else are preparing to do so safely. For them, a delay or even a return to abstinence is likely to be unacceptable or not feasible. Although condoms remain central to HIV prevention and must be provided in all PrEP services, health care providers should note that young people who request or could benefit from PrEP will often have difficulties in using condoms or negotiating their consistent use.



2. PrEP for HIV Prevention



What you must know about oral PrEP

2.1 Oral PrEP

Oral PrEP for HIV prevention is the use of ARVs by HIV-negative persons to prevent them from acquiring HIV. PrEP is not only recommended for KPs in Ghana—including FSWs, MSM, transgender people, and PWID— but persons who independently seek to access oral PrEP are also deemed eligible. Other categories of people considered eligible to access oral PrEP based on risk include:

- HIV-negative persons in sero-discordant relationships
- Sexual partners of unknown HIV status
- Individuals with recent or recurrent STIs

- Multiple or concurrent sexual partners
- History of inconsistent or no condom use
- PEP users
- History of sex while under the influence of alcohol or recreational drugs

2.2 Indications for Oral PrEP

PrEP should only be given to HIV-negative persons at substantial risk of acquiring HIV, usually based on history in the past six months. WHO also recommends that oral PrEP taken before and after sex in some subgroups of MSM can prevent HIV infection (this is known as event-driven oral PrEP, see Section 2.7). Table 2 shows steps in assessing substantial risk in serodiscordant partnerships but note that PrEP is for anyone who is at risk of acquiring HIV irrespective of his/her partnerships.

Table 3	<i>Screening for substantial risk among sexual or injecting-use partners</i>
Steps to follow to determine indication of a potential PrEP user among sexual partners and/or injecting-use partners	
Client reports a history of sharing injection material and/or equipment with another person in the past six months.	
Client reports having a sexual partner in the past six months who is HIV positive and who has not been on effective HIV treatment.	
If the HIV-negative partner is not confident of the HIV-positive partner's adherence to treatment or has other sexual partners besides the partner on treatment.	
If the couple is not communicating openly about treatment adherence and viral load test results.	
If the HIV-negative partner is aware of gaps in the HIV-positive partner's treatment adherence.	
If the HIV-positive partner has been on ART for less than six months. <ul style="list-style-type: none"> • It takes three to six months on ART to suppress viral load. • In studies of serodiscordant couples, PrEP has provided a useful bridge to full viral suppression during this time. 	

Only clients who have been offered and received HIV testing services from an NACP-accredited center or community outreach site (including DICs) should access PrEP services. It is advisable that the providers of PrEP be trained on HTS protocol using the Ghana HTS algorithms and guidelines to minimize losses of clients who may be at risk of not completing referrals.

NEW: HIV self-testing (HIVST) complements existing HIV testing strategies for PrEP services and enables DSD approaches for PrEP with reduced clinic visits. It enables increased access to PrEP, uptake, persistence and effective use. It gives PrEP users a choice of convenient, private and self-managed care when starting, restarting or continuing PrEP.

2.3 Oral PrEP Eligibility Criteria (see Appendix 6 for risk assessment)

- HIV seronegative
- No suspicion of acute HIV infection
- At substantial risk of HIV infection*
- Creatinine clearance (eGFR) >60ml/min**
- Willingness to use PrEP as prescribed
- Client is requesting PrEP
- Hepatitis B infection***
- Hepatitis C infection***

*After screening for substantial risk, provide other available preventive services such as condoms and lubricants, as well as other PrEP options like dapivirine vaginal ring and injectable PrEP. Use the substantial risk assessment as a conversation tool to counsel on the need to be mutually faithful with their partners, test regularly for HIV and STIs, avoid misusing drugs and alcohol as they impair decision-making about unsafe sexual encounters. Substantial risk assessment should not be a barrier to PrEP by screening people out.

****NEW:** Measuring Kidney function and creatinine clearance

Measuring kidney function is optional for all who are 49 years old and below who have no kidney-related co-morbidities and are requesting PrEP. This is due to the low risk of kidney impairment in this age groups. However, within the first three months of oral PrEP initiation, it is recommended that clients 49 years and below be screened once. More frequent screening (every 6–12 months) is suggested for individuals with co-morbidities, those aged 50 years and older, and those with a previous kidney function test result suggesting at least a mild reduction in function (eGFR <90 mL/min per 1.73 m²).

Kidney function test should be requested and used to make an informed decision in the management of the PrEP client within the context of good clinical practice. Unavailability of the test should not be a barrier to PrEP service provision

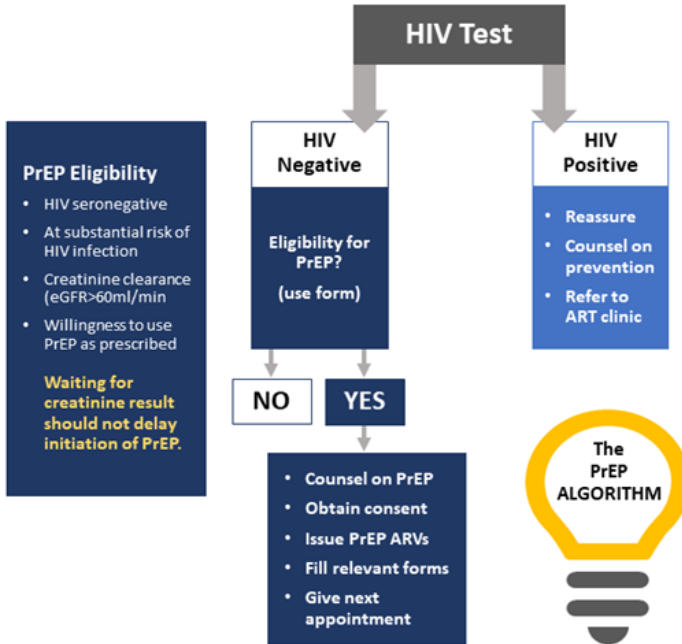
*****NEW:** PrEP services provide an important opportunity to screen for HBV and HCV infection with linkage to care when required. HBV and HCV testing even though not a requirement for PrEP initiation is encouraged. The testing can be done once at initiation or within 3 months of PrEP initiation but should not be a barrier to initiation. Both

TDF-based daily oral PrEP or event-driven oral PrEP can safely be offered to people with HBV or HCV infections.

2.4 Laboratory Support for oral PrEP Administration

In addition to the initial HIV test and the subsequent three-month test to assure HIV status, the following tests are recommended to ensure PrEP service delivery is of high quality.

1. Creatinine clearance (CrCl): Should be ≥ 60 ml/min (Cockcroft-Gault) to safely use tenofovir. An online calculator can be found here: <http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/>.
 - a. For clients of any age who have kidney-related co-morbidities, clients aged 50 years and above as well as clients who have a mild reduction in kidney function, good clinical practice should guide measuring kidney function before initiation.
 - b. PrEP is contraindicated or should be stopped if eGFR is <60 ml/min
 - c. There is no need to get the creatinine test before initiating PrEP in clients 49 years and below who have no kidney-related co-morbidities.

Figure 3: Oral PrEP algorithm

- d. Monitor kidney function once or twice a year in clients who have co-morbidities or are 50 years and above
- e. For clients who can afford it, the kidney function can be measured before initiation or within the first 3 months of initiation.
- f. Where there is no access to the test, PrEP should not be unreasonably withheld.

2. Hepatitis B surface antigen: TDF/FTC or TDF/3TC is active against hepatitis B virus (HBV). Patients with chronic HBV can use TDF/FTC or TDF/3TC for PrEP but should have liver function tests monitored every 6 to 12 months during PrEP use and after discontinuing PrEP.

- a. Such PrEP users should be cautioned that hepatitis can flare if PrEP ARVs is discontinued.
- b. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.

3. Other STI testing if and when available

2.5 Oral PrEP Dosage

Following WHO recommendations, the approved regimens containing tenofovir disoproxil fumarate (TDF) for oral PrEP in Ghana are:

- A fixed-dose combination of TDF 300mg/FTC 200mg (emtricitabine) per oral daily, or
- A fixed-dose combination of TDF 300mg/3TC 300mg (lamivudine) per oral daily⁵

2.6 How to Give oral PrEP

- Give PrEP after eligibility determination and evaluation
- Give one (1) bottle of 30 pills in the first instance. This should cover a period of one month on average. Increase the number of bottles to three to cover about three months if client is adherent and expresses demand.

⁵ARV class: Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). Mechanism of action: interferes with a process called reverse transcription (when HIV turns its RNA into DNA, using building blocks called nucleotides). NRTIs contain faulty building blocks that stop DNA from being made properly.

2.6.1 Starting and stopping oral PrEP (NEW)

- For all clients who are females at birth (cisgender women) and transgender women (males at birth) who are taking or using oestrogen/oestradiol hormones:
 - ▶ If using oral PrEP to prevent HIV acquisition from non-sexual exposures such as sharing of needles and sharps, take a single pill daily for 7 days before the potential exposure to HIV.
 - ▶ To stop taking oral PrEP, take a single pill daily for 7 days after last exposure to HIV.
- Clients who are using daily oral PrEP because they are not eligible for ED-PrEP are to take one pill daily (at the same time as much as possible) for as long as they are at risk.
 - ▶ When no longer at risk and want to stop, they can stop by taking their daily dose for 7 days after the last exposure to HIV.
- People with male sex at birth (cisgender males, transgender women and gender diverse people) who are not taking or using oestrogen/oestradiol hormones can use daily oral PrEP or Ed-PrEP.
 - ▶ For daily oral PrEP, they take one pill daily for as long as they are at risk.
 - ▶ For ED-PrEP, see Section 2.7 below for guidance on how to use it.
 - ▶ When no longer at risk and want to stop, can stop by taking a single pill daily for 2 days after the last exposure to HIV. This applies whether they are taking daily oral PrEP or ED-PrEP.

2.7 Event-driven PrEP (ED-PrEP)

Give oral PrEP when demanded in anticipation of a high-risk exposure. Providers should always avoid being judgmental when providing PrEP services like ED-PrEP. ED-PrEP is only appropriate for the prevention of HIV acquisition from sexual exposure.

- WHO updated its recommendation for PrEP to include event-driven PrEP (ED-PrEP) taken before and after sex (also called on-demand PrEP or the 2+1+1 schedule) as an HIV prevention option for cisgender men, transgender females and gender diverse people who are at substantial risk and are not taking or using oestradiol/oestrogen hormones.
- The 2+1+1 schedule entails taking double dose of TDF 300mg/FTC 200mg (or TDF 300mg/3TC 300mg) between two and 24 hours before sex is anticipated, and then 24 hours after sex has occurred, and after another 24 hours.
- For whom is ED-PrEP appropriate?
 - Cisgender men (male sex at birth)
 - Transgender women (male sex at birth) who are not taking oestradiol/oestrogen hormones.
 - Gender diverse people (with male sex at birth) who are not taking oestradiol/oestrogen hormones
- For whom is ED-PrEP NOT appropriate? Oral daily PrEP is not appropriate for these groups.
 - Cisgender women
 - Transgender women (male sex at birth) taking oestradiol/oestrogen hormones
 - Transgender men (female sex at birth)

2.8 Side Effects of Oral PrEP
























Every medication has side effects. Always weigh the benefit of a medication against the risk of a side effect. With PrEP, the benefit is staying HIV negative weighed against the minor, often transient, side effects. One in 10 PrEP users report minor side effects which usually last for no longer than a month. These include:

- Gastrointestinal - nausea, vomiting, abdominal cramps
- Headache

2.9 Oral PrEP Initiation and Follow up Schedule

Table 4

Oral PrEP initiation and follow-up schedule

Period in PrEP administration	Day 1	Month 0	Month 3	Month 6	Visit clinic every other 3 months
Services at visit to PrEP facility	Review HIV-negative status. (Applies to ED-PrEP)				
	Check Hepatitis B status, offer immunisation if negative		-	-	-
	Check serum creatinine if age 50+, co-morbidities or eGFR<90ml/min		-		-
	Medication-adherence counseling				
	Counseling on safe sex practices				
	Prescribe: FDC TDF 300mg/3TC 300mg or TDF 300mg/FTC 200mg per oral				
	Screen and treat STIs				

2.10 Oral PrEP Adherence Counseling

- Evidence shows that, when taken consistently and correctly during periods of risk, PrEP reduces the chances of HIV infection to near zero.
- PrEP is cost effective and acceptable to people at higher risk of HIV infection.
- PrEP does not protect against other STIs; therefore PrEP needs to be delivered as part of a comprehensive package of HIV and STI prevention services.
- PrEP effectiveness decreases rapidly if not taken regularly as prescribed, so addressing adherence barriers is key for success.
- Confirm that the client has understood the following:
 - PrEP is being offered as an informed choice.
 - PrEP is highly effective when used as prescribed.
 - Effectiveness is linked to consistency of use.
 - Condom use and other positive behavioral attitudes should be implemented alongside PrEP (e.g., avoidance/reduction in alcohol and substance abuse).
 - Adherence is improved when taken as part of daily routine, e.g., when waking up, going to sleep, or at regular mealtimes.
 - Access to join PrEP-user support groups; available social media groups can be found here: <https://www.facebook.com/groups/PrEPFacts>
 - Commitment to use PrEP if risk exposure persists
 - Discontinuing PrEP

- If the person taking PrEP is no longer at substantial risk of HIV acquisition
- If the person experiences complications related to the drugs
- Discuss the decision to stop with the facility PrEP provider
- Possibly discuss plans to stop PrEP with your partners and get tested for HIV (use 4th generation test)
- Advisable to continue taking PrEP for 2 days (male sex at birth or not using oestrogen/oestradiol hormones) or 7 days (females and male sex at birth taking/using oestrogen/oestradiol hormones) following the last possible exposure to HIV.
- Period of risk may be associated with a relationship, alcohol and drug use, leaving school or home, trauma, or other events
- Dosage and interval of taking PrEP ARVs
- Potential minor side effects and average duration when they happen
- Date of next appointment
- For effective use, PrEP providers should be thorough in the adherence counseling process emphasizing consistent use of PrEP during periods of risk. PrEP providers should provide follow-up support at every scheduled visit. Providers should assess challenges with the use of PrEP at every visit. Remember to ask at every clinical assessment visit:
 - What challenges have you had taking your oral PrEP ARVs?
 - What days/time of day are you most likely to forget taking your meds? (weekends, weekdays, mornings, evenings?)
- Remind PrEP users of the importance of perfect adherence at every clinic visit, while providing risk-reduction counseling.
- Give practical strategies on how to achieve optimal

adherence:

- Build ARVs into the daily routine (e.g., before washing face, after evening meal)
- Ask a trusted peer to remind you
- Set a daily alarm on the cell phone
- Keep a “drug diary” and mark every tablet taken
- Encourage honest dialogue. Avoid giving the impression of “policing” the client. Work with them to help them achieve good adherence.

2.11 **Injectable PrEP (NEW)**

Long-acting cabotegravir (CAB-LA), an integrase strand transfer inhibitor (INSTI), has been recommended by WHO as pre-exposure prophylaxis (PrEP) for HIV-1. It is also safe and highly effective in preventing acquisition of HIV infection among those who are at substantial risk.

2.11.1 Eligibility for CAB-LA

- HIV seronegative
- No suspicion of acute HIV infection
- At substantial risk of HIV infection
- Liver function test (LFT)/Alanine Transaminase (ALT) normal
- Willingness to use CAB-LA as prescribed
- Client is requesting CAB-LA
- Client weighs at least 35Kg
- Any one requesting PrEP

2.11.2 Laboratory Support for CAB-LA Administration

- Assess LFT looking at ALT before and during CAB-LA use but this should not be a barrier to accessing CAB-LA. CAB-LA injections should also not be delayed while waiting for results of LFT. Avoid in people with advanced liver disease or acute viral hepatitis and discontinue if hepatotoxicity develops. CAB-LA may be contraindicated for those requiring treatment for HBV as CAB-LA is not active against HBV so TDF-based oral PrEP is recommended in this case.
- Assess HBsAg and HCV status
- No kidney toxicity is anticipated during use of CAB-LA so measuring kidney function is not required for CAB-LA use.
- Screen for STIs

2.11.3 Dosage of CAB-LA

- 600mg given IM each time.

2.11.4 How to give CAB-LA

It is an injectable and each single dose vial contains a suspension of CAB-LA. The first two injections are given intramuscularly 4 weeks apart followed by one injection every 8 weeks.

After the first dose, the next dose can be given 7 days before or 7 days after the appointment date.

If client missed appointment greater than 3 months after last injection, re-initiate with 2 doses one month apart and continue the same every 2 months.
























2.11.5 Side effects of CAB-LA

- Hepatotoxicity can occur in a few patients.
- Headache
- fever
- Injection site – pain, swelling, warm to touch

2.11.6 CAB-LA Initiation and follow-up schedule

Table 5:

CAB-LA initiation and follow-up schedule

Period in CAB-LA administration	Day 1	Month 1	Month 3	Month 5	Visit clinic every 2 months
Services at visit to PrEP facility	Review HIV-negative status				
	Check Hepatitis B status and offer immunisation if negative		-	-	-
	Check LFT, ALT		-		-
	Medication-adherence counseling				
	Counseling on safe sex practices				
	Prescribe: IM 600mg CAB				
	Screen and treat STIs				

2.12 Dapivirine vaginal ring (NEW)

Dapivirine vaginal ring (DPV-VR) is an additional preventive choice recommended by WHO for women at substantial risk of HIV infection as part of combination prevention approaches. It is offered as a PrEP option for women who do not want or are unable to take a daily oral tablet. It is not a contraceptive but is effective in reducing the risk of acquiring HIV infection. It belongs to the class of antiretrovirals called non-nucleoside reverse transcriptase inhibitors (NNRTIs).

2.12.1 Eligibility for DPV-VR

- HIV negative
- Cisgender women (female sex at birth)
- Adolescent girls and young women
- Transgender men (female sex at birth)
- Gender diverse (female sex at birth)
- HBV infection

2.12.2 Lab support for DPV-VR

No specific labs required before or during use.

2.12.3 Dosage

The ring contains 25mg of Dapivirine (NNRTI) which is released slowly for 28 days once inserted in the vagina.

2.12.3 How to use DPV-VR

It is a bendable silicone ring which is inserted and worn inside the vagina for 28 continuous days after which it must be replaced with a new ring. It is not contraceptive but can be used with other contraceptives.

2.12.4 Side Effects of DPV-VR

- Generally, well tolerated
- Few reported vaginal discharge, itching and urinary tract infection which were resolved without disruption of ring use.

2.12.5 Initiation and follow-up schedule

After assessing for HIV negative status and substantial risk of acquiring HIV infection, ring is provided, and insertion may be assisted by health care provider. Client is reviewed after the first 28 days for adherence and compliance after which multi-month dispensing can be done for 6 monthly reviews. Screen and treat STIs as part of the initiation and follow-up schedule.

2.13 Location and Demand Strategies for PrEP Beneficiaries

Potential PrEP beneficiaries may be found in the facility and within the community. PrEP may be accessed in various places that are KP-friendly and where other people with high risk of acquiring HIV commonly access health services. PrEP programmes should work with other health systems to design strategies that identify people both in health facilities and the community who are at high risk of acquiring

HIV. In Ghana, the following places are approved to provide PrEP services:

2.13.1 Public and Private Health facilities.

Common service delivery points where potential PrEP users may be found include:

- ART clinic
- STI clinic
 - Many KP members accessing health service for STIs may not identify as a KP member. Careful use of the PrEP eligibility screening form will help define the indication.
 - STI clinic attendees may also be used for estimation of likely PrEP users in a facility and within a region where subnational and local HIV incidence rates are not available.
- Outpatient department (through active referrals from outpatient clinic or department)
 - HIV testing (the most common)
 - Testing for STIs
- Family planning clinic
 - To identify women in serodiscordant partnerships
- Antenatal clinic
 - Women in serodiscordant partnerships
 - HIV-negative pregnant and breastfeeding women in high prevalence HIV settings
 - HIV-negative pregnant and breastfeeding women at risk of acquiring HIV infection are eligible for PrEP
- Sexual and gender-based violence services
- Harm reduction and other drug treatment services

- PEP services
 - Clients completing PEP services may be referred for PrEP
 - PrEP offers more consistent protection against HIV than repeated PEP

2.13.2 Community.

Notable locations to find potential PrEP users include:

- KP civil society organizations
- Hot spots
 - MSM and FSW hot spots should be targeted with appropriate messaging
- Drop-in centers (DICs)
 - Safe space for KP community activities with their peer navigators and educators
- Mobile clinics
- Community refill centres
- Community-based and outreach HIV testing
 - Clients tested may be referred for PrEP in the nearest PrEP facility or within the community where available
- Drug treatment and rehabilitation centres
- Accredited community pharmacies
 - Screening tool used for multiple users of contraceptive pills and clients requesting PrEP or HIV self-testing kits

2.14 Who Should Prescribe and Distribute PrEP

The following categories of individuals are recommended to be trained to provide PrEP services:

- Clinicians (Doctors, Physician Assistants, etc.)
- Nursing cadres, health care workers who are Case Managers
- Pharmacy cadres (Pharmacists, Dispensing Assistants)
- Counsellors*
- Case Managers (i.e. Peer Educators for KPs)*
- Peer Educators*

*These are allowed to distribute only

2.15 PrEP Programme Management



PrEP implementation among KPs and other users requires strong team building for effective coordination of internal and external referrals with the community. An integrated programme management approach for each PrEP facility and among CSOs that generate and sustain demand is critical for monitoring, evaluation, and sustainability.

A. PrEP focal person

1. Reports to ART focal person or hospital management team (HMT).
2. In small facilities, the ART focal person or facility head could also serve as the PrEP focal person.

3. Collect and collate all records on daily PrEP use in the facility and aggregate on the monthly summary form (MSF) for submission to NACP and the implementing partner through the HMT.
4. Ensure a minimum stock of two months of ARVs for PrEP use in the facility.
5. Provide contacts and be the lead person for liaison with CSOs and users of PrEP in the community.
6. Facilitate and coordinate tracking and home visits of PrEP users where need arises.
7. Leads the monthly joint facility PrEP programme review meeting with the linked CSOs.
8. Provide linkages and referrals to other services such as STI screening and treatment

B. Facility PrEP dispensing officer

1. Receive and warehouse all PrEP ARV allocation for the facility.
2. Generate PrEP ARV facility supply through quantification from projection records with PrEP use in the facility over the quarter.
3. Ensure a minimum stock of two months of ARVs for PrEP use in the facility, and alert PrEP focal person for requisition submission to the regional medical store (RMS).
4. Fill and submit all pharmaco-vigilance forms in the rare event of an adverse reaction or side effect with use of PrEP. The Pharmacist-in-charge in the facility can facilitate the reporting.
5. Complete and submit PrEP specific commodity consumption reports to inform forecasting and quantification.

C. CSO PrEP representative

1. Serve as community focal person for PrEP liaison with the health facility.
2. Form the community hub for PrEP education and demand creation for PrEP.
3. Coordinate with peer navigators and educators to sustain good adherence among KPs.
4. Co-facilitate monthly review meeting with the PrEP focal person to review PrEP uptake, monitoring, and issues related to commodity availability, seroconversion, etc.
5. Provide linkages and referrals to other services such as STI screening and treatment



3. Integrating PrEP and STI Services



3.1 Integrating STI services in PrEP services

PrEP services provide an opportunity for preventing, identifying, and treating other sexually transmitted infections besides HIV and Hepatitis B. Integrating STI services into PrEP services is essential, practical, convenient, and efficient in preventing, diagnosing, and treating STIs in persons at higher risk of such infections. It also provides an avenue for diagnosing and treating those who have been infected or are consequently infected with an STI. Since STIs can be asymptomatic particularly in females, integrating both services provide an opportunity to identify and curtail sequelae that otherwise might be missed. Although it is not currently feasible to offer STI services to all people on PrEP everywhere, the gradual addition of services using a stepwise approach can encourage and advance integration of STI

services. Capacity building and task sharing is needed as PrEP and STI services are integrated and coverage expanded. Demand generation for PrEP services should be done with STI screening and treatment supported by an M&E system. The high burden of STIs among KPs and AGYW coupled with access issues demands integration of services and making these services available in the communities as much as possible to meet clients at their point of need. This guideline is therefore being introduced not only for integration purposes but to harness the benefits of interacting with the community of various at-risk populations to institute a holistic intervention for HIV, HBV and other STIs.

3.2 Providing information and promoting health-seeking behaviours in respect of STI

The healthcare provider must take advantage of every visit to offer STI-related services aside from testing for HIV, HBV and HCV. Every effort must be made during the client's first encounter with health services to provide basic information on STIs, including self-assessment for signs and symptoms (Assessment Tool 1) and prevention strategies. The information provided must address issues of the stigma associated with STIs. It should clarify to the client that other non-STI-related pathogens or conditions can cause some symptoms associated with STIs. It must also be emphasized that STI infection can be asymptomatic, particularly in females.

People who use PrEP should be made aware that it will reduce the risk of acquiring HIV, but it will NOT reduce the risk of getting other STIs

Assessment Tool 1: Self-Assessment for Signs and Symptoms of STIs

If you have any of the following symptoms, you may have an STI:

- ulcers or sores on the genitals or anal areas or in the mouth*
- discharge from the penis or vagina
- unusual or odorous vaginal discharge
- bumps or warts on the genitals, anal area, or in the mouth
- painful or burning urination
- unusual vaginal bleeding
- pain during sex
- sore, swollen lymph nodes, particularly in the groin
- lower abdominal pain

** Some of these symptoms may not be caused by an STI. Patients should be advised to seek care as soon as possible and refrain from sex until they receive a diagnosis and treatment, if appropriate.*

** Some STIs can cause ulcers and sores in the mouth when oral sex is performed on a person with infection, but there are many other causes of oral ulcers that are not related to sex.*

3.3 Counselling Relating to STI Care

STI-related counselling and care must be made an integral component of PrEP services. PrEP should also be an important part of STI services as HIV is also an STI and the risk of acquiring HIV is higher in those with other STIs. Quality counselling is an essential component of client-centred care. It must be extended to persons accessing PrEP to enable them to make informed decisions so that a care plan can be designed for taking relevant action to improve their health. For example, some behaviours associated with increased risk for HIV and STIs, such as using sex dating apps and Chemsex, particularly among men who

have sex with men, are becoming more frequent. It is essential for those providing counselling to raise awareness of the risks of such practices. Counselling may enhance relationships between providers and clients and may encourage access to services, including STI services. Information sharing on STI risks, diagnosis and treatment modalities must be done comprehensively in a welcoming environment. Clients with STIs or at risk of such must be counselled to notify their partners for possible expedited partner treatment (EPT). Clients should be urged and assured of support services for vaccination, testing, linkage to care and treatment completion.

Effective counselling by care providers must be aimed at prompting clients to notice STI signs and symptoms they may have through the conduction of STI self-assessment, promote positive health-seeking behaviours, and provide appropriate STI services.

WHO does not recommend counselling to change people's behaviours as it is ineffective in reducing HIV/STI incidence.

3.4 STI prevention

STI prevention services are critical to the overall healthcare provision, including PrEP. PrEP does NOT protect against STIs, so it is imperative that prevention including PrEP is presented as a package of measures for STI prevention. STI Prevention approaches must include a combination of the following:

- female condoms
- male condoms
- lubricants
- vaginal rings* – protect against HIV transmission but NOT other STIs
- vaccination for hepatitis A and B and HPV when appropriate

*Dapivirine vaginal ring and rings for contraception do NOT protect against STI infection.

Vaccines and condoms are primary STI prevention tools (Table 1). Currently, Ghana recommends post-exposure prophylaxis (PEP) for bacterial STIs only in the case of sexual assault/rape.

Table 6: Recommendations for STI prevention

Vaccines	<ul style="list-style-type: none"> • Hepatitis A: WHO recommends vaccination for people at higher risk of contracting hepatitis A virus in low-endemicity settings, including men who have sex with men and people who inject drugs.
	<ul style="list-style-type: none"> • Hepatitis B: WHO recommends vaccination for people at high risk of infection, including those with multiple sexual partners, persons in prisons and other closed settings, people who inject drugs, men who have sex with men and other people at risk of HIV infection. Routine pre-vaccination or post-vaccination testing is not recommended. Where laboratory or testing facilities are available, and pre-vaccination testing is considered cost-effective, serological testing may reduce the number of unnecessary vaccinations of people who are already immune to the hepatitis B virus.
	<ul style="list-style-type: none"> • HPV: Current HPV vaccines effectively protect against high-risk HPV types known to be carcinogenic and low-risk HPV types known to cause genital warts. The quadrivalent and nonavalent HPV vaccines cover both high- and low-risk HPV types. The HPV bivalent vaccine only protects against the HPV virus types that cause cancer.
STI PEP	<ul style="list-style-type: none"> • PEP for other STIs is recommended by WHO for use only following sexual violence/abuse, together with emergency contraception and PEP for HIV.
Barrier methods	<ul style="list-style-type: none"> • All condoms provide a high degree of protection against many STIs when used correctly and consistently with all partners and at every act of penetrative sex, starting before intercourse and continuing throughout. Condoms also have the advantage of offering protection against pregnancy.
	<ul style="list-style-type: none"> • External condoms (male condoms) used during penetrative oral, anal or vaginal sex.
	<p>Internal condoms (female condoms) are used internally during vaginal or anal sex.</p> <p>A dental dam is a square, stretchy sheet made from latex or polyurethane plastic that can be used during oral sex to keep the mouth from touching genitals and body fluids.</p> <ul style="list-style-type: none"> ▪ Placing the dental dam over the vulva or anus makes transmission less likely. ▪ In the case of oral (mouth- penis) sex, an external condom offers better protection
Lubricants	<ul style="list-style-type: none"> • Lubricants are commonly used, particularly during anal sex, with or without condoms, and improve sexual health and well-being. Even when used without condoms, lubricants can provide some protection by reducing the risk of microtrauma during penetrative sex.
	<p>Water-based or silicone-based lubricants should always be provided with condoms. Using lubricants with condoms during anal and vaginal sex offers extra protection against HIV and other STIs because lubricants help prevent condom breakage and reduce the risk of microtrauma to the mucosa during penetrative sex.</p>
	<p>Oil-based lubricants (butter, mineral or vegetable oil, or skin hydration creams) cannot be used with condoms, as they damage the latex.</p>

3.5 STI Diagnosis

Diagnosing STI is generally essential for all clients and critical to persons who are at-risk of acquiring STIs including HIV such as FSW and MSM. Although the Aetiological Approach delivers the gold standard for diagnosis, the universal application of such is challenging due to logistical and human resource restrictions. The Syndromic Approach provides a more practical and realistic way of diagnosing and treating STIs at all levels of care. In Ghana, the National Guidelines for Management of STIs provides the approaches to STIs diagnosis and management. Refer to the National STI Guidelines (2022) on the various diagnostic algorithms and management protocols for the different syndromes and where available, syphilis testing using rapid diagnostic tests or nucleic acid amplification tests for other STIs should be used.

3.6 Partners services

Treatment of sexual partners prevents reinfection and interrupts the chain of transmission and must be undertaken consistently using the various approaches tailored in a differentiated manner to meet the peculiar needs of a particular client. Healthcare providers must explore options to notify and treat sexual partners, including expedited partner therapy (EPT). Ghana recommends that providers aid clients who test positive for HIV or other STIs to tell their partners and link them to care. Partner services' strategies (such as assisted partner notification services) are proven highly efficient and effective in detecting new cases.

3.6.1 Practical strategies for partner services

- **User referral partner notification:** A client who tests positive for HIV or other STIs (the index case) can be issued a contact-tracing card for sex partners along with an invitation to attend the clinic for assessment and, if necessary, treatment.
- **Provider referral partner notification:** The health care provider obtains contact details from the index case and then attempts to contact the sex partners in person or by telephone, through SMS messages, or other ways, with the agreement of the index case.
- **Contractual partner referral:** The index case and service provider agree that the index case will contact the sex partners, and the partners will present for examination and treatment within a certain amount of time, after which the health care provider will try to contact the sex partners.
- **Social network-based referral:** In an extension of partner services, a trained provider asks all clients at high risk of infection, independently of test results, to encourage and invite individuals in their sexual, drug-injecting or social networks to participate in voluntary testing services.
- **Expedited partner therapy (EPT):** The client diagnosed with a bacterial STI is given a prescription or medicines to give to sex partners without examination by the health care provider.

Partners given EPT should be encouraged to report at a health facility for further evaluation to prevent recurrence of the STI and account for the medications given with feedback to the health care provider on completion of medication.

3.7 Consultation and physical examination

To establish a correct diagnosis, the health care provider must ensure a conducive environment for people to discuss their sexual history freely. Taking a sexual and medical history is also central to providing quality PrEP and STI care, and it is an essential component of people-centred care.

Obtaining clients' sexual history will help providers to gauge a person's likelihood of being infected with an STI. During the physical exam, the provider should look for signs and symptoms of STIs.

As with counselling, taking a sexual history should not be a requirement for clients to access PrEP or to be tested and treated for STIs.

Box 9: Physical exam for signs and symptoms of STIs During the physical exam, the provider should look for:

- lymph nodes: swelling/buboes
- inside the mouth: thrush, sores, other lesions
- skin over the abdomen: swelling
- palms of hands and sole of feet, thighs and buttocks: rashes, ulcers
- external genitals: discharge, sores, ulcers, warts, parasites, excoriations
- penis: look at glans and at the urethra for discharge
- vagina: manual exam for abnormal masses, tenderness
- anal area: discharge, rashes, ulcers, warts. In settings where speculum exam and/or anoscopy is available,

The provider should also examine the:

- vaginal mucosa and cervix
- rectal mucosa.

For a step-by-step guide to performing a clinical examination, (WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 13. Integrating STI services. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.)

3.8 Treatment for common STIs

At both the STI clinic and PrEP facility, correct and effective STI treatment should be provided and taken on the first contact between clients and health care providers. A client prescribed an STI treatment should be counselled on medication information, risks and benefits, adverse reactions, dosing and adherence. Rapid treatment of sexual partners is also critical to avoid reinfection and to break the chain of transmission, which should include expedited partner treatment. Treatment given on the same visit is especially relevant in settings where users' return rates are low for reasons such as distance to the clinic, clinic fees, and transport fees, among others. This will reduce costs for both the user

and the health care system. Standardized treatment protocols for STIs ensure appropriate treatment at all levels of health care services and help reduce the risk of developing resistance to antimicrobials. Refer to the National Guidelines for the Management of STIs for guidance.

The correct, effective and timely treatment of STIs will cure the infection and reduce the risk of developing complications and antimicrobial resistance.

Clinical follow-up

Follow-up is generally limited to those with persistent symptoms after a stipulated period after the recommended treatment. Clients may return for further assessment if the condition has not resolved or recurs. The health care provider must determine the reason for the user's return to guide the next steps.

Referrals and linkages

- If possible, refer complicated conditions to a higher level of care
- Have a pre-established mechanism to assure linkage to care and to provide feedback to the referral facility

Health care workers should be provided with clear and easily accessible information on referral and counter-referral mechanisms. Sometimes people diagnosed with an STI need to be referred to another level of care. For example, someone with an abnormality in the anorectal area may need to be referred to a colorectal surgeon or oncologist for diagnostic tests.

However, when referring someone to another facility, it is critical to consider the loss of follow-up due to individual, programmatic and environmental factors (see Box 1). Loss-to-follow-up results in poorer outcomes. These include the long-term consequences of the infection and missed opportunities to stop the chain of transmission. Some effective strategies to support linkage to HIV care can also be applied when clients must be referred to another service for STI testing or treatment, as listed in Box 1 below.

Box 1

Suggested strategies to support linkage care that could be applied to STI referrals

- Friendly services that are inclusive and non-judgemental increase acceptability and access to care. Stigma and discrimination related to STIs constitute important barriers to healthcare-seeking behaviour.
- Flexible services regarding opening hours and days.
- Adoption of self-care services, such as self-collection of samples at home or the facility.
- Services that are free of cost to users and financial support to access other referral facilities if needed.
- Availability of peer and community support and follow-up, including client navigators and linkage escorts.
- Digital platforms, including social media, videos, text messaging and other digital applications, are promising for improving linkage to care and may be less costly than intensive in-person approaches.
- National policies must help sites, and health care workers support linkage to care. Programme managers should consider adopting and implementing a clear linkage strategy and policy, including specific approaches, interventions and designation of cadres supporting association to manage and monitor its effectiveness.

Before assuming that routine referral is needed, providers should consider that most STIs can be dealt with routinely at the facility level and during one visit.



4. PrEP Demand and Delivery System



4.1 Community Engagement and Communication

Ensure community participation and leadership by the CSOs. Effective engagement and planning with the management of CSOs in the implementation process will address demand and adherence questions. The messaging and awareness creation should also have a broad audience, including faith-based organizations (FBOs) and other community gatekeepers, the private sector, mass media, PLHIV, and potential PrEP users. All communication and messaging should provide knowledge and create awareness that will reflect in generating high demand from the eligible target population.

4.2 Service Delivery

PrEP could be delivered using facility-based delivery models in outpatient department (OPD), antenatal care (ANC), ART, family planning (FP), and STI clinics, as well as through community-based locations that are considered safe and where confidentiality can be maintained to meet the minimum standard for service delivery. DICs supported by projects are good community outlets for PrEP.

The delivery of PrEP should be done through a hub of a PrEP facility linked to spokes of CSOs (especially for KPs). This will facilitate ease of referrals and follow-up. When the management of CSOs and a PrEP-supporting health facility collaborate, they create a KP-friendly pathway and facility ambience for PrEP service delivery, access, and retention. In addition, this creates opportunities to reinforce links between complementary services such as reproductive health and STI. HIV testing is the gateway to PrEP initiation. All HTS providers should be mobilized to ensure everyone identified to be at substantial risk of HIV acquisition through a behavioural risk assessment during HIV pre-test and post-test counseling are linked to PrEP services. This is in addition to persons who independently seek to access PrEP (in alignment with WHO recommendations that people requesting PrEP are likely at substantial risk).

A directory of PrEP services should be developed as part of the national programme and shared with all HTS service delivery points across the country. Novel HTS approaches such as outreach testing at hot spots and the use of HIV self-testing provide additional opportunities for more eligibility assessments for PrEP in the community. WHO supports initiating/continuing clients based on an HIVST result verified by a

provider so as to make PrEP easily accessible. Self-testing is currently included in the 2022 Consolidated Guidelines for HIV care in Ghana.

4.3 Capacity Building

Ensure appropriate training on the science and use of PrEP is provided to all would-be providers to keep its use within the boundaries of prescription restrictions. The training should be in a centralized comfortable environment to encourage open and relaxed communication; ensure all anxieties and ambiguities related to the use of PrEP are cleared. The participants should include the list of potential PrEP prescribers. Peer educators at CSOs, community health volunteers, members of youth networks who will also promote PrEP use at the community level should be trained. A central training of trainers (TOT) should be regularly conducted to maintain a large pool of master PrEP trainers for country use. Staff at PrEP facilities will require continuous on-the-job training using case scenarios.

4.4 Monitoring and Evaluation

Supportive supervision and mentorship for PrEP uptake and use will be done quarterly and on demand to ensure continuous quality control and improvement (CQI) of the programme. Relevant PrEP programme recording and reporting tools in the Appendices will be used in the monitoring and evaluation of the programme. Data collection should be done at facility, district, regional and national levels. There will be the need to institute quarterly reports on regional basis and annual reports at the national level. Same reporting tools should be used by all implementers and CSOs should feed their data into their linked facility reports.

4.5 Supply Chain for PrEP Commodities

There should be continuous capacity building of Commodity managers in good inventory management practices to equip them with the knowledge and skills to ensure commodities are managed appropriately. Logistics reporting tools will be deployed to ensure that enough data is available to support PrEP implementation across the country. There is the need to synchronise all national logistics management systems to ensure accurate documentation using appropriate PrEP logistics tools. This will produce accurate and reliable data for national consumption projection, quantification, and documentation of lessons learned. It is important to involve all stakeholders and partners in this endeavour.

4.6 Pharmacovigilance

Monitoring and reporting of adverse drug events should be done according to Food and Drugs Authority (FDA) guidelines. Adverse drug reactions reporting forms as well as other means recommended by the FDA can be used to submit reports. Health facilities must record adverse drug reactions and report them to the FDA using the appropriate channels. Furthermore, facilities are encouraged to use the information to monitor clients.



5. Differentiated PrEP Service Delivery



5.1 Background

In most countries, individuals interested in PrEP for HIV prevention must go to a healthcare facility (often an HIV clinic) to obtain a prescription from a medical provider (often a physician). In recent years, and particularly during the COVID-19 pandemic, a shift towards differentiated PrEP service delivery has accelerated. A differentiated PrEP service delivery approach is person-centred and adapts services to the needs and preferences of the people who are interested in and could benefit from PrEP. Differentiated PrEP service delivery also supports efficient and cost-effective use of healthcare resources. The four building blocks of differentiated and person-centred PrEP service

delivery are: WHEN, WHERE, WHO, and WHAT to deliver. WHO has released recommendations and guidance on differentiated service delivery for HIV testing and treatment. This section provides guidance on differentiated service delivery for PrEP.

5.2 Delivery of PrEP outside of traditional healthcare facilities

5.2.1 PrEP delivery in pharmacies

Pharmacists often play an important role in healthcare systems by providing treatment (e.g., for STIs) and prevention services (e.g., contraception). Pharmacies may be more accessible and acceptable and provide more convenient and easier engagement with clients than traditional healthcare facilities. In resource-limited settings, individuals commonly first seek healthcare services from pharmacies before going to healthcare facilities.

As done for the community ARV refill, PrEP delivery in pharmacies have the potential to reduce travel time, cost, ease of access and convenient for PrEP uptake.

To create a pharmacy-based PrEP delivery system, pharmacists need to have the legal authority to implement PrEP services and have access to the necessary infrastructure (e.g., for HIV testing), be trained and willing to provide PrEP, and have adequate physical space to ensure privacy.

5.2.1.1 Selection of Pharmacies

1. A pharmacy assessment and selection criteria and tool will be developed and used for selecting pharmacies to offer PrEP by the NACP or any of its assigned implementing partners.
2. Clear guidance will be provided by the NACP or any of its assigned implementing partners on the selection of staff at these pharmacies to provide PrEP
3. There will be capacity building and guidance on supply chain issues including how pharmacies will receive drugs, distribute to clients and report to the programme

5.2.2 PrEP in fixed and mobile community settings

PrEP service models that deliver PrEP in fixed community sites (e.g., in non-governmental organisations) and mobile and semi-mobile sites (e.g., vans parked in community settings) have been implemented. A systematic review of community-based PrEP delivery identified diverse models demonstrating the feasibility of these approaches in a range of settings, but data on effectiveness were limited.

In order to improve the community PrEP services, existing Drop-In-Centres (DICs) must play an integral role in providing client-centred services to target population in specific geographical locations. This will help in bringing PrEP services close to target populations such as MSMs, FSWs, hrM and SDC in order to save time and cost of travel. The link between clients receiving services outside of the facility and the facility is critical for looping clients back to facilities for routine labs and periodic care review. The facilities where nurses affiliated to DICs

work will be used for linking clients for care. It is recommended that clients should go back to the facility after about 2 refills (7 months) for a clinical review.

Table 7: *PrEP delivery in Drop-in-centre (DIC)*

When	Where	Who	What
<ul style="list-style-type: none"> • When client has adhered to PrEP for at least six months • When client expresses interest to receive PrEP at the DIC 	Drop-In-Centre (DIC) Fixed	Trained Nurse Trained community cadre	<ol style="list-style-type: none"> 1. Convenient space and privacy 2. HIV test to rule out acute HIV infection 3. 1 to 3 months PrEP refill 4. Data tool for reporting 5. Sample taking by trained nurses for Creatinine clearance testing

Table 8:**PrEP delivery in mobile clinic**

When	Where	Who	What
<ul style="list-style-type: none"> • When client has adhered to PrEP for at least six months • When client expresses interest to receive PrEP services via the mobile clinic service 	Well equip mobile van	Trained Nurse Trained health care provider Trained community cadre	<ul style="list-style-type: none"> • Convenient space and privacy • HIV test to rule out acute HIV infection • 1 to 3 months PrEP refill • Data tool for reporting • Sample taking by trained nurses for Creatinine clearance testing • Robust referral pathway

5.2.3 Community door-to-door PrEP delivery services

Community level PrEP delivery must include a system to allow trained KP community cadres to deliver PrEP refills to their peers at their doorstep or places of convenience. The cadres must include peer educators, lay counsellors, case managers and PrEP champions. The cadres must be supervised by a trained care provider.

Table 9:

Community door-to-door PrEP delivery services

When	Where	Who	What
<p>When client has adhered to PrEP for at least six months</p> <p>When client expresses interest to receive PrEP services through the community door to door system</p>	<p>KP hot spots</p> <p>Other preferred locations</p>	<p>Supervising Health Care Provider</p> <p>Peer Educators</p> <p>Lay Counsellors</p> <p>Case managers</p> <p>PrEP Champions</p>	<ul style="list-style-type: none"> • Pre-Packaged 1 to 3 months PrEP refill • Data tool for reporting

5.3 Telehealth for PrEP delivery

The use of information and telecommunication technologies to deliver PrEP services has the potential to remove barriers to PrEP uptake, ensure persistence and support effective use of PrEP. Examples of telehealth for PrEP have emerged, particularly in response to the COVID-19 pandemic. A systematic review identified a range of case studies of PrEP service delivery via telehealth platforms, including telehealth counselling and prescription with PrEP initiation and refills via home delivery or pharmacy or clinic pick-up. Several randomised controlled trials of home and telehealth-based PrEP delivery are ongoing in the Ghana especially with the QuickRes online application system. Telehealth services may be preferred for individuals who are stably on PrEP and have few challenges to effective use. Clinical oversight and clear referral pathways are important in the uncommon event when PrEP users have issues or more complex needs.

Table 10:**PrEP delivery via telehealth**

When	Where	Who	What
<ul style="list-style-type: none"> When clients demanding for PrEP services When clients are interested in accessing services through online service When clients need PrEP either than the conventional PrEP services available 	<p>Web or application based online systems equipped with infrastructure to link clients to available service delivery points</p>	<p>Trained health care providers</p> <p>Trained community cadres</p> <p>Peer educators</p>	<ul style="list-style-type: none"> An assessment tool that checks client's eligibility for PrEP A robust referral system that links clients to available service delivery point

Points to note:

- Differentiated PrEP service delivery can leverage on existing DSD Models as captured in the Operational Manual for DSD in Ghana (November 2021).
- All DSD models should take into consideration ED PrEP since ED PrEP is slightly different from Daily PrEP in terms of use but this should not affect service delivery models.
- Service providers should be trained to provide good counselling to clients.
- PrEP initiation should be done at the approved facilities or service points and then refills provided through the DSD Models
- Virtual apps (eg QuickRes) and platforms are being developed for demand creation, booking of appointments, distribution of HIVST kits and PrEP medication.



6. Pharmacovigilance



Pharmacovigilance refers to the activities set up for the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

- Adverse drug reactions (ADRs) can be detected by either a drug user, guardian, or health care practitioner.
- Report all ADRs (minor and serious) that are a concern to either a patient or guardian (e.g., persistent fever) and to the health care provider (e.g., jaundice).
- Serious ADRs should be reported as soon as possible to the Food and Drugs Authority.
- ADRs are considered serious if they result in any of the following: death, life-threatening, disability, hospitalization/ prolonged hospitalization, congenital anomaly, require

intervention to prevent impairment/damage, and any other important medical event. Serious ADRs (e.g., death) must be reported within 24 hours.

6.1 How to Fill Out the ADR Reporting Form

All sections of the form must be filled in with adequate details. The following basic information is required:

- Identifiable source of information or reporter
- Identifiable patient
- Name(s) of the suspected product(s)
- Description of the suspected reaction



7. Supply Chain



This section describes the supply chain management system that will support continuous availability of ARVs for PrEP use in Ghana. At the national level, PrEP commodity procurement and distribution will be a component of the HIV programme supply chain management. Commodity procurement, warehousing, and distribution for HIV programmes is described in the 2022 Consolidated Guidelines for HIV Care in Ghana (Chapter 11). These sections emphasize the due diligence required in record keeping in HIV commodity utilization, forecasting, supply planning, procurement, warehousing, and distribution.

An effective national supply chain system requires close in-country coordination among the Procurement and Supply Directorate (P&S) of the Ministry of Health and the Supplies and Drug Management Division

(SSDM) of the Ghana Health Service, the National AIDS/STI Control Programme (NACP), central medical store (CMS), regional medical stores (RMSs), and service delivery points (SDPs). A typical sequence of responsibility is described below:

- Health facility staff will ensure filling and timely reporting of commodity use on appropriate LMIS forms.
- The NACP supply chain team reviews submitted forms, and then works with appropriate stakeholders (P&S, SSDM, CMS, RMS, and implementing partners) to ensure timely and uninterrupted supply of health commodities.
- Collaboration between the NACP and key stakeholders is required before authorization of the following activities involving movement of ARVs and HIV test kits:
 - Requesting additional supplies from CMS
 - Disposing of expired/damaged stocks
 - Emergency distribution, particularly for replenishment between distribution cycles to ensure continuous availability of ARVs and test kits at facilities to provide uninterrupted HIV services to clients
- The ARVs and medical supplies move downward from the CMS to the regions.
- The supply chain system implements a regular distribution cycle from the RMSs.

The PrEP dispensing officer is responsible for determining commodity order or re-order quantities based on consumption patterns and available stocks and submits same to the logistics management information system (LMIS) for review by the regional health directorate and other stakeholders.

7.1 Preparing the Stock Report

The health facility PrEP dispensing officer uses the following information to complete logistics reports:

- Consumption data from PrEP dispensing register (DR)
- Stock-on-hand data from stock card or physical count report
- Losses and adjustments data from stock card

PrEP logistics report should be completed at the end of every month for timely requisition and resupply of PrEP drugs. The following activities should be implemented before completing the LMIS tool:

- Confirm each commodity is sorted by the expiry date
- Ensure all stocks are available to be counted, including those in bulk or store, at the clinic store and at HIV testing rooms, etc.
- Do a physical count of available stocks to determine the stock on hand (SOH)

7.2 Receiving ARVs and Medical Supplies at Facility Store

- PrEP ARV supplies should be received by the facility stores according to the recommended practices of the MOH.
- The person receiving the commodities at the facility should inspect the entire consignment based on facility regulations:
 - Physically count all re-packed/loose units. Originally sealed boxes do not need to be opened for counting of units.
 - Check expiry date for all ARV packs.
 - Write the physical count for each item into the respective box on the delivery document. Write zero (0) for any items not received – do not leave any check box empty.

- Sign, date, and stamp the delivery note to confirm receipt of the items as indicated.
- The person signing on the delivery note is accountable for all items s/he has signed for. The PrEP dispensing officer will be held responsible for any discrepancies noted later.

7.3 Moving ARVs and Medical Supplies to Storage

- Immediately move the ARVs received into a secure storage area at the facility (clean, dry, cool, and off the floor).
- Enter quantity and date of receipts on stock cards without delay.
- Arrange items by expiry date to make it easy to follow the “first expiry, first out” (FEFO) principle.

7.4 Issuing ARVs and Medical Supplies to Clinic or Pharmacy

- Fill requisition and issue vouchers for all commodities requested from the clinic.
- Follow the FEFO principle ALWAYS.
- Update stock card immediately when moving items out of the pharmacy/clinic.

7.5 Requesting Adjustment and Stock Redistribution

Good planning and coordination will prevent PrEP ARV expiry and stock-out, however, in the unlikely event of a risk of PrEP ARV stock expiry or stock-out, PrEP focal persons should establish contacts with the regional health directorate immediately and contact a neighboring facility for stock redistribution. Before establishing the contact, prepare the following information:

- Number of packs/bottles of PrEP ARVs required
- Expiry date for each ARV drug
- Number of PrEP users on the regimen at your facility and approximate average monthly consumption (AMC)



8. Monitoring and Evaluation



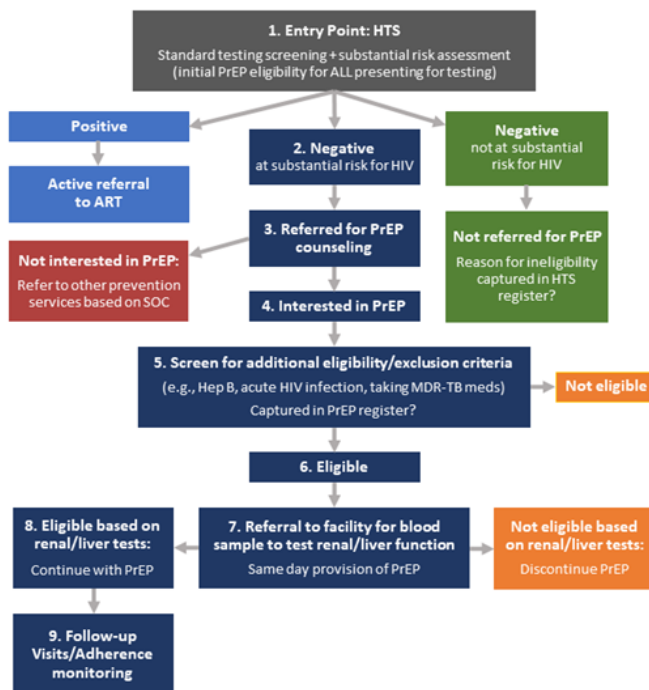
NACP relies heavily on accurate and timely data for programme evaluation, strategic planning, and research. Cleaned data will be shared with donors and stakeholders for drug quantification and procurement. PrEP data analysis and reporting will be done from client PrEP dispensing cards and facility registers at selected PrEP facilities.

- Reporting is done monthly for PrEP, even though daily and weekly summaries are advisable to track missed appointments and losses to follow-up.
- All PrEP reports are to form part of the integrated HMIS reporting form to the MOH.
- Reports from facilities are to be completed within five working days after the end of the reporting period.
- PrEP monitoring and evaluation will be part of the

comprehensive PrEP training schedule.

- Follow the PrEP eligibility algorithm and client flow (Appendix 2) to identify the appropriate tool for reporting.

Figure 4: Flow chart for oral PrEP data collection



8.1 Commonly Used Tools for PrEP Monitoring and Evaluation

- PrEP screening for substantial risk and eligibility
- PrEP screening log
- PrEP facility register
- PrEP follow-up register (PrEP client card)
- PrEP monthly summary form
- Sero-converter tracker
- PrEP quarterly cohort report

8.2 Screening for Substantial Risk and PrEP eligibility

- Administered at the HIV testing site to HIV-negative clients who are potential candidates for PrEP.
- Screening looks at the following:
 - Assessment of substantial risk for HIV infection as a conversation tool for counselling
 - Possibility of acute HIV infection
 - Weight
 - History of liver disease
 - Taking MDR TB drugs

8.3 PrEP Screening Log

The PrEP screening log is completed after the initial PrEP screening. It should include everyone screened for PrEP, regardless of whether they are eligible for PrEP or decline it.

The log shows how many of those screened are eligible for PrEP, and among those eligible, how many accept or decline PrEP.

Consult the PrEP Screening for Substantial Risk and Eligibility form.

- The data help to inform clinics and NACP of the PrEP eligibility and acceptability rate and the main reasons that individuals are ineligible for or decline PrEP.
- The data can inform increased outreach and education efforts and information, education, and communication (IEC) materials.
- The fact that many people screened are ineligible can inform how the screening form might be revised—for example, by adding additional KP or vulnerable groups.

8.4 PrEP Facility Register

- Administered at PrEP dispensing point
- Documents enrollment data from the PrEP enrollment registers
- Captures all follow-up information:
 - Adherence (pill count, missed doses)
 - HIV test results
 - Side effects
 - Next appointment
- Complete the PrEP Facility Record (Appendix 8) with the client using the PrEP Screening for Substantial Risk and Eligibility form (Appendix 6) and guided by the standard operating procedures (Appendices 3–5).
- Complete the PrEP Follow-Up Visits section of this form at each follow-up visit.

8.5 PrEP Follow-Up Register

- Administered at PrEP dispensing point
- Documents enrollment data from PrEP facility registers

Captures all follow-up information:

- Adherence (pill count, missed doses)
- HIV test results
- Side effects
- Next appointment

8.6 PrEP Monthly Summary Form

Optimally, all data from all HIV testing points referring individuals for PrEP within a facility should be combined and reported here.

- The number of clients testing HIV negative is the “denominator” for assessing coverage of who is eligible for PrEP screening. Data for the HIV testing and results table should be taken from clinic HIV testing services registers.
- Source documents to complete this form: Use the PrEP screening log and PrEP client register.
- Sero-converter Tracker
- The tracker is completed during follow-up visits for PrEP clients who seroconvert to HIV positive.
- Source documents to complete this form: PrEP client register and ART records.
- Refer to the variable and code definitions as needed when completing the tracker. The tracker will help ensure appropriate linking and follow-up of clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.

8.7 Sero-converter Tracker

The tracker is completed during follow-up visits for PrEP clients who seroconvert to HIV positive.

Source documents to complete this form: PrEP client register and ART records.

Refer to the variable and code definitions as needed when completing the tracker. The tracker will help ensure appropriate linking and follow-up of clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.

8.8 PrEP Quarterly Cohort Report

This form is used to collect and track data per quarter and PrEP cohort. Source document to complete this form: PrEP client register.

8.9 Confidentiality of Patient Records

- All PrEP client cards and clinic registers are property of the NACP/GHS and may be kept only at the respective facilities or at the National Archives.
- Client cards and clinic registers must be kept in a locked room and are to be accessed only by clinic staff responsible for providing the respective service and by the national supervision team. PrEP clients and named partners may have access to their own individual cards.

8.10 Use of PrEP Facility Registers

- Use only one PrEP facility register in each facility; all multipoint PrEP services must be documented in this single register.
- Turn to a new page when starting to register clients in a new month. Leave any unused rows at the bottom of the previous page empty. This is to separate the month when adding page totals.
- Assign continuous registration numbers (by sequence of registration). Take care not to duplicate registration numbers.
- Continue assigning cumulative registration numbers in the PrEP facility register. These number series are never re-started.



9. Appendices

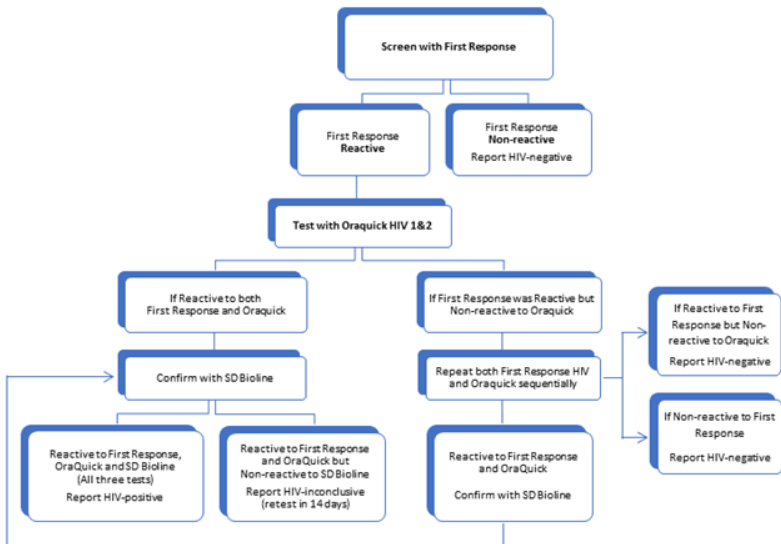


Appendix 1: Training and Certification

All eligible PrEP providers, irrespective of educational level and capacity, must be trained on PrEP service delivery, including the science of PrEP, eligibility determination, platform for service delivery, medication adherence strategies, and monitoring and evaluation. The PrEP Training Package developed by ICAP at Columbia University has been adapted to align with specific policies, the health system, and epidemic context for use with KPs in Ghana. The three-day training package includes:

Day One	Day Two	Day Three
<ul style="list-style-type: none"> • HIV and PrEP basics • ARVs for PrEP and PrEP misconception • PrEP screening and eligibility • Adapted clinical scenarios 	<ul style="list-style-type: none"> • Initial and follow-up PrEP visits • Understanding adherence • Integrated next-steps counseling • Clinical role-plays • Monitoring and managing PrEP side effects 	<ul style="list-style-type: none"> • PrEP follow-up visits • Entry points for PrEP • PrEP monitoring and evaluation • Commodity management and reporting

Appendix 2: National HIV Testing Algorithm for Non-Pregnant Women and General Population in Ghana



Appendix 3: Summary of Sample tools used for collecting data

The integration of PrEP and HIV self-test services entails reporting on both services once they are provided.

TOOL NO.	TOOL NAME	FREQ.
ENGAGING KEY POPULATION SIZE ESTIMATION, MAPPING, AND PROGRAM PLANNING		
1	Peer Educators Daily Activity Sheet	Daily
PEER OUTREACH		
2	Key Population Individual Tracking Sheet	Daily
3	Pre-Exposure Prophylaxis (PrEP) Monthly Summary Form	Monthly
4	Pre-Exposure Prophylaxis (PrEP) Assessment and Eligibility Tool	As needed
5	Pre-Exposure Prophylaxis (PrEP) Register	As needed
6	Client Appointment Card	As needed
7	Self-Testing Referral Coupon	As needed
8	Consolidated ARVs Report	Monthly
9	HIVST Monthly Inventory Reporting Form	Monthly
CLINICAL SERVICES		
10	HIV Testing and Counselling (HTC) Monthly Summary Form	Monthly
11	HIVST Kits Distribution Tally Book	As needed
12	HIV Testing and Counselling (HTC) Register	As needed
13	Monthly Commodity Management and Reporting Form	Monthly
STRUCTURAL INTERVENTION		
14	Social Harm/Adverse Events Register	As needed
15	Social Harm/Adverse Events Screening Tool	As needed

Appendix 4: Standard Operating Procedures (SOPs) for Pre-Exposure Prophylaxis (PrEP)

Indicator	Indicator Priority	Disaggregation	Data Source	Frequency of Reporting	Level of Use
Number of people screened for PrEP	Primary	Age, gender and facilities	PrEP Assessment and Eligibility Tool, PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District
Number of people Eligible for PrEP services	Primary	Age, gender and facilities	PrEP Assessment and Eligibility Tool, PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District
Number of eligible persons who initiated on PrEP	Primary	Age, gender and facilities	PrEP Assessment and Eligibility Tool, PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District
Number of PrEP users who continued on PrEP having been initiated PrEP	Primary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District
Number of PrEP people who Seroconvert	Primary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District
Number of PEP users who transitioned from PEP to PrEP	Secondary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Facility, Sub-district & District

Indicator	Indicator Priority	Disaggregation	Data Source	Frequency of Reporting	Level of Use
Percentage of eligible persons who initiated on PrEP	Primary	Age, gender and facilities	PrEP Assessment and Eligibility Tool, PrEP Client Register & PrEP Monthly Summary Form	Monthly	Regional & National
Percentage of PrEP users who continued on PrEP having been initiated PrEP	Primary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Regional & National
Percentage of PrEP users who Seroconvert	Primary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Regional & National
Percentage of PEP users who transitioned from PEP to PrEP	Secondary	Age, gender and facilities	PrEP Client Register & PrEP Monthly Summary Form	Monthly	Regional & National

Appendix 5a: Pre-Exposure Prophylaxis (PrEP) Assessment Tool

1. Facility Information		
Facility Name		
Date of Initial Client Visit (<i>dd/mm/yyyy</i>) ____/____/____	Person Completing Form	
2. Client Information		
First Name	Middle Name	Surname
Address	Telephone #	
Client ID Number		
3. Client Demographics		
What was your sex at birth?	<input type="checkbox"/> Male <input type="checkbox"/> Female	
What is your current gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender (male to female) <input type="checkbox"/> Transgender (female to male) <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No response/Prefer not to say	
What is your age? (Specify number of years.)	_____	
HIV Test Result	Positive <input type="checkbox"/> . Negative <input type="checkbox"/> . Don't know <input type="checkbox"/> . (If negative or not known, offer testing)	
4. Screening for Substantial Risk for HIV Infection – use information as counselling tools		
Client is at substantial risk if he/she belongs to categories ①, ②, or ③ below	Question Prompts for Providers	
① If client is sexually active in a high HIV prevalence population PLUS reports ANY one of the below in the last 6 months	Have you been sexually active in the last 6 months?	
<input type="checkbox"/> Reports sexual intercourse without condoms	In the last 6 months, have you had unprotected sex?	
Client population type	FSW <input type="checkbox"/> Adolescent <input type="checkbox"/> MSM <input type="checkbox"/> Transgender <input type="checkbox"/> Serodiscordant <input type="checkbox"/> PWID <input type="checkbox"/> High risk man <input type="checkbox"/> High risk woman <input type="checkbox"/>	
<input type="checkbox"/> History of a sexually transmitted infection (STI) based on self-report, lab test, syndromic STI treatment	In the last 6 months, have you had an STI?	
<input type="checkbox"/> History of use of post-exposure prophylaxis (PEP)	In the last 6 months, have you taken post-exposure prophylaxis (PEP) following a potential exposure to HIV?	

<p>2 If client reports history of sharing injection material or equipment in the last 6 months</p> <p><input type="checkbox"/> History of sharing injection material or equipment</p>	<p>In the last 6 months, have you shared injecting material with other people?</p>
<p>3 Do you know if your partner is HIV positive?</p>	<p>Yes <input type="checkbox"/>. No <input type="checkbox"/>. Don't know <input type="checkbox"/></p>
<p>Is client at substantial risk?</p>	<p>Yes <input type="checkbox"/>. No <input type="checkbox"/></p>

5. Recent Exposure to HIV

<p>Ask the client: In the past 72 hours, have you had sex without a condom with someone whose HIV status is positive or not known to you, or have you shared injection equipment with someone whose HIV status is positive or unknown to you?</p>	<p><input type="checkbox"/> *Yes</p>	<p><input type="checkbox"/> No</p>	<p><input type="checkbox"/> Don't know</p>
<p>In the past 28 days, have you had symptoms of a cold or flu, including fever, fatigue, sore throat, headache, or muscle pain or soreness?</p>	<p><input type="checkbox"/> *Yes</p>	<p><input type="checkbox"/> No</p>	<p><input type="checkbox"/> Don't know</p>

*** If the client reports potential exposure to HIV within past 72 hours, do NOT offer PrEP. Follow facility procedures to evaluate further or refer for evaluation for post-exposure prophylaxis (PEP).**
**** If the client reports flu-like symptoms or other signs of acute HIV infection, do NOT offer PrEP and evaluate further, following facility procedures to diagnosis acute HIV infection.**

6. PrEP Eligibility

<p>Client is eligible if any of the criteria below is fulfilled.</p>	
<p><input type="checkbox"/> HIV negative</p>	<p>Date client tested: (dd/mm/yyyy): ____/____/____</p> <p>Date client received test results: (dd/mm/yyyy): ____/____/____</p> <p>—</p> <p>Test result: <input type="checkbox"/> Negative <input type="checkbox"/> Positive (Refer to HIV medical care.) <input type="checkbox"/> Inconclusive (Re-test in 14 days.)</p> <p>Type of test used: <input type="checkbox"/> First Response <input type="checkbox"/> Combo <input type="checkbox"/> OraQuick <input type="checkbox"/> SD Bioline</p>
<p><input type="checkbox"/> At substantial risk of HIV</p>	<p>At least one item/risk in Section #4 above is ticked.</p>
<p><input type="checkbox"/> Has no signs/symptoms of acute HIV infection</p>	<p>See Section #6 below to confirm no recent exposure to HIV</p>
<p><input type="checkbox"/> Creatinine clearance (eGFR) >60 ml/min (where required)</p>	<p>Result: _____ Date of creatinine test (dd/mm/yyyy): ____/____/____</p>

This assessment tool should be used as a guide to counsel clients and not a barrier to accessing PrEP

7. Services Received by Client

PrEP offered.

• PrEP accepted.

Daily oral PrEP

Event-Drive (ED) PrEP

DPrV-VR

CAB-LA

• PrEP declined. *(If declined, see Reasons for Declining PrEP, below).*

Date eligible (dd/mm/yyyy): ___/___/_____

Date initiated (dd/mm/yyyy): ___/___/_____ *Same-day initiation recommended.*

Reasons for Declining PrEP

(Check all that apply.)

No need for PrEP

Does not wish to take a daily medication

Concerns about side effects

Concerns about what others might think

Concerns about time required for clinic follow-up

Concerns about safety of medication

Concerns about effectiveness of medication

Other *(specify):*

Referred for PrEP evaluation

Referred for PCR/HIV Ag test or follow-up HIV re-testing (if suspicion of acute HIV infection)

Appendix 5b: Standard Operation Procedures for PrEP assessment tool

Tool 9: Pre-Exposure Prophylaxis (PrEP) Assessment Tool	
This tool records information and data on clients screened for PrEP initiation eligibility, those initiated and monitored on PrEP. On the tool, transfer each client information from the screening tool to this register.	
Who should complete	Health facility staff
When to complete	Each time a client is accessing PrEP services in the health facility
BACKGROUND INFORMATION	INSTRUCTIONS
REGION	Name: Write the name of the region where the health is located
DISTRICT	Name: Write the name of the metropolitan, municipal or district where the health facility is located
SUB-DISTRICT	Name: Write the name of the sub-district where the health facility is located
FACILITY	Name: Write the name of the health facility
SERVICE DELIVERY POINT	Name: Write the name of the health facility where the service is provided (Tick against Facility if the PrEP service is provided in a health facility or Tick against Community if the PrEP service is in a community)
DATE OF CLIENT FIRST VISIT	Write the date the client is visiting the facility for the first time for this screening service. The date should take the format DD/MM/YYYY
PERSON COMPLETING FORM	Name: Write the name of the health staff providing the screening service
IMPLEMENTING PARTNER	Write the name of the organization such as Ghana Health Service, WAPCAS, etc.
YEAR	Name: Write the name of the year the PrEP distribution is taking place
NEW VARIABLES ADDED TO SCREENING TOOL	DEFINITION
TYPE OF CLIENT NEW [] OLD [] CONTINUING []	Tick against the type of client presenting in your facility
CLIENT ID: ECOWAS/GHANA CARD [] NHIS ID []	Tick against the national identity card(s) among these two cards the client is presenting at health for the PrEP services
CLIENT ID NUMBER	Write the national identity number of the card(s) a client is presenting in a health for the PrEP screening and services.
CLIENT POPULATION TYPE FSW [] MSM [] PWID [] HIGH RISK MAN [] HIGH RISK WOMEN [] SERODISCORDANT [] ADOLESCENT [] TRANSGENDER []	Tick against the specific population type the client belongs to
IS CLIENT AT SUBSTANTIAL RISK YES [] NO []	Tick against the appropriate response following the complete screening (after taking the client through all the questions)
IS CLIENT ELIGIBLE FOR PrEP? YES [] NO []	Tick against the appropriate response following the complete screening (after taking the client through all the questions)
IS CLIENT MOVING FROM PER TO PrEP? YES [] NO []	Tick against the appropriate response following the complete screening (after taking the client through all the questions)

Appendix 6a: Client Appointment Card

REGISTRATION/START FACILITY					NEW FACILITY (REFERRED CLIENTS FOR CONTINIUM OFCARE)			
Region: District: Sub-district: Facility:					Region: District:			
Sex: Date of Birth: Age:					Sub-district:			
National ID Type & ID No [Type: Ecowas/Ghana Card [] NHIS [] ID No.:					New Facility:			
Start ID:					Date of Referral:			
Registration/E-Tracker No					Date Seen at New Facility:			
Date First Seen in Registration/Start Facility:					New Facility ID (if Any)			
Date	Regimen	Dose & Frequency	Duration of Supply	Next Appointment Date	Next Refill Date	Date Refill Is Done	Name of Person doing Refill	Remarks

Appendix 6b: SOP for Client Appointment Card

Tool 10: Client Appointment Card	
This tool records information and data on clients HIV care appointment and referral services. This tool will ensure effective continuum of care for all HIV clients.	
Who should complete	Health facility staff
When to complete	Each time a client is accessing PrEP services in the health facility
BACKGROUND INFORMATION	INSTRUCTIONS
REGION	Name: Write the name of the region where the health is located
DISTRICT	Name: Write the name of the metropolitan, municipal or district the health facility is located
SUB-DISTRICT	Name: Write the name of the sub-district where the health facility is located
FACILITY	Name: Write the name of the health facility
SEX	SEX: Write the sex (male or female) of the client
DATE OF BIRTH	Write the client date of birth using the format DD/MM/YYYY . If the client is not able to tell the date of birth, use any of the national identity cards such as ECOWAS/GHANA CARD, NHIS CARD etc., the date of birth should be referenced on it of the health staff providing the screening service
AGE	Write the client age in completed years. Use the date of birth to guide in the age determination if client is not able to tell
NATIONAL ID TYPE & ID NO.: ECOWAS/GHANA CARD [] NHIS ID []	Tick against the national identity card(s) among these two cards the client is presenting at the health facility
ID NUMBER	Write the national identity number of the card(s) a client is presenting at the health facility
START ID	Write the serial number the client is assigned with in the health facility register
REGISTRATION/E-TRACKER NUMBER	Write the client registration number or e-tracker number the client is assigned with in the health facility
DATE FIRST SEEN IN REGISTRATION/START FACILITY	Write the date the client is visiting the facility for the first time for the service. The date should take the format DD/MM/YYYY
NEW FACILITY	Write the name of the health facility the client is presenting for continued HIV care services
DATE OF REFERRAL	Write the date the client is being referred to the new or receiving health facility for continued HIV care services. The date should take the format DD/MM/YYYY
DATE SEEN AT NEW FACILITY	Write the date the client is seen in the new or receiving health facility upon the referral. The date should take the format DD/MM/YYYY
NEW FACILITY ID (IF ANY)	Write the client serial or any number the client is assigned with in the new or receiving health facility
DATE	Write the date the client is being provided with first HIV care service e.g., ARVs supply, PrEP medicines supply. The date should take the format of DD/MM/YYYY
REGIMEN	Write the name of the ARVs dispensed to the client
DOSE & FREQUENCY	Write the daily dose and number of times the client is expected to take the ARVs
DURATION OF SUPPLY	Write number of months ARVs the client is supplied with
NEXT APPOINTMENT DATE	Write the new date the client is scheduled to revisit the health facility. The date should take the format of DD/MM/YYYY
NEXT REFILL DATE	Write the date the client is scheduled to revisit health facility for ARVs resupply. The date should take the format of DD/MM/YYYY
DATE REFILL IS DONE	Write the date the client is revisited the health facility and additional ARVs resupplied. The date should take the format of DD/MM/YYYY
NAME OF PERSON DOING REFILL	Write the full name of the health staff providing the client with the additional ARVs on scheduled revisit date. The full name should take the form of: Last Name Surname Other Names
REMARKS	Write any observation made on the client whilst on HIV care. It can be on ARVs adherence, appointment date adherence, pill count, viral load test, viral load result etc.

Appendix 7a: PrEP Register

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF			
SN	Date of PrEP Initiation	Type of Client ID (ECHO WAS/ Ghana Card NHIS)	Client ID Number	Client Registration Number	PEP Client? (Yes/No)	Suriname	Other Names	Traceable address	Contact Number(s)	Date of Birth	Age (Years)	Sex at Birth (M/F/O/No R)	Gender (M/F/T/G/O)	Key Populations Client (Facility/Community)	Point of initiation (Refer to Code at Bottom of Page)	Client Move from PrEP to PrEP (Yes/No)	PrEP (ARVs) Prescribed	No. of Days Prescribed	PrEP Option	Visit Date	HIV Testing	Result (Neg/Pos/Inc)	PrEP Side Effects (Refer to Codes at Bottom of Page)	PrEP (ARVs) Prescribed	No. of Days Prescribed	Visit Date	HIV Testing	Result (Neg/Pos/Inc)	PrEP Side Effects (Refer to Codes at Bottom of Page)	PrEP (ARVs) Prescribed	No. of Days Prescribed			
1															Y / N		<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR																	
2															Y / N		<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR																	

AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ
Follow-Up Visit 3					Follow-Up Visit 4					Follow-Up Visit 5					PREP	Re-Initiation of PREP													
Visit Date					Visit Date					Visit Date					Date	Date	Stopped Date	Reasons	Reasons	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	Died	Lost to Follow-up	Other	Type of Client	New, Old, Continuing & Transfer	
HIV Testing Date: _____ Result: _____ (Refer to column 10 of Annex 1)					HIV Testing Date: _____ Result: _____ (Refer to column 10 of Annex 1)					HIV Testing Date: _____ Result: _____ (Refer to column 10 of Annex 1)					Reasons (tick codes)	Date (Enter visit information in first available follow-up column)	Reasons (Refer to codes in column of report)	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	Died	Lost to Follow-up	Other	Type of Client	New, Old, Continuing & Transfer			
PREP (ARVs) Prescribed (Refer to column 11 of Annex 1)					PREP (ARVs) Prescribed (Refer to column 11 of Annex 1)					PREP (ARVs) Prescribed (Refer to column 11 of Annex 1)					Reasons (tick codes)	Date (Enter visit information in first available follow-up column)	Reasons (Refer to codes in column of report)	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	Died	Lost to Follow-up	Other	Type of Client	New, Old, Continuing & Transfer			
<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					Reasons (tick codes)	Date (Enter visit information in first available follow-up column)	Reasons (Refer to codes in column of report)	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	Died	Lost to Follow-up	Other	Type of Client	New, Old, Continuing & Transfer			
<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					<input type="checkbox"/> TDF/FTC <input type="checkbox"/> CAB-LA <input type="checkbox"/> DPV-VR					Reasons (tick codes)	Date (Enter visit information in first available follow-up column)	Reasons (Refer to codes in column of report)	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	No. of Days Prescribed	Died	Lost to Follow-up	Other	Type of Client	New, Old, Continuing & Transfer			

CODES:**PrEP Side effects:**

A = Abdominal pain, S = Skin rash, Nau - Nausea, V = Vomiting,
D = Diarrhoea, F = Fatigue, H = Headache, L = enlarged lymph nodes,
R = Fever, O = Other (specify)

Reasons for stopping PrEP:

H = Tested HIV +, R = No longer at substantial risk, S = Side effects,
C = Client preference, AB = Abnormal creatinine result, O = Other
(specify)

Key Population:

MSM = Men who have sex with men, TG = Transgender, SW = Sex
worker, PWID - Person who injects drugs, PP = Person in prison,
O = Other (specify)

Appendix 7b: SOP for Facility Pre-Exposure Prophylaxis (PrEP) Register

Tool 9: Pre-Exposure Prophylaxis (PrEP) Register	
<p>This tool records information and data on clients screened for PrEP initiation eligibility, those initiated and monitored on PrEP. Most of the information and data for this register can be obtained from the PrEP assessment and eligibility tool the tool.</p>	
Who should complete	Health facility staff
When to complete	Each time a client is accessing PrEP services in the health facility
NEW VARIABLES ADDED	INSTRUCTIONS
TYPE OF CLIENT ID ECOWAS/GHANA CARD, NHIS ID	Write the national identity card(s) among these two cards the client is presenting at the health facility
PEP CLIENT (YES/NO)	Indicate by writing Yes if the client is on Post-Exposure Prophylaxis (PEP) or No if the is not on Post-Exposure Prophylaxis (PEP)
CLIENT MOVE FROM PEP TO PREP (YES/NO)	Indicate by writing Yes if the client was on Post-Exposure Prophylaxis (PEP) and now moved to Pre-Exposure Prophylaxis (PrEP) or No if the is not on moving from Post-Exposure Prophylaxis (PEP) to Pre-Exposure Prophylaxis (PrEP)
TYPE OF CLIENT NEW [] OLD [] CONTINUING []	Tick against the type of client presenting in your facility

Appendix 8a: PrEP Monthly Summary Form

PRE-EXPOSURE (PrEP) MONTHLY SUMMARY FORM										
Region:		District:			Sub-district:					
Facility:		Month:			Year:					
Indicator(s)	Gender/ Population	Age Group (Years)								Total
		15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
Number of Peoplescreened for PrEP	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other(s)									
Number of PeopleEligible for PrEP services	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other(s)									
Number of PeopleWho initiated on PrEP	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other (s)									
Number of Continuing on PrEPHaving Initiated	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other (s)									
Number of PEP Users Who Transitioned to PrEP	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other (s)									
Number of PrEP Users Who Serocovert	Male									
	Female									
	Transgender									
	MSM									
	FSW									
	Other(s)									

Completed By:

Designation:

Contact:

Date

Endorsed By:

Designation:

Contact:

Date

Appendix 8b: SOP for Pre-Exposure Prophylaxis (PrEP) Monthly Summary Form

Tool 8: Pre-Exposure Prophylaxis (PrEP) Monthly Summary Form	
This monthly reporting form provides data on the key indicator variables for programmatic decisions at the national and sub-national levels.	
Who should complete	Health facility staff
When to complete	Monthly
BACKGROUND INFORMATION	INSTRUCTIONS
REGION	Name: Write the name of the region where the health facility is located
DISTRICT	Name: Write the name of the metropolitan, municipal or district the health facility is located
SUB-DISTRICT	Name: Write the name of the sub-district where the health facility is located
FACILITY	Name: Write the name of the health facility
MONTH	Name: Write the name of the month for the service data
YEAR	Name: Write the year for the service data
INDICATOR(S)	DEFINITION
INDICATORS	The data variables under measurement
NUMBER OF PEOPLE SCREENED FOR PrEP	This is the number of clients screened for PrEP by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up male, female, transgender, MSM, FSW, Others
NUMBER OF PEOPLE ELIGIBLE FOR PrEP SERVICES	This is the number of clients screened and qualified for PrEP initiation by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up of male, female, transgender, MSM, FSW, Others
NUMBER OF PEOPLE WHO INITIATED ON PrEP	This is the number of clients qualified for PrEP and initiated on PrEP by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up of male, female, transgender, MSM, FSW, Others
NUMBER OF CONTINUING ON PrEP HAVING INITIATED	This is the number of clients initiated on PrEP and they continuous to be on PrEP by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up of male, female, transgender, MSM, FSW, Others
NUMBER OF PEP USERS WHO TRANSITIONED TO PrEP	This is the number of clients started on PEP and now moved to PrEP by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up of male, female, transgender, MSM, FSW, Others
NUMBER OF PrEP USERS WHO SEROCOVERT	This is the number of clients that started PrEP with negative HIV test but later tested HIV positive whilst on PrEP by age bracket and gender categorizations obtained from the PrEP register. The age bracket starts at 15 years to 59 years+. The gender is made up of male, female, transgender, MSM, FSW, Others
COMPILED BY	This is the name of the person completing the reporting form for that month and year

DESIGNATION	The is the professional grade/cadre of the officer completing the reporting form for that month and year
DATE	This is the date the officer is completing the reporting form for that month and year. The date should take the format DD/MM/YYYY
SIGNATURE	This is the official or formal signature the officer completing the reporting form for that month and year is identified and associated to
CONTACT NUMBER	This is the personal mobile phone number the officer completing the reporting form for that month and year is known to use in his/her personal daily communications
ENDORSED BY	This is the name of the supervisor of the person completing the reporting form for that month and year who is authorizing the report
DESIGNATION	The is the professional grade/cadre of the supervisor of the officer completing the reporting form for that month and year who is authorizing the report
DATE	This is the date the supervisor is authorizing the report for the month and year. The date should take the format DD/MM/YYYY
SIGNATURE	This is the official or formal signature of the supervisor authorizing the report for the month and year
CONTACT NUMBER	This is the personal mobile phone number of the supervisor authorizing the report for the month and year

Appendix 9a: Self-Testing Referral Coupon

The Ghana Health Service

SELF TESTING REFERRAL COUPON

Date: _____

Referring Facility: _____

Service Referred for: _____

Facility Referred To: _____

Officer Name: _____ Contact: _____

Signature _____



Ghana Health Service
Your Health - Our Concern

Appendix 9b: SOP for Self-Testing Referral Coupon

Tool 13: Self-Testing Referral Coupon

This tool will be used to refer clients to health facilities for confirmatory testing.

Who should complete	Health facility staff, HIVST distribution point/outlet officer, peer educator, model-of-hope
When to complete	Transactional (as and when it is required)
BACKGROUND INFORMATION	INSTRUCTIONS
DATE	This is the date the client is been referred to the health facility for confirmatory testing. The date should take the format of DD/MM/YYYY
REFERRING FACILITY	Write the name of the health facility or distribution point/outlet referring the client for further services in another or different health facility
SERVICE REFERRED FOR	Write the list of services the client is referred to the other health facility for. This can be for confirmatory HIV testing, for PEP, for PrEP etc.
FACILITY REFERRED TO	Write the name of the health facility the client is referred to for the services
OFFICER NAME	This is the name of the person referring the client and completing the referral coupon
CONTACT	This is the personal mobile phone number the officer referring the client and completing the referral coupon
SIGNATURE	This is the official or formal signature the officer referring the client and completing the referral coupon is identified and associated to

Appendix 10a: Social Harm/Adverse Events Screening Tool

INTRODUCTION: This tool can be administered to any client that accesses any of the HIV care services, either health facility-based or community-based service. Any additional support services such as referral to Legal Aid, DOVVSU, Police, CHRAJ, Medical Service in a Health Facility, Social Welfare. Please you are assured that your answers to this screening shall be kept strictly confidential. This tool should be administered on clients seeking any form of HIV care services.

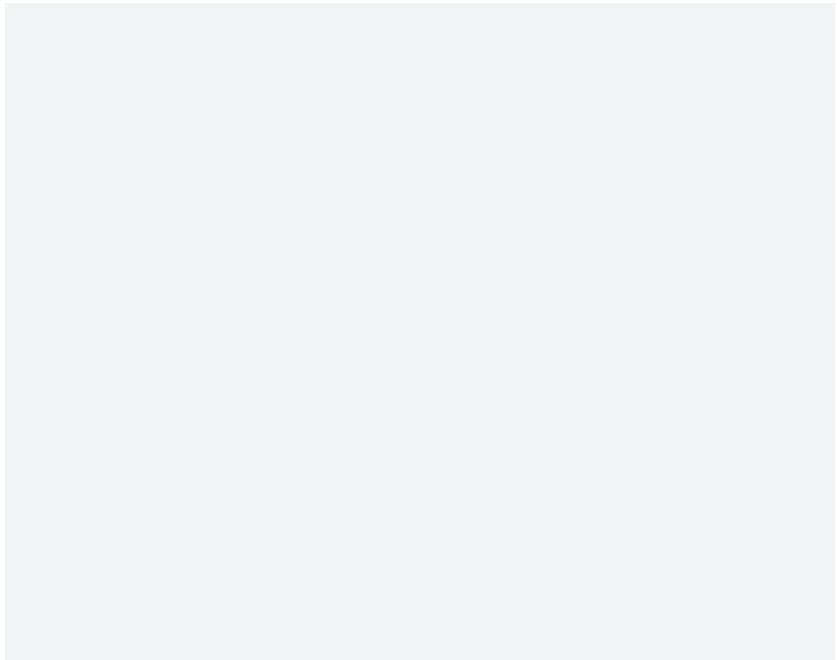
Region: _____ District: _____ Sub-district: _____

Service Delivery Point: _____ Name: _____

Service Accessed HIVST Kit PEP PrEP Age: ____ Sex: _____

Date Commenced: _____ Date: _____

Implementor Organization/Partner: _____



Have you experienced any of the following in the last month?	Response		Comment/Remarks
	Yes	No	
Tick appropriately			
1. Have you been physically assaulted by your partner (s) (current/previous) or any other person?			
(If Yes) What is the relationship between you and that person? <input type="checkbox"/> Husband <input type="checkbox"/> Wife <input type="checkbox"/> Ex-Husband <input type="checkbox"/> Ex- Wife <input type="checkbox"/> Boyfriend <input type="checkbox"/> Girlfriend <input type="checkbox"/> Ex-Boyfriend <input type="checkbox"/> Ex-Girlfriend <input type="checkbox"/> Family Member <input type="checkbox"/> Friend <input type="checkbox"/> No Relationship			
If Yes to question 1, did you sustain any injury that required attention?			
Service Provider (what action did you take to support victim) *Referred for treatment for injuries sustained Yes *referred to the DOVVSU (Mfriend) and legal counsel with informed consent from the survivor. No *referred to police (Mfriend) with consent from the survivor.			
2. Have you had sex against your will with or without a condom? If Yes to question 2, who forced you to have the sex against your will with or without a condom? <input type="checkbox"/> Husband <input type="checkbox"/> Wife <input type="checkbox"/> Ex-Husband <input type="checkbox"/> Ex-Wife <input type="checkbox"/> Boyfriend <input type="checkbox"/> Girlfriend <input type="checkbox"/> Ex-Boyfriend <input type="checkbox"/> Ex-Girlfriend <input type="checkbox"/> Family Member <input type="checkbox"/> Friend <input type="checkbox"/> No Relationship			
If Yes, did it happen within the last 3 days?			
If Yes, did you access,			
Rapid HIV Test			
STIs Screening/Treatment			
Emergency contraceptive service (for female clients only)			
PEP Services			
PrEP Services			
Other (Specify)			
3. Does your sexual partner or any other person deliberately tell you things in order to hurt you or threaten to harm you? If Yes to question 3, what is the relationship between you and that other person? <input type="checkbox"/> Husband <input type="checkbox"/> Wife <input type="checkbox"/> Ex- Husband <input type="checkbox"/> Ex-Wife <input type="checkbox"/> Boyfriend <input type="checkbox"/> Girlfriend <input type="checkbox"/> Ex-Boyfriend <input type="checkbox"/> Ex-Girlfriend <input type="checkbox"/> Family Member <input type="checkbox"/> Friend <input type="checkbox"/> No Relationship			
4. Does your sexual partner or any other person deliberately deprive you of economic support? If Yes to question 4, What is the relationship between you and that other person? <input type="checkbox"/> Husband <input type="checkbox"/> Wife <input type="checkbox"/> Ex-Husband <input type="checkbox"/> Ex-Wife <input type="checkbox"/> Boyfriend <input type="checkbox"/> Girlfriend <input type="checkbox"/> Ex-Boyfriend <input type="checkbox"/> Ex-Girlfriend <input type="checkbox"/> Family Member <input type="checkbox"/> Friend <input type="checkbox"/> No Relationship			
5. Which of these did you experienced? <input type="checkbox"/> Marriage Break-Up <input type="checkbox"/> Blame <input type="checkbox"/> Verbal Abuse <input type="checkbox"/> Physical Abuse <input type="checkbox"/> Sexual Abuse <input type="checkbox"/> Economic <input type="checkbox"/> Hardships <input type="checkbox"/> Frustration <input type="checkbox"/> Decreased Trust <input type="checkbox"/> Weaker Relationships <input type="checkbox"/> Coercion <input type="checkbox"/> Test <input type="checkbox"/> Coercion to Disclose <input type="checkbox"/> Suicide Intentions <input type="checkbox"/> Victim is Dead <input type="checkbox"/> Others (Specify)			
6. Has victim been referred to any level for redress and support services?			
If Yes to question 6, where has victim been referred to ?			
DOVVSU			
CHRAJ			
Legal Aid			
Social Welfare			
Police			
Health Facility			
Others (Specify)			
7. Was Psychosocial support provided to victim? If No *Survivors should be offered psychosocial support with Social Welfare			

Service Provider:

Contact No.:

Signature:

Date:

Appendix 10b: SOP for Social Harm/Adverse Events Screening Tool

Tool 5: Social Harm/Adverse Events Screening Tool	
<p>This tool records the various community/household levels social harms/adverse events persons using the intervention are experiencing and reporting to the officer or identified during the screening process. This Screening can be used on both HIVST Users and PrEP Users.</p> <p>On the main tool, ask/assess the client for each of the questions and provide the appropriate responses. Write down any observed or client-self reported issue at the comment/remark's column during the screening process.</p>	
Who should complete	Health staff, distribution point officers, peer educators, model-of-hope
When to complete	Each time the health facility staff, distribution point/outlet attendant or peer educator or model-of-hope encounters a client (new or old)
BACKGROUND INFORMATION	INSTRUCTIONS
REGION	Name: Write the name of the region where the health facility/distribution point/outlet is located
DISTRICT	Name: Write the name of the metropolitan, municipal or district the health facility/distribution point/outlet is located
SUB-DISTRICT	Name: Write the name of the sub-district where the health facility/distribution point/outlet is located
SERVICE DELIVERY POINT	Name: Write the name of the HIVST Kits health facility/distribution point/outlet
NAME	Write the name of the client the service is being provided/conducted for in the format of last Name: Surname: Other Names:
AGE	Write the client complete age in years as at the day of the service Provision
SEX	Write the sex (male or female) the client is identified with
DATE	Write the date service is being provided to the client. The date should take the format DD/MM/YYYY
SERVICE ACCESSED	Tick against the service the client is currently seeking (HIVST Kit, PEP or PrEP) Add up all sex tallied totals under each of the age brackets, 15 years to unknown age
DATE COMMENCED	Write the date the service accessed started. The date should format of DD/MM/YYYY
IMPLEMENTING ORGANIZATION/PARTNER	Write the name of the organization such as Ghana Health Service, WAPCAS, etc.
SERVICE PROVIDER	This is the name of the officer that is providing the service to the client
CONTACT NUMBER	This is the personal mobile phone number the officer providing the services to the client is known to use in his/her personal daily communications
SIGNATURE	This is the official or formal signature the officer providing the services to the client is identified and associated to
DATE	This is the date the officer is providing services to the client The date should format of DD/MM/YYYY

Appendix 11a: Social Harm/Adverse Events Register

NATIONAL AIDS/STI CONTROL

REGION:		DISTRICT:		SUB-DISTRICT:		FACILITY:														
No.	Date	Name	Age	Sex	Type of Social Harm/Adverse Event Identified (Tick All That Apply)															
					Marriage Break Up	Blame	Verbal Abuse	Physical Abuse	Sexual Abuse	Economic	Hardships	Frustration	Decreased Trust	Weaker Relationships	Coercion to Test	Coercion to Disclose	Suicide Intentions			
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
TOTAL				M= F=																

PROGRAMME (NACP)

IMPLEMENTING ORGANIZATION/PARTNER:

MONTH:

YEAR:

s)	Victims Referrals for Redress & Support Services								Assistance Provided				Clinical Care Services Provided					
	Tick All That Applies								(CHRAJ) Mediation, education, investigation & other services	(DOVVSU) Police Report filed, obtain medical report, legal advice, prepare case docket & other services.	(LEGAL AID) Legal Advise and other services	(SOCIAL WELFARE) Psycho-social support and other services	Tick All That Applies					
	Victim is Dead	Other (Specify)	DOVVSU	CHRAJ	Legal Aid	Social Welfare	Police	Health Facility					Others (Specify)	Rapid HIV Test	STIs Screening/Treatment	Emergency Contraceptive	PEP Services	PrEP Services

Appendix 11b: SOP for Social Harm/Adverse Events Register

Tool 6: Social Harm/Adverse Events Register

This register records the details of individual clients provided with social harm/adverse events screening services. On the screening tool, transfer each client information onto this register. This Register should be used to record service data for both HIVST Users and PrEP Users.

Who should complete	Health staff, distribution point officers, peer educators, model-of-hope
When to complete	Each time a client (new or old) is accessing services and the tool is completely filled
BACKGROUND INFORMATION	INSTRUCTIONS
REGION	Name: Write the name of the region where the health facility/distribution point/outlet is located
DISTRICT	Name: Write the name of the metropolitan, municipal or district the health facility/distribution point/outlet is located
SUB-DISTRICT	Name: Write the name of the sub-district where the health facility/distribution point/outlet is located
FACILITY	Name: Write the name of the health facility/distribution point/outlet
IMPLEMENTING ORGANIZATION/PARTNER	Write the name of the organization such as Ghana Health Service, WAPCAS, etc.
MONTH	Name: Write the name of the month the service is taking place
YEAR	Name: Write the name of the year the service is taking place

