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Standard Operating Procedures (SOP) for Addressing Adverse Events in Index Testing Services

SOP NO. 1	**TITLE:**	**Adverse Events from Index Testing SOP**	
	PROJECT:	**Uasin Gishu County and USAID AMPATH *Uzima***	
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May 2022	May, 2022	• Change of mechanism from AMPATHPlus to USAID AMPATH *Uzima*	

1. Purpose/ Background:

The purpose of this SOP is to guide the implementation of adverse events monitoring, reporting, documentation and follow-up for remedial plans. This SOP will help standardize the process and procedures for providing immediate response to any Severe and Serious Adverse Events (SAEs) that occur in relation to Intimate Partner Violence (IPV) and Index service provision before, during and after Index Testing Services. This will help ensure no harm comes to the index client, their partner(s), family members, or the index testing provider as a result of index testing services. This SOP will provide guidance on; **systems of avoiding the occurrence of adverse events in index testing**, **systems to be put in place by allowing clients to report adverse events** in instances that they may occur, **systems for immediate response to any reported adverse event** as well as **responsibilities of each person in addressing reported adverse events.**

Scope

This SOP will provide guidance to all healthcare providers offering Index testing services to clients. These will be HTS counselors, nurses, lab persons, clinicians, and all others (including CCC persons) who are concerned with Index testing services. This SOP will be printed and kept at an appropriate point for reference and providing guidance in ensuring quality, safe and ethical index testing services.

2. Definitions of terms

2.1. Adverse Events

An adverse event (AE) in relation to index testing is an incident that results in harm to the client or their partner(s), family members or the index testing provider as a result of their participation in index testing services as defined by the Safe and Ethical Index Testing guidance document.

2.1.1. Categories of Adverse Events;

Severe

1. Threats of physical, sexual, or emotional, harm to the index client, their partner(s) or family members, or the index testing provider
2. Occurrences of physical, sexual, or emotional harm to the index client, their sexual or drug-injecting partner(s) or family members, or the index testing provider
3. Threats or occurrences of economic harm (e.g. loss of employment or income) to the index client, their partner(s) or family members
4. Withholding HIV treatment or other services
5. Forced or unauthorized disclosure of client or contact's name or personal information
6. Abandonment or forced removal of children < 19 years old from the home

Serious

1. Failure to obtain consent for participation in index testing and for notifying partners
2. Health site level stigma or criminalization (e.g. sharing personal information about KP/PLHIV seeking care with the criminal justice system)

2.2 Harm

Harm includes any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves or an institution to a person, occurring before, during or after index testing services.

3. Detailed Procedures

3.1 Index client awareness creation for adverse events

- All index clients will be sensitized on their rights to receive quality index testing services
- They will also be informed of their right and ability to make a complaint if their rights are violated.

- This will be done by displaying this right on a wall job aid or provision of IEC materials containing this information to all index clients before index testing services are offered.
- The same information on the right to make a complaint will be emphasized by the provider throughout the index service provision period
- A patient charter will be well displayed at the health facility with emphasis on the voluntary nature of services being provided; confidentiality and safety assurance; and freedom to make a complaint in a free and confidential manner.

3.2 Adverse event documentation and reporting

- Copies of the Adverse Event Report Form for index testing will be placed in an open and accessible point at all index testing service delivery points.
- All index clients participating in index testing services will be made aware of the forms' availability by the service providers
- The forms will be designed to enable the index client to report any adverse event occurrence either anonymously or confidentially *(The report form is attached in appendices)*
- A suggestion box/a collection point will be availed in each facility at a strategic point to allow clients to drop the filled Adverse Events Report Form
- The suggestion box will remain under strict lock and key with no access to unauthorized persons.
- The key will be kept and managed by the quality improvement lead person in the facility. He/she will be opening this box every day in the morning to pick up the contents in it.
- He/she will document the forms picked from the box in a book named 'Adverse Event Filled Report Forms'. The book will capture the date the form was picked, the date the complaint was raised as indicated in the report form and a brief summary of the complaint'
- These forms will then be filed in a special file and kept in a lockable cabinet for further action as detailed in section 3.3 below.
- On a quarterly basis, the facility will initiate a process of engaging index clients to determine if they (clients) might have gone through adverse events and failed to report.
- The clients will be actively issued with adverse events report forms and asked to fill and drop them in the suggestion box as they exit the facility.
- The issuance will be done by a neutral person (who is not a direct provider of index testing services); this will allow objectivity and avoid chances of intimidation for the index clients.
- Facilities reporting a very high index testing acceptance rate will be encouraged to continue with the good work; they will also be visited for supervision to ensure index testing services are meeting the set requirements.

- Facilities reporting a very low index testing acceptance rate will be visited for support and engagement with the team to determine challenges leading to the low performance. A Root Cause Analysis (RCA) will be conducted to determine the causes and remedial measures implemented.

3.3 Addressing Reported Adverse Events

- Led by a facility quality improvement lead person, a multi-disciplinary team of at least five persons will be formed in high and mid-volume facilities for addressing adverse event reports. For small health facilities, the facility manager will take the lead in ensuring any adverse event is addressed within the recommended 2 - 4 days.
- The leading team will be meeting as guided by the quality improvement lead person based on any reported adverse event requiring attention. In small facilities, the facility manager will be responsible for immediate addressing of reported adverse events.
- This team will address reported adverse events and ensure corrective actions are taken; the corrective actions will be based on the kind of complaint raised. The actions could include stopping index testing services where necessary
- In the event that the complaining index client chooses a confidential approach, the committee will ensure a report reaches the index client – indicating actions taken to prevent such occurrences in the future.

4. Roles and Responsibilities

4.1. Index Testing providers

- The providers will communicate and empower clients on their rights to receive index testing services voluntarily, confidentially, and in a safe manner
- The providers will reach out to the index clients during their second visit to determine any possibility of adverse events or IPV
- They will also have a responsibility of informing the clients of adverse events reporting systems; including the availability of reporting forms and suggestion boxes
- The providers will be tasked to implement any corrective action given by the committee to avoid similar future complaints as much as possible.
- Providers will also be tasked to screen for IPV for all elicited partners and document appropriately

4.2 Quality Improvement Lead

- Will ensure communication materials on adverse events are available at all index testing service delivery points
- Will be in charge of the suggestion boxes together with ensuring all dropped report forms are safe
- He/she will lead the investigative committee to have all reported adverse events addressed and corrective actions taken and implemented

4.3 Adverse Events Committee

- The committee will investigate all reported adverse events and ensure necessary corrective actions are taken within 2-4 business days.

- It will identify facilities reporting very high index testing service uptake and institute a supervision plan to ensure services are meeting set standards
- It will participate in monitoring reasons for clients' refusal of index testing services and institute remedial strategies.

Annexed

1. Adverse Events Index Client Complaint Form
2. Patients Charter
3. Adverse Events Report Form
4. Adverse Events Investigation Form

Adverse Event Report Form for Index Testing services

Instruction: Healthcare workers at the facility should use this form to document any reports of adverse events reported by clients during or following their participation in index testing services. The completed form should then be given to the facility managers so that an investigation into the adverse event can begin. Any report of a serious or severe adverse event should be investigated within 2-4 business days from the day the form has been completed.

Note: Partners include both sexual and needle-sharing partners

1. Procedural information		
Date Form completed :		
Facility or site Name:		
Facility type (Circle one): 1) MOH 2) Key Population 3) Private 4) Other …….		
Date and Time Adverse Event Occurred:		
Name, Title, and Phone Number of persons completing this Report:		
2. Participant information		
Clients Name or ID Number:	Clients Age:	Client's Gender:
Participant Type (Circle): 1) Client of HTS Site 2) Client of ART Site 3) Community Member 4) Other		
3. Event information		
Types of Events (Please circle all that apply) **1) Severe** a) Threats of Physical, sexual, or economic harm to the index client, their partner(s) or family members, or the index testing provider b) Occurrence of physical, sexual, or economic harm to the index client, their partner(s) or family members, or the index testing provider c) Withholding treatment or other services d) Forced or un-authorized disclosure of client's or contacts name or personal information e) Abandonment/Forced removal from home for children <19yrs old 2) **Serious** Failure to obtain consent for participation in index testing and/or for notifying partners Health site-level stigma or criminalization (e.g. sharing personal information about KP/PLHIV seeking care with the criminal justice system) **3) Others, Specify:**		

Client complaint form for HIV Services by Index Client

Instructions: You have the right to receive HIV services that respect your needs as a person and that are free of discrimination. If you feel like your rights have not been respected or that you received inadequate health services, we ask that you complete this form so that we can improve our services. You can choose to make your complaint anonymous or confidential

Anonymous-You choose not to share any personal information with us. This means we will not be able to identify you.

Confidential-You share your name and phone number with us. We may use this information to contact you and ask additional questions about your complaint. We will keep this information safe. This means we will not share with anyone not involved in handling your complaint.

INFORMATION ABOUT YOU

Today's Date_____

Do you want this complaint to be?[] Confidential []Anonymous Please skip to the next section

Your Name_____

Your Address_____

Your Phone Number _____Your Email address_____

INFORMATION ABOUT YOUR COMPLAINT

Date incident occurred_____Time incident occurred _____

Place where incident occurred_____

Name of Healthcare workers involved (if Known)_____

Please Tell us about what happened_____

INFORMATION ABOUT HOW YOU THINK WE CAN IMPROVE OUR SERVICES

Is there something you would like to see happen as a result of your complaint [] Yes [] No

If yes please tell us what you like to see happen?_____

Thank you, Please place this complaint form in the drop box in the facility anytime

Adverse Event Investigation Form

Instruction: Please use this form to document results of investigations into reports of adverse events arising from site level monitoring, community-led monitoring and/or client feedback. Include any actions planned and/or taken to address the complaints and prevent future adverse events.

1. Procedural information
Date Investigation Completed:
Facility or site Name:
Facility type (Circle one): 1) MOH 2) Key Population 3) Private 4) Other ……..
Name, Title, and Phone Number of persons completing this Report(Indicate all committee members):
2. Summary of Adverse Events That Led to this investigation
3. Brief summary of the findings of the investigation
4. Corrective Action taken

Patients' Rights

At this health facility, you have the right to receive medical services that are:

- ✓ **Voluntary:** (You should be given information about the benefits and risks of the services, and treatment offered at this clinic so you can make informed decisions. You can say no to any service or medical test that you do not want to receive)
- ✓ **Free from Coercion** (Refusing one service will not affect your right to receive any other health care services at thus facility.)
- ✓ **Delivered in a non-discriminatory manner** (You should be treated as an individual with respect and dignity. You should not be discriminated against based on your age, gender, risk behaviour, or any other personal characteristics)
- ✓ **Safe** (You should not feel threatened, harassed, or harmed as a result of the services you received)
- ✓ **Of high quality** (All services should meet national standards)
- ✓ **Confidential** (Your personal information should be kept secure and not shared with anyone outside of the health care team)

You have the **right to make a complaint** if you feel that the services you received at this facility have not met these rights

To make a complaint, please complete the **client complaint form** and place it in the secure drop box in the facility. You can also call the facility service quality improvement lead person at……They can make a complaint on your behalf if you do not feel comfortable doing it on your own.

ADVERSE EVENTS FROM INDEX TESTING SOP ATTESTATION BY STAFF

	STAFF NAME	DATE SOP RECEIVED AT SITE	DATE READING COMPLETED	SIGN
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				