



1. Background

HIV STAR will introduce HIVST to general populations in Malawi and conduct implementation research to investigate the social, economic and health impacts of HIVST. This sub-study consists of a cluster randomized trial (CRT) investigating the impact of introducing HIVST to the general population in Malawi through Community Based Distribution Agents (CBDAs).

2. Purpose

This SOP describes the community liaison system for reporting social harms and Serious Adverse Events (SAEs) linked to HIV testing/Self-testing as part of the STAR project.

3. Definitions

A. Social harms (within the context of HIV testing)

Social harm is defined as the intended or unintended cause of physical, economic, emotional, or psychosocial injury or hurt. It can be from one person to another, or a person to themselves. It can occur before, during or after self-testing for HIV. It may be the result of the threat of or actual force or power. Examples include forced or unwanted pressure to test and disclose HIV status; psychological or economic pressure after testing; physical, sexual, verbal or emotional abuse following self-testing, and forms of Gender Based Violence (GBV).

Social harms of interest include:

- Being beaten by a partner or relative
- Sexual violence, including rape by partner
- Intimidation at work, school or else where
- Verbal, psychological or emotional abuse
- Extreme forms of discrimination
- Marriage dissolution

B. Gender Based Violence

The Declaration on the Elimination of Violence against Women (United Nations 1993), defines GBV or violence against women as “any act of gender-based violence that results in, or is likely to result in, physical, sexual or psychological harm or suffering to women, including acts such as arbitrary deprivation of liberty, whether occurring in public or in private life.” This definition should encompass, but is not be limited to, acts of physical, sexual, and psychological violence in the family, community, or perpetrated or condoned by the State, wherever it occurs. These acts include: being beaten by a partner, relative or community member, rape by a partner, harassment and intimidation at work, in school and elsewhere, psychological or emotional abuse.

Below are some of the forms of violence that can occur:

- **Sexual violence** – Any act, attempt, or threat of a sexual nature that result, or is likely to result in, physical, psychological and emotional harm. Examples of sexual violence includes rape by partner.
- **Physical violence** – Refers to the deliberate use of physical force with the potential of causing harm or hurt, such as battery and enslaving.
- **Emotional and psychological violence** – Psychological abuse, also referred to as psychological violence, emotional abuse or mental abuse, is a form of abuse characterized by a person subjecting or exposing another to behavior that may result in psychological trauma, including anxiety, chronic depression, post-traumatic stress disorder, humiliation and confinement.
- **Verbal abuse** – Verbal abuse (also known as reviling or "verbal bullying") is described as a negative defining statement told to the victim or about the victim, or by withholding any response, thereby defining the target as non-existent.

C. Serious Adverse Events (within the context of HIV testing)

An adverse experience or adverse event is any undesirable experience associated with the use of a HIV rapid diagnostic test for self-testing by an individual. This could include Intimate Partner Violence which may result into death of a person or inpatient hospitalization or results into significant disability or incapacity.

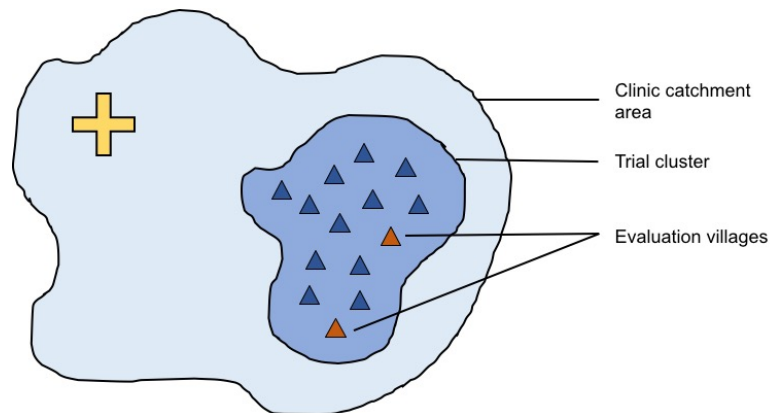
In the context of HIVST, SAEs include all undesirable experiences that result directly from the use of a self-test kit itself or as a reaction from other individuals due to the presence of the kit, the use of the kit or the results that the kit will produce (e.g. being severely beaten which leads to hospitalization or death).

SAEs of interest include:

- Death of a person as a result of any of the experiences mentioned above
- Hospitalization
- Serious injury of a person that requires serious medical attention
- Attempted suicide

D. Trial areas

- **Intervention clinic** – Clinics where CBDAs are distributing HIVST kits and reproductive health products. There are 11 intervention clinics in STAR.
- **Control clinic** – Clinics where CBDAs are only distributing reproductive health products. There are 11 control clinics in STAR.
- **Trial cluster** – A select cluster of villages within the clinic catchment area where STAR implementation and M&E activities are taking place. There is only one cluster per clinic and each cluster ranges in size.
- **Evaluation village** – Select villages within the trial cluster where more rigorous M&E activities are taking place. There are two evaluation villages per trial cluster.



4. Responsibility

The Community Liaison Officer will be responsible for training the Community Based Distribution Agents (CBDA) and community stakeholders on this SOP. The CBDAs, CBDA supervisors and community stakeholders will be responsible for implementing this SOP.

5. Procedures

A. Overview of the social harms reporting system

The social harms report system aims to capture and report the following social harms and Serious Adverse Events (SAEs):

- All forms of GBV
- Any physical injury or related hospitalization associated with the use of the self-testing kit
- Death as a result of violent assault

Other potential social harms, such as being denied access to household resources, marriage break-up or verbal abuse, will be reported and CBDAs or members of the social harms reporting system will provide referrals to appropriate institutions for counselling.



The reporting of social harms will take on different forms in the evaluation villages versus the rest of the trial cluster. A more **rigorous** social harms reporting system will be set up in the **evaluation villages**, with CBDAs collecting reports of social harms from designated members within the system. PSI M&E Officers will then collect these reports of social harms, as recorded on **PS505 – Social Harms Reporting Form**. In the **trial cluster**, CBDAs will only report social harms that have been disclosed to them by the client. CBDA supervisors will record these reports in **PS505 – Social Harms Reporting Form**.

Therefore, the critical difference is that in the **evaluation villages**, the CBDA completes the form using information provided by members of the social harms reporting system. **In the trial cluster**, the CBDA supervisors complete the form using information provided by the CBDAs.

B. Roles and responsibilities (trial cluster)

The role of the CBDA in the trial clusters is to notify the CBDA supervisor when a social harm or SAE has been reported to them by a client. The CBDA should only report social harms that were disclosed by the client and were verified as stemming from a self-test.

The CBDA supervisor will then record the details of the social harms or SAE in **PS505 – Social Harms Reporting Form**.

C. Roles and responsibilities (evaluation villages)

i. Members of the Social Harms Reporting System (evaluation villages)

Members of the social harms reporting system include community-based institutions such as CBO and FBO staff, health workers and promoters, and community leaders.

Their roles in the system are:

- Receive oral reports of social harms and SAEs linked to HIV testing from residents in their communities.
- Record the social harms reported through the social harms registry.
- Inform CBDAs about reported cases so that the CBDAs should record this information in **PS505 – Social Harms Reporting Form**.
- Provide feedback to the Community Liaison Officer on the functionality of the system.

ii. Community Based Distribution Agents

The role of the CBDAs in the evaluation villages are to:

- Collect oral accounts of the occurrence of social harms and SAEs from kit users, community members and social harms members and record this information on the **Social Harms Reporting Form (PS505)**
- Verify or confirm that the social harm or SAE actually occurred to an individual and is related to HIV testing.
- Refer the victims and affected individuals to the appropriate community institutions and structures to address the problem. These community-level mechanisms will have been identified during the situation analysis.
- Compile a report using social harms and SAEs reporting form (**PS505 – Social Harms Reporting Form**)
- If the issue is a SAE and require urgent attention, notify the CLO within 24 hours of confirming the occurrence of an incident for guidance on appropriate action.

iii. PSI and MLW data clerks

The role of the PSI M&E officer and CBDA supervisor will be to collect **PS505 – Social Harms Reporting Form** from the CBDAs in the intervention clinics. The MLW data collector will similarly collect the forms from the control clinics.



This will occur weekly during the first four weeks and then monthly. Each will submit the forms to the MLW Data Officer or CLO for processing.

iv. Community Liaison Officer

The Community Liaison Officer receives the social harms reports and provides monthly summary reports. For quality assurance, CLO will travel to the villages where the system is running, monthly to check the functionality of the system and concerns raised by members of the Social Harms Reporting system in the respective villages. The CLO will be responsible for notifying the CBDA about the visit. The CBDA will then be responsible for informing other social harms reporting systems members in their respective villages. The CLO will communicate the visit schedule at least 7 days prior to the meeting.

During the monitoring meeting, the CLO will conduct a roll call and complete participant log form. The CLO will revisit what was discussed in the previous meeting, what was taught on social harms monitoring, reporting and management, and the knowledge of participants on these topics. This includes: the definition of social harms, how to monitor social harms related to HIV testing and self-testing, and how to manage and provide assistance to victims of social harms. Members of the reporting system will also be asked if they remember how to use their reportin tools and revise them where they have forgotten and do not understand. Using a checklist, the CLO will then assess the functionality of the reporting system. This will be used to determine the number of cases reported, number of members trained, number of members not trained, number of members requiring refresher trainings, number of members present and absent during monitoring, and general comments from members on the functionality of the reporting systems.

D. Telephone Hotline

A Telephone hotline will be established and managed by PSI Malawi through which Social harms and SAEs will be reported. PSI M & E will coordinate with STAR CLO to report any cases of social harms and SAEs for processing.

6. Health and Safety

- N/A

7. Associated Procedures

- SOP-T20 – Community Stakeholders Workshop
- SOP-C53 – Stakeholder mapping/Situation analysis

8. References

- N/A



9. Appendices

Social harms and Adverse Events Grading

	GRADE 1 (MILD) – No effect on social life or work. No need for Doctor	GRADE 2 (Moderate) – Some effect on social life or work. Doctor may be needed	GRADE 3 (Severe) – Unable to socialize or work. Doctor needed	GRADE 4 (Very severe) Reported within 7 days – Life-threatening/Disability and completely fails to socialize
Scenarios	<ol style="list-style-type: none"> 1. Verbal, emotional or psychological Intimate-Partner Violence (IPV) 2. Denying access to household resources 3. Being ignored 4. Being controlled (e.g. not allowed to leave house) 5. Being shouted at 	<ol style="list-style-type: none"> 1. Coercion to self-test. 2. Coercion to disclose a self-test result 3. IPV that includes e.g. pushing, or slapping with an open hand that does not result in pain or visible marks >24hrs 4. Threatened Severe physical violence 5. Psychologically coercive sex. 6. Being discriminated 	<ol style="list-style-type: none"> 1. IPV that leads to pain, bruising or marks >24hrs. 2. Verbal threats of potentially lethal violence (e.g. statement of intent to kill, mock strangulation, threatened with a knife or gun 3. Physically coercive sex 4. Marriage break-up 	<ol style="list-style-type: none"> 1. IPV leading to hospitalization or death 2. Suicide or attempted suicide 3. Attack using potentially lethal force (e.g. knife, gun, hammer, kicks to head, asphyxiation)
Steps	<ul style="list-style-type: none"> • Referred to community based institutions for assistance. e.g. CBOs, Police. 	<ul style="list-style-type: none"> • Referred to community based institutions for assistance. • Reported to relevant authorities. e.g. Community Liaison Officer. • Refer to community-based GBV support organizations 	<ul style="list-style-type: none"> • Report to marriage councilors • Report to relevant authorities. e.g. Community Liaison Officer. • Refer to community-based GBV support organizations 	<ul style="list-style-type: none"> • Report to police/chief (Homicide) • Report to police (Suicide) • Report to relevant authorities e.g. Community Liaison Officer • Report to CLO (Tingling of the gum) • Refer to community-based GBV support organizations • Ensure safe alternative abode before discharge



10. Training log

Name of trainee	Name of trainer	Signature / date of trainee	Signature / date of trainer