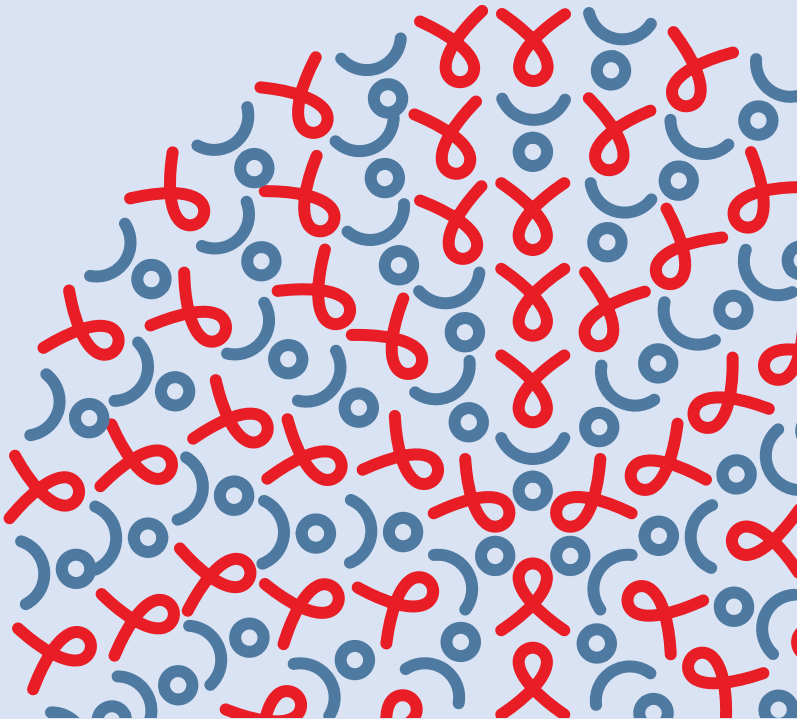
COOPERATIVE AGREEMENT NO.
7200AA19CA00002

STANDARD OPERATING PROCEDURE

for Adverse Event Monitoring, Investigation, and Response in the Context of Index Testing



PEPFAR

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EpiC
Meeting Targets and Maintaining Epidemic Control

Adverse Event Monitoring, Investigation, and Response

in the Context of Index Testing

STANDARD OPERATING PROCEDURE

January 2021

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Contents

Abbreviations and Acronyms 1
Definitions 1
Purpose 1
Scope 2
Responsibilities 3
Procedures 3
1.0 Ensuring an environment in which safe and ethical index testing can occur 3
2.0 Integrating adverse event mitigation and monitoring into clinical processes 5
3.0 Responding immediately to adverse events 7
4.0 Documenting, investigating, reporting, and remediating adverse events 7
5.0 Data review 7
Appendix A. Content Recommendations for SOPs Describing Clinical Violence Response Services 9
Appendix B. Index Testing Script 12
Annex C. Adverse Event Report Form for Index Testing Services 17
Annex D. Adverse Event Investigation Form 19
Annex E. Beneficiary Abuse Disclosure and Response Form and Instructions 21
Appendix F. Patient Rights Poster 27
Appendix G. Customer Complaint Form 28
Appendix H. Implementer Security Incident Log 29

Abbreviations and Acronyms

GBV	Gender-based violence
HIV	Human immunodeficiency virus
IPV	Intimate partner violence
PEP	Post-exposure prophylaxis
SOP	Standard operating procedure
STI	Sexually transmitted infection
WHO	World Health Organization

Definitions

Adverse event* associated with index testing: an incident that results in **harm** to the client or others as a result of their participation in index testing services or because they were offered index testing services and declined to accept them.

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

Categories of adverse events:*

Severe

1. Threats of physical, sexual, or emotional harm to the index client, their partner(s), or family members, or to 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 from the person offered index testing, their partners, or family members
5. Forced or unauthorized disclosure of client's or contact's name or personal information
6. Abandonment or forced removal of children < 19 years old from the home

Serious

1. Contacting partners without obtaining consent for participation in index testing and/or for notifying partners
2. Stigma perpetrated by health site staff (e.g., intentionally prolonging clients' wait times, discriminatory behavior) or criminalization (e.g., sharing personal information with the criminal justice system about a KP member and/or person living with HIV who is seeking care)

**The definition of adverse event and categories of adverse events are adapted from U.S. President's Emergency Fund for AIDS Relief (PEPFAR). PEPFAR guidance on implementing safe and ethical index testing services. Washington: PEPFAR; 2020.*

Purpose

This standard operating procedure (SOP) is intended to help facility managers/administrators and facility-based health care workers involved in index testing to 1) prevent adverse events from occurring, 2) encourage clients to report adverse events when they occur, 3) support providers [titles of relevant providers here] to respond to and document adverse events, and 4) inform site managers about how to investigate, report, and remediate adverse events.

This document helps sites meet the following PEPFAR requirements

- Adhere to the 5 Cs (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- Conduct a risk assessment for intimate partner violence (IPV) for each named partner and provide "first-line" response, including safety checks and referrals to clinical and nonclinical services (if not provided on site) if violence is disclosed
- Have in place a site level adverse event monitoring and reporting system
- Train and supervise providers on index testing procedures including 5 Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and "do no harm")
- Ensure forms are available at the facility or site for staff to document and monitor consent, IPV, and frequency of adverse events
- Flag sites with unusually high acceptance of index testing services for a supportive supervision monitoring visit to ensure that index testing is being offered as a voluntary service
- Actively monitor reasons for clients' refusal of index testing services, prevalence of IPV, and other adverse events (e.g., confidentiality breaches, stigmatization, coercive tactics, etc.) for improvement
- Investigate each reported adverse event and follow up

Scope

The procedures described in this SOP pertain to both the environment in which index testing is conducted (e.g., building infrastructure that ensures privacy, forms available onsite, the storage of physical and digital data) and also the actions required of health care workers who conduct index testing. Those tasked with implementing this SOP will also need to be aware of SOPs about identifying violence in the context of index testing and violence response. Content recommendations for violence response services are provided in Appendix A.

This SOP can be integrated into a larger SOP covering index testing. It does not need to be a stand-alone document.

Responsibilities

All staff who manage index testing services or who are involved in conducting index testing are responsible for understanding and following this SOP.

- *[Program to fill in appropriate position(s)]* is responsible for training program staff to work with clients in accordance with this SOP and for day-to-day oversight and support of relevant staff.
- *[Program to fill in appropriate position(s)]* has ultimate responsibility for ensuring that all applicable staff members follow this SOP.

Procedures

1.0 Ensuring an environment in which safe and ethical index testing can occur

1.1. *All staff conducting index testing must be trained on the following:*

1.1.1. ***Adherence to the 5 Cs*** (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment). Use of a script, such as the one found in Appendix B, can help to ensure that providers' interactions with clients cover the essential messages.

1.1.2. How to ***conduct an IPV risk assessment*** and how to ***provide first-line support*** if violence is disclosed; this includes skills to provide psychological first aid, discuss safety, and refer effectively (active referral). See *Standard Operating Procedure for Identifying and Responding to Intimate Partner Violence in the Context of Index Testing (Nov 2020)* for more.

1.1.3. Documentation forms and procedures when ***adverse events are reported*** (including IPV related to index testing). See Appendix C, Appendix D, and Appendix E. You do not need to use all three; you may use either Appendices C and D together, or Appendix E on its own.

1.1.4. How to ***follow-up with a client*** to determine if they have experienced an adverse event after participating in index testing services, including as described in Appendix B.

1.2 *The index testing site must have in place the following.*

1.2.1 ***The minimum requirements for conducting IPV screening*** in order to avoid adverse events related to partner violence (see *Standard Operating Procedure for Identifying and Responding to Intimate Partner Violence in the Context of Index Testing* for more details on each of these requirements):

- A written protocol/SOP that describes the provision of violence response services and is accessible to providers
- A standard set of questions about violence AND safe storage of any data on violence

- Infrastructure that allows providers to ask about IPV in a private location where the client cannot be seen or overheard
- A referral system that can be employed to support those who report violence
- Trained providers (see section 1.1 of this SOP)

1.2.2 ***An index testing register*** that includes opportunities to document consent, reasons for nonparticipation, the conduct of an IPV risk assessment, and IPV risk assessment results.

1.2.3 ***Posters and/or other materials*** (e.g., patient handouts) that notify clients of the below. See Appendix F for an example from PEPFAR that can be adapted to your context

- Their right to receive quality, confidential services, that are free of coercion
- The right to decline any service you do not wish to receive
- The ability to make a complaint if these rights are violated
- Information on how to make the complaint

1.2.4 ***Multiple pathways for clients to share concerns and complaints*** about index testing services. At least some of these options must be anonymous. Options include:

- Suggestion boxes; see Appendix G: Customer Complaint Form
- Hotlines
- Client surveys
- Online submission options

1.2.5 ***Pathways for providers to share complaints and concerns, including anonymously.***

1.2.5.1 Providers should be able to take advantage of one of the anonymous options provided to clients.

1.2.5.2 Providers should also be able to share their concerns openly, especially those related to their own security. An implementer security log (Appendix H) can be used to document security incidents that affect providers. Question 12 asks whether the incident was specifically related to index testing (which would then indicate that it must be documented as an adverse event in other tools [Appendices C and D or E]).

1.2.6 ***A process for connecting clients who experienced adverse events to appropriate services.*** To the extent possible, these services should include:

- Medical support
- Legal support
- Social support
- Psychosocial support and counseling
- Other IPV services, such as shelter

1.2.7 ***A process and forms to document and investigate adverse events.***

1.2.7.1 Adverse events should be documented on a form [Appendix C / Appendix E/ create your own].

1.2.7.2 All serious and severe adverse events must be investigated by [*the site manager or another individual tasked with investigation; program to fill in appropriate position*]. This person should investigate the adverse event and fill out [Appendix D or Appendix E or the site's own form].

1.2.7.3 Follow-up steps and actions should be identified in order to prevent similar adverse events in the future.

1.2.7.4 When the adverse event is IPV, it should not be investigated as other adverse events would be. Instead, the investigation should focus on whether procedures were followed regarding IPV assessment, provision of psychological first aid, and appropriate referrals.

1.2.8 ***A process to determine changes needed,*** if any, to avoid future adverse events.

1.2.8.1 [These individuals/positions] will be responsible for reviewing investigation findings to determine the changes/trainings/tools needed.

1.2.8.2 The [*site manager/program to fill in appropriate position]* will communicate the needed changes to the relevant staff and ensure that trainings/tools are developed as required. If the adverse event is determined to be the result of a provider's failure to abide by minimum standards for index testing, the provider should immediately be stopped from offering services until remedial actions can occur.

1.2.9 ***Community advisory boards*** (composed of community leaders and people living with HIV) are recommended. Board members can act as liaisons between the facility and community. Community advisory boards can make a complaint on a client's behalf if the client does not feel comfortable making the complaint alone.

2.0 Integrating adverse event mitigation and monitoring into clinical processes. Many of these processes can be supported through the use of the Appendix B: Index Testing Script.

2.1. When introducing index testing, the provider will ensure that the ***client understands that index testing*** is voluntary and will ask for the client's consent before soliciting partners' names and before contacting those partners.

2.1.1. ***Consent or reasons for nonparticipation should be captured*** by the provider conducting index testing in the index testing register. The list below can be adapted to capture the reasons relevant to the site:[1]

- Declined to answer/no reason given

[1] These examples are taken from PEPFAR Guidance on Implementing Safe and Ethical Index Testing Services. They may be adapted. For example, if the partner lives far away, some facilities may be able to contact the partner and refer them to testing elsewhere. In this case, "partner lives/works far away" may not be necessary to capture.

- No time for elicitation interview
- Does not believe services are confidential/afraid partner will learn my identity
- Afraid of IPV/abandonment by partner
- Partner is already stable on treatment (confirmed by counselor)
- Partner lives/works far away
- Clinic hours are inconvenient for my partner
- Other, specify_____

2.2. If the client consents to index testing, the provider should ***conduct a risk assessment for IPV*** with each named partner using the questions below or an adaptation of these questions.

- Has [partner's name] ever made you feel afraid, bullied or insulted you, threatened to hurt you, or tried to control you (for example, not letting you go out of the house)?
- Has [partner's name] ever hit, kicked, slapped, or otherwise physically hurt you?
- Has [partner's name] ever forced you into sex or forced you to have any sexual contact you did not want?

2.2.1. If IPV is disclosed, follow the steps outlined in *Standard Operating Procedure for Identifying and Responding to Intimate Partner Violence in the Context of Index Testing* (Jan 2021).

2.2.2. If IPV is not disclosed for all partners, and with the client's consent, index testing can be carried out with the partners who have not committed abuse.

2.3. ***The provider should routinely follow up*** with index clients to ask if they experienced any adverse event due to index testing.

2.3.1. The provider should ask "In the time since you participated in index testing services, did you experience any harm from your partner, health care provider, or anyone else at this facility [or site]? This includes physical, emotional, sexual, or economic harm?"

2.3.2. This follow-up question should be asked during the client's first two to three clinic appointments OR through follow-up (e.g., via phone) 4-6 weeks after testing of the client's contact(s).

2.3.3. As long as contacts are being actively traced, these follow-up questions should be asked by the provider.

3.0 Responding immediately to adverse events

3.1. If an adverse event is reported, ***offer relevant services*** from those named in section 1.2.6 of the SOP. If the adverse event included violence, provide LIVES and follow your facility's SOP on violence response. If your site needs to create an SOP on violence response, see Appendix A for SOP content suggestions.

3.2. If the complaint was submitted via suggestion box or other mechanism (not shared with a provider) but was not anonymous, the [*site manager/program to fill in appropriate position]* should ***offer support to the person who experienced the adverse event.***

4.0 Documenting, investigating, reporting, and remediating adverse events

4.1. Each time an adverse event is reported to a provider, that provider must fill out either Appendix C or E.

4.2. The provider who received the report must then immediately notify the *[site manager/program to fill in appropriate position]* and provide the site manager with the documentation of the adverse event.

4.3. If an adverse event is submitted anonymously via suggestion box or other mechanism, the *[site manager/program to fill in appropriate position]* must enter this information into Appendix C or E.

4.4. The *[site manager/program to fill in appropriate position]* will investigate any adverse event and fill out either Appendix D or complete Appendix E.

4.5. The *[site manager/program to fill in appropriate position]* must complete an investigation and notify the stakeholders below within 2-4 days of receiving the report. Stakeholders can include:

- Implementing agency
- Implementing partner
- Ministry of Health

4.6. A remediation plan should be developed to address adverse events. Stakeholders should discuss the plan and report back to the community and the facility.

4.6.1. *[Describe that process at your facility here]*

5.0 Data review

5.1. Review data at the site level to determine periods or providers with unusually high acceptance of index testing services; in such cases, consider requesting a supportive supervision monitoring visit to ensure that index testing is being offered as a voluntary service.

5.2. Actively monitor reasons for refusing index testing services, prevalence of IPV, and other adverse events (e.g., confidentiality breaches, stigmatization, coercive tactics, etc.) for improvement.

5.2.1. Request technical assistance if retraining is needed.

5.2.2. Use this information to inform the services offered on site; for example, high rates of IPV disclosure could indicate the need for more social workers/mental health professionals or other GBV-response services.

Appendices

Appendix A. Content Recommendations for SOPs Describing Clinical Violence Response Services 9
Appendix B. Index Testing Script 12
Annex C. Adverse Event Report Form for Index Testing Services 17
Annex D. Adverse Event Investigation Form 19
Annex E. Beneficiary Abuse Disclosure and Response Form and Instructions 21
Appendix F. Patient Rights Poster 27
Appendix G. Customer Complaint Form 28
Appendix H. Implementer Security Incident Log 29

Appendix A. Content Recommendations for SOPs Describing Clinical Violence Response Services

According to the WHO Manual for Health Managers,[2] a complete SOP covering the clinical response to violence should:

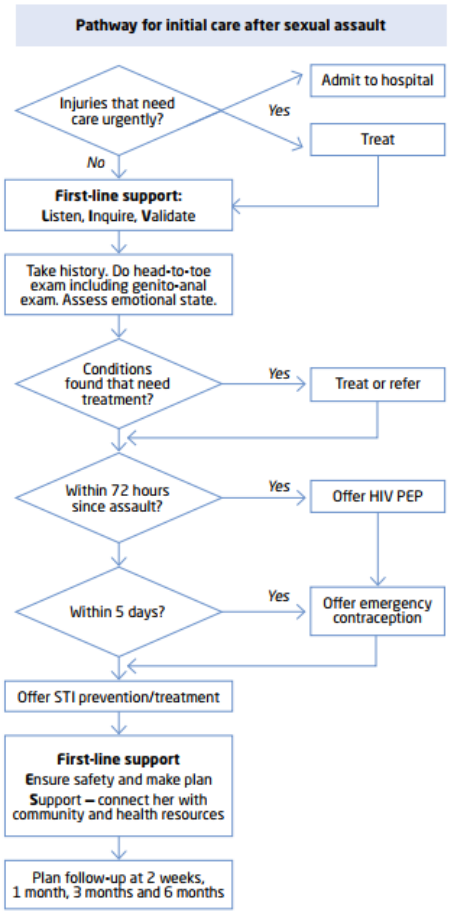
- Specify the role of each health worker who interacts with a client from the time the individual who discloses violence enters the facility to the time they leave. This will be specific to the site; as needed, describe referrals that will be made for other clinical and non-clinical services that cannot be provided onsite.
- Indicate how providers will be supported in self-care and coping with burnout.
- Define the core elements of an essential package of services for survivors of violence (see list below). Offer as many of these services as possible onsite.
- Describe patient flow and procedures that promote privacy and eliminate waiting time for individuals who have experienced violence.
- Provide a simple pictorial reference for health-care providers that depicts the flow diagrams or algorithms.

The SOP should be shared with staff who provide the following essential services onsite:

- **Identification** of those subjected to violence
- **Management/treatment** of any immediate or urgent medical conditions associated with violence.
- **Provision of first-line support** to individuals subjected to intimate partner violence and sexual violence—includes supportive listening, safety planning, and enhancing social support through referrals.
- **Clinical care for sexual assault—**includes taking history; providing medical examination and, where appropriate, forensic examination and investigations; providing tests and treatment for management of injuries; offering services/commodities to prevent pregnancy, STIs, and HIV; and providing follow-up care.
- **Provision of mental health care** to individuals subjected to intimate partner violence or sexual violence—includes basic psychosocial support as well as assessments, management, and referrals for more severe mental health problems.

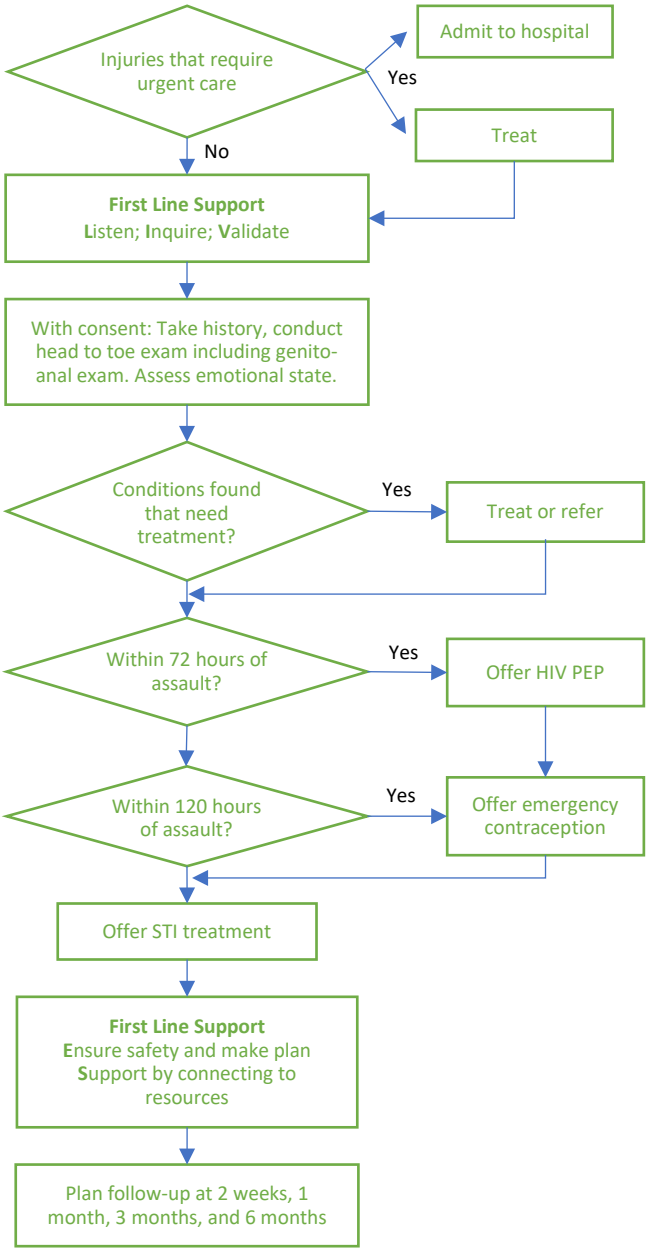
The SOP should be designed to facilitate access to services in an order that is based on clinical need. See images below regarding pathways of care for victims of sexual assault and IPV.

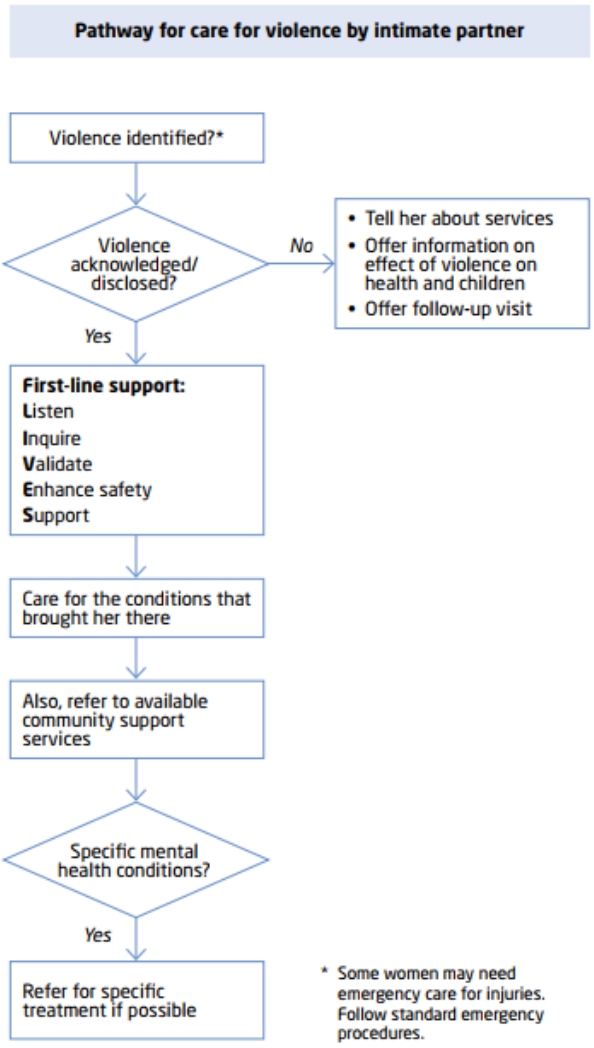
[2] WHO. Caring for women subjected to violence: a WHO curriculum for training health-care providers. Geneva: WHO; 2019. Available from: https://www.who.int/reproductivehealth/publications/caring-for-women-subject-to-violence/en/.

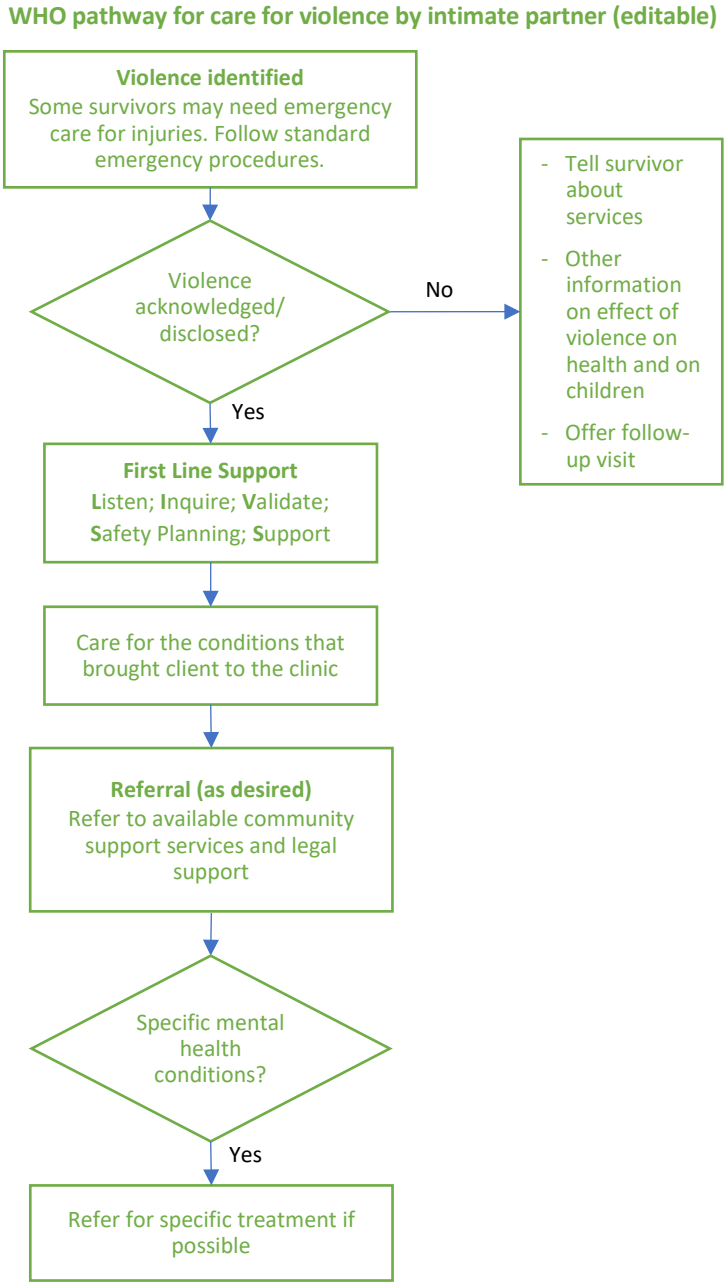


[1] Health care for women subjected to intimate partner violence or sexual violence. Geneva: World Health Organization; 2014 (http://www.who.int/reproductivehealth/publications/violence/vaw-clinical-handbook/en/).

WHO Pathway of care for sexual assault (editable)




Pathway for care for violence by intimate partner
Violence identified?*
Violence acknowledged/ disclosed?
No
• Tell her about services
• Offer information on effect of violence on health and children
• Offer follow-up visit
Yes
First-line support:
Listen
Inquire
Validate
Enhance safety
Support
Care for the conditions that brought her there
Also, refer to available community support services
Specific mental health conditions?
Yes
Refer for specific treatment if possible
* Some women may need emergency care for injuries. Follow standard emergency procedures.


WHO pathway for care for violence by intimate partner (editable)
Violence identified
Some survivors may need emergency care for injuries. Follow standard emergency procedures.
Violence acknowledged/ disclosed?
No
- Tell survivor about services
- Other information on effect of violence on health and on children
- Offer follow-up visit
Yes
First Line Support
Listen; Inquire; Validate; Safety Planning; Support
Care for the conditions that brought client to the clinic
Referral (as desired)
Refer to available community support services and legal support
Specific mental health conditions?
Yes
Refer for specific treatment if possible

Appendix B. Index Testing Script

This script is designed to help you introduce and conduct index testing, including violence identification and response and adverse event monitoring. It can be adapted.

This script should be used with your SOPs for index testing. The bullets below in quotations are meant to guide what the provider says to the client. Italicized sub-bullets provide guidance on how to adapt what is said. Non-italicized bullets are instructions to the provider.

Before bringing up the topic of index testing/partner notification, make sure that the client is alone (no one other than a child under the age of two should be with them). Make sure that no one can overhear the conversation between the client and the provider.

If the provider does not already know the client, begin with introductions and creating a safe space.

Introducing index testing (use in all settings)

- "Your sexual partners (regular and casual partners), biological children, and/or people with whom you inject drugs may be living with HIV. They could benefit from HIV testing and counseling services."
- "I would like to talk to you about offering HIV testing to these individuals. We believe everyone should know their HIV status in order to access treatment and live a healthy life, but we would never contact someone without your consent. If you would like them to get tested, I can help you reach out to them, or I contact them myself, to encourage them to come in for services or be linked or referred to testing services elsewhere."
- "With your consent, I would like to ask you about your partners, biological children, and your injecting partners. You will have the chance to tell me if each person named should be contacted, and how that contact should occur."
- "If I contact them, your information will be kept confidential; no information about you will be disclosed to the people concerned and these people will not know that we spoke with you. Regardless of whether you decide to share the names of your partners and children, the services that you receive here will not change. You will continue to receive the same level of care. Would it be OK if I ask you the names of your partners, biological children, and your injecting partners? Giving their names does not mean you have provided permission for me to contact them. It is just the first step in the conversation."
- If consent to begin partner elicitation is given, ask about all sexual and injecting partners within the past 12 months. Ask about any biological children under the age of 19. Make sure to document their age, sex, and the relationship to the index client.

Introducing the topic of violence (use with all index clients)

- "Thank you for sharing your partners' names with me. As I said earlier, we will only contact these individuals with your consent. Your safety is important for us to consider before we decide whether we can contact these individuals."
- "Many people experience problems with their spouse or partner. This may include violence. Violence from a partner can negatively affect many aspects of your life, including your health. Because I care about your health and well-being, I want to ask you the following

questions before we talk further about partner notification. I want you to know that I will keep anything you tell me confidential unless you give me permission to share it."

- *Remember, if there is mandatory reporting in your context, the underlined text above must be revised to reflect any limits on confidentiality.*

- "Because your safety is important to me and because your safety directly affects your health and well-being, I would like to ask you the following questions:

  Has [partner] ever hit, kicked, or slapped you?

  Has [partner] ever threatened to harm you, humiliated you, or controlled your movements?

  Has [partner] ever forced you to do anything sexual that made you feel uncomfortable?"

  - *Ask these questions about each named partner. You can revise these questions or add others as needed. Questions should be standardized across providers at the facility.*

- If the client discloses violence <u>from any partner</u>, follow your clinic's SOP regarding violence response or a specific SOP related to violence detection and response within index testing. In both cases you will follow the LIVES technique described in the SOPs.
- After completing LIVES, recommend that the client does not move forward with index testing with any partners who have been violent or who have ever threatened violence. If the client wishes to move forward with index testing anyway, AND you believe it can be done safely, consider an option that does not require disclosure of the client's status to the violent partner. If it cannot be done safely, do not move forward with index testing of the partners who have perpetrated violence.
- If the client does not disclose violence and you do not suspect violence from a named partner or partners, with the client's permission continue with index testing for those nonviolent partners.

Helping clients decide how to contact partners (use when clients want to go forward with index testing)

- "There are different ways to invite partners and children to come for testing that protects you and the partners and children. You can use different options for each partner as needed. Choose whichever you think is best for each person. Here are some of the options:

  1. "You can encourage your partner to come for a test. This may or may not involve sharing your HIV status."
  2. "A counsellor or other health care provider can call or visit your partner and inform them they need to test for HIV. They will not share your name with the contact."

     - *If the client wants to know what will be shared with a partner who is contacted by a health care worker, note that there are options such as, 'We are reaching out to everyone in this community to offer HIV testing (or more generally health services) as part of X campaign,' or 'We received your contact information anonymously as someone who could benefit from HIV testing.' The client's recommendation on messaging that can safely be used should guide what the provider says when reaching out to the index case.*

3. "You and a counsellor can work together to notify your partner. You will have 30 days to tell them, after which, with your permission, the counsellor will contact your partner."
4. "The counsellor can sit with you and your partner and help you talk about getting tested. This may or may not involve telling your partner about your HIV status."

- "Now that you understand the options, do you have any questions? Are you comfortable moving forward with index testing for the individuals we have agreed are safe to contact?"
- Document consent in the index testing register.

Make a plan for moving ahead (use relevant approach based on client preference)

OPTION ONE: Index client informs their sexual partner:

- "Let's make a plan for how to talk to your partners. Think about these questions."
- "When and where is a good time and place to help you feel safe?"
- "How might your partner react?"
- "What questions will they have? What can you say in response?"
- "Consider having someone nearby for support if you need it. Also, we can practice until you feel comfortable."

OPTION TWO: Provider contacts the index case*:*

- "Let me explain how I will contact your partners."
- "We can help contact your partners."

  "We need a phone number or other form of contact. If you have it, we need a physical address."
- "We'll call first and follow up in person if that doesn't work."
- "We will not share your name or any information about you."
- "Please know that to protect your partners' confidentiality, we cannot tell you the results of the contact and, if they get tested, their test result."

OPTION THREE: Provider speaks to index client and index case together:

- "Let me describe how we can have this conversation together with your partner."
- "Talking with a partner about a sensitive topic can be hard, but you don't have to do it alone. I can help you have this discussion, but we need to plan how to do this."
- "Where would you feel most comfortable having this talk?"
- "When would be the best time to have this talk?"
- "In order for me to best support you, I need to know a bit more about how I can help."

  "What do you want me to say to your partner?"

  "Is there anything you want to ensure I do not say?"

- "What do you see as some of the challenges we might face having this discussion with your partner?"

    "How do you think they might react?"

    "What questions might they ask?"

- "How do you think we can overcome these challenges?"

    "When you have had these kinds of problems in the past with your partner, how were you able to address them?"

Wrapping up an index testing conversation (use when the client consents to having a partner and/or child contacted)

- "Thank you for taking time to talk with me today about how we can get your partners and/or children tested for HIV. I know it can be a difficult topic, but you've shown you are the type of person who looks out for others, even when it isn't easy!"
- Briefly review the conversation with your client:
    - "You said that: [*summarize client's key reasons for wanting to help with partner notification*.]"
    - "You mentioned a few worries: [*briefly summarize client's key concerns*.]"
    - "We agreed that to overcome those barriers, you/we will: [*summarize the key plans*.]"
- "Does what I shared seem correct to you? What would you add or change?"
- "After discussing all of this, how are you feeling now?"
- "Is there anything else I can help you with today?"
- "I'd really like to talk with you again, to see how you are doing and how it has been going referring your partners. When would be a good time to do that?"

Following up regarding adverse events (use for all who participate in index testing)

- Facilities should routinely ask index clients if they experienced any adverse events (described below) after participating in index testing services.
- Follow-up should be done during the client's first two to three clinic appointments OR through follow-up (phone or otherwise) four to six weeks after testing the client's contact(s) by asking the question below. Because an unintended negative outcome as result of HIV disclosure could still occur in the future, follow-up should occur while all contacts are being actively traced.
    - "In the time since you participated in index testing services, did you experience any harm from your partner, health care provider, or anyone else at this facility [or site]? This includes physical, emotional, sexual, or economic harm?"
- Document any adverse events following the procedures and using the forms outlined in your facility's Adverse Events Related to Index Testing SOP.

By adverse events related to index testing, we mean:

1. Threats 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
2. Occurrences of physical, sexual, or emotional harm to the index client, their sexual or drug-injecting partner(s), or family members or to the index testing provider
3. Threats or occurrences of economic harm (e.g., loss of employment or income) to the index client, their sexual or drug-injecting partner(s), or family members
4. Abandonment or forced removal of children < 19 years old from the home
5. Withholding HIV treatment or other services
6. Forced or unauthorized disclosure of client's or contact's name or personal information
7. Failure to obtain consent for participation in index testing and/or for notifying partners
8. Stigma or criminalization perpetrated by health site staff (e.g., sharing personal information with the criminal justice system about a KP member and/or person living with HIV seeking care)

Annex C. Adverse Event Report Form for Index Testing Services

This form is an adaptable example provided by PEPFAR. It is used to document adverse events.

Instructions: 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 manager so that an investigation into the adverse event can begin. Any report of a serious or severe adverse event should be investigated within 2 to 4 business days of this form being completed.

Note: Partners include both sexual and needle-sharing partners.

I. 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 Person Completing This Report:		
II. Participant Information:		
Client's Name or ID Number:	Client's Age:	Client's Gender:
Participant Type (circle one): 1) Client of HTS site 2) Client of ART site 3) Community member 4) Other: _____		
III. Event Information:		

Type of Event (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. Occurrences 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 unauthorized disclosure of client or contact's name or personal information
   e. Abandonment/forced removal from home for children less than 19 years old

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

3) **Other, Specify**_____

Does the event meet the definition of a Social Harm? (Definition: damage to subjects' reputation, risk of harm or legal action, compromised confidentiality, etc.) 1) Yes 2) No
Was the adverse event directly caused by Index Testing services or practices? 1) Yes 2) Possible 3) No
Descriptive summary of adverse event:
Describe any immediate actions taken in response to the adverse event report (e.g., was the client referred to services)? If so, which services (e.g., legal, medical, social, counseling etc.):
Name and title of person who will conduct investigation into the adverse event:

Signature of Person Completing the Report: Date of Form Completed (MM.DD.YYYY):

_____ ____ /____ /_____

Annex D. Adverse Event Investigation Form

This form is an adaptable example provided by PEPFAR. It is used to investigate adverse events.

Instructions: Please use this form to document the result 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 complaint and prevent future adverse events.

I. 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 Person Completing This Form:
II. Summary of Adverse Event That Led to This Investigation
III. Brief Summary of the Findings of the Investigation
IV. Corrective Actions Taken

V. Follow-Up Required Including Timeline and Person Responsible

VI. Results of Follow-Up
Has the event been resolved? Yes No If no, what is the plan for further follow-up?

Facility/Site POC signature: Date:

_____ ____/____/_____

Annex E. Beneficiary Abuse Disclosure and Response Form and Instructions

This form can be used in place of Appendices C and D. The portions in red are mandatory to collect for adverse event monitoring and investigation. Instructions on how to complete the form are immediately after the form.

Instructions: Unless otherwise specified, mark only one response field for each question.

PART 1 – Administrative Information and Information about the disclosure, the survivor, and the incident

To be completed by the individual to whom the survivor disclosed, with help from an outreach supervisor as needed (in case of peer disclosure). For anonymous disclosure via complaint box or other format, the focal point at the facility should enter this information.

1. Date form completed (Day/Month/Year):

_____/_____/_____

2. Location/means of disclosure (select all that apply): □ Hotline □ Mobile app (such as WhatsApp, Vibr) □ Online □ CSO or private clinic □ Public clinic □ Community □ CSO offices/DIC □ Complaint form □ LINK □ Other (specify): _____

3. Was the abuse disclosed anonymously? □ Yes □ No

If yes, write or select "unknown" or "N/A" to all questions for which the information is not available.

4. Name of person filling out Part 1 of this form:

5. Job title of person to whom survivor disclosed: □ Outreach worker □ Peer educator □ Peer navigator □ Health Care Worker □ Crisis Response Team member □ Community Advisory Board member □ N/A □ Other (specify): _____

6. UIC or program ID of survivor:

7. Age of the survivor in years:

8. Gender identity of the survivor: □ Man □ Woman □ Other □ Refuse to answer □ Unknown

9. Sex assigned at birth: □ Male □ Female □ Other □ Refuse to answer □ Unknown

10. Population type (can select multiple):
□ Sex worker □ MSM □ PWID □ Transgender □ Client of sex worker □ PLHIV □ Adolescent girl/young woman □ In a serodiscordant relationship □ None □ Unknown □ Other priority populations: _____

11. Program participant type: □ HIV testing client (include self-testing) □ ART client □ PrEP client □ Outreach □ Non-client □ Unknown □ Other: _____

12. Date of most recent reported abuse (Day/Month/Year):

13. Location of abuse (e.g., hot spot name, health facility name, or a more general term such as "at home" or "online"):

14. When was the incident disclosed? □ Within 24 hours of abuse □ >24 and ≤72 hours after □ >72 and ≤1 month □ >1 month and ≤3 months □ >3 months after abuse □ Unknown

15. Type of abuse that occurred (can select multiple):

□ **Physical** (includes hitting, slapping, kicking, shoving, choking, use of a weapon to physically harm someone)

□ **Sexual** (includes rape; sexual abuse that includes physical contact, regardless of penetration; forced sex without a condom)

□ **Emotional** (includes humiliation, verbal harassment, psychological torture, and threats)

□ **Economic** (includes denial of resources, blackmail, theft, being forced to leave one's home)

□ **Health facility-based human rights violation** (check all that apply):

- □ Withholding treatment or other services
- □ Forced/unauthorized disclosure of personal information
- □ Failure to obtain consent for participation in index testing/partner notification
- □ Stigmatizing treatment from providers
- □ Sharing client information or information about their named partners with authorities

□ Other **human rights violation** (e.g., condom and/or lubricant confiscation, arbitrary arrest, forced removal of children under 19): _____

16. A brief description of the incident:

17. Who committed the abuse? (Select all that apply)

- □ Local leader(s)
- □ Law enforcement (including police and military)
- □ Private security guard(s)
- □ Madam(s)/Pimp(s)/bar manager(s) or owner(s)
- □ Local gang(s)
- □ General community
- □ Family member(s)
- □ Regular intimate partner or past intimate partner
- □ Sex work client(s)
- □ Healthcare facility staff: (Provide name if possible) _____
- □ Peer/outreach worker (Provide name if possible) _____
- □ Other (specify): _____
- □ Unknown

18. Was the abuse directly caused by the offering or use of any of these services (select all that apply)?

□ Index testing/partner notification □ PrEP □ HIV testing
□ Community outreach □ PEP □ ART □ HIV self-test
□ Other_____ □ None □ Unknown

19. Was the abuse related to measures to prevent COVID-19 (such as curfew or lockdown)? □ Yes □ No □ Unknown

20. Response services provided at initial disclosure: □ Listened empathetically □ Inquired about survivor's needs □ Provided validating messages □ Enhanced survivor's safety □ Provided information on available services □ Referred to services □ Accompanied to services

PART 2 – Information about service eligibility and services received after initial disclosure

To be completed by the facility/site point of contact for adverse events, the case manager, OR a health worker providing response services.

21. Job title of person who is completing Part 2: □ Outreach supervisor □ Case manager □ HCW □ Index testing site point of contact □ Other: _____

22. Name of person filling out Part 2:

23. Name of health facility or CSO where person filling out Part 2 works:

24. When violence was disclosed, was the individual eligible for HIV post-exposure prophylaxis? □ Yes □ No □ Unknown

25. When violence was disclosed, was the individual eligible for emergency contraception? □ Yes □ No □ Unknown

26. Note the services or referrals provided following the disclosure of abuse (mark all that apply). These can be services provided directly or via referral.	Check boxes to indicate whether the service was provided at a PEPFAR-supported clinic/CSO or through referral; then show whether referral was completed.			
	Provided at a PEPFAR-supported site reporting on GEND_GBV	**Provided** at a PEPFAR-supported site not reporting on GEND_GBV	**Referral made** to other provider (write organization name)	**Referral completed**
Initial assessment to determine services that should be offered to the survivor				
Treatment of injuries				
Forensic examination ("rape kit")				
Rapid HIV testing				
Post-exposure prophylaxis (PEP)				
STI screening/treatment				
Emergency contraception (EC)				
Immediate psychosocial counseling				
Mental health evaluation				
Tetanus vaccine				
Initiation of ART				
Link to PrEP				
Longer-term psychosocial support (e.g., support group)				
Legal counsel				
Law enforcement intervention				

Child protection services for minor children of survivor				
Economic empowerment				
Temporary shelter				
Crisis response team				
Other (specify): _____				

27. Was PEP completed? □ Not applicable □ Yes □ No □ Unknown

28. For violence resulting in a risk of HIV: Did the survivor receive an HIV test 3 months post-violence?
□ Not applicable □ Not tested □ Tested negative □ Tested positive □ Unknown

29. Follow-up actions taken to support the survivor (if not noted under Q25).

PART 3 – Adverse events related to index testing
To be completed by the facility/site point of contact for adverse events related to index testing.
If the abuse was not related to index testing (question 18), leave this section blank.

30. Write the name and title of the person who will conduct the investigation:
*Recall that investigations related to IPV should focus ONLY on whether all procedures were followed (e.g., risk assessment, LIVES, appropriate referrals, etc.) to protect the safety and confidentiality of the client.

31. Summarize investigation findings:

32. What follow up steps and actions were undertaken to prevent similar events from occurring in the future?

33. Has the issue been resolved (e.g., does it seem unlikely to occur again)? □ Yes □ No

If no, please describe additional follow-up planned, including personnel and timeline:

Facility/Site POC signature: Date:

_____ ____ /____ /_____

Detailed Instructions to Complete Beneficiary Abuse Disclosure and Response Form

Background

Please note that this tool originally comes from the LINKAGES M&E guidance, where it is Tool 12. Changes made to this tool allow it to capture the information required by PEPFAR on adverse events related to index testing. Using this form also supports documentation of GEND_GBV (MER indicator) and GBV_REPORT_COMM (custom indicator).

Countries with their own violence incident reporting forms have the option of including domains that are newly presented in this form as an annex to their existing forms. Alternatively, they may choose to fill the form out, in addition to their other forms, when adverse events related to index testing are reported.

The portions of this form in red are required. Black domains are optional.

Instructions

The Beneficiary Abuse Disclosure and Response Form should be completed whenever abuse of a beneficiary is disclosed to program staff (health care workers, peers, crisis response team members, etc.). It may take several weeks or even months to complete the form as it documents the initial abuse and then all the services provided to the survivor* as well as actions taken by the clinic to prevent future abuses (should the abuse be related to index testing). If a new abuse is reported by the survivor at a future date, a new form should be completed.

The disclosure of violence could be made during IPV screening as part of index testing or PrEP use; during a risk assessment conducted in the community; spontaneously to any program staff person; or in any other context. The abuse can be disclosed either in-person, via hotline/website, or anonymously via LINK or a complaint form.

Adverse events from index testing should also be captured in this form, regardless of how they are disclosed.

Part 1 of the tool should be completed by the program staff person who received the disclosure of abuse. If this person needs support to complete the form (e.g., a peer educator would like the assistance of an outreach worker or supervisor) then the support person will fill it out by asking the individual to whom the disclosure was made for information. If any information is not available, simply check “unknown,” or leave blank if the question is open-ended.

Q2 – Select the answer that best describes how/where the disclosure of abuse was made.

Q3 – If abuse that occurred in a health facility is disclosed anonymously, via complain forms or LINK, select “yes” here.

Q5 – Select the title of the person to whom the survivor disclosed, even if this is not the person who is filling out Part 1. Please note that “health care worker” refers to anyone providing clinical services (doctors, nurses, HIV counselors).

** “Survivor” throughout this form refers to the person who experienced an abuse.*

Q9 – “Other” should be selected if the individual was determined to be intersex at birth.

Q12 – If the survivor reports multiple abuses, note the date of the most recent abuse.

Q13 – Answer this question according to the most recent abuse disclosed.

Q14 – Answer this question according to the most recent abuse disclosed.

Q15 – Answer this question according to the most recent abuse disclosed.

Q16 – Answer this question according to the most recent abuse disclosed. As needed, describe past abuses or patterns of abuse that were disclosed in order to fully document the situation.

Q17 – Answer this question according to the most recent abuse disclosed.

Q18 – If the abuse occurred because a service was offered or used, select the relevant service(s). IPV disclosed in the process of initiating index testing should not be classified as a result of index testing. However, IPV that occurs because of index testing should be recorded as such. Whenever “index testing/partner notification” is selected under Q18, answers to questions 30—33 are required.

Q19 – If violence occurred due to COVID-19—for example, if someone was abused when they were forced to stay at home during lockdown or someone was harassed by law enforcement when police enforced curfew—select “yes.”

Q20 – Most of the items under Q20 are part of first-line support. Checking these boxes shows that first-line support is being provided per PEPFAR and WHO requirements.

Part 2 should be completed by an individual acting as a case manager (for example, if service provision is handled by a crisis response team or a counselor is managing the person’s violence response care), by a health care worker or counselor at the site, or by the index testing point of contact (in case of an adverse event related to index testing).

Q24 – Select “yes” here if the survivor was eligible for PEP (meaning they sought services within 72 hours of an assault that carried a risk of HIV transmission). If the assault did not carry a risk of HIV transmission or the person came past 72 hours, select “no.”

Q25 – Select “yes” here if the survivor was eligible for EC (meaning they sought services within either 72 or 120 hours of an assault that carried a risk of pregnancy, depending on local guidance re: EC provision). If the assault did not carry a risk of pregnancy or the person came past 72/120 hours (depending on country context), select “no.”

Q26 – If the PEPFAR-supported facility named in Q23 has GEND_GBV targets and provided services to the survivor, place checkmarks as relevant in the first column on the left. If the PEPFAR-supported facility that provided services to the survivor does not have GEND_GBV targets, place check marks in the second column from the left. If referrals were made beyond PEPFAR-supported facilities, place a check mark in the third column. Place a check mark in the fourth column if you determine that these

referrals were completed (meaning the survivor arrived at the referral site). Whenever a check mark is made in the first column, this should be reported under GEND_GBV.

Please note that countries can adapt the list of services under Q26 to add others as relevant.

Q27 – If PEP was not initiated, select "not applicable." If PEP was initiated and completed, select "yes." If PEP was initiated but not completed, select "no." If PEP use or completion is unknown, select "unknown."

Q28 – If the survivor reported an assault that carries a risk of HIV exposure, they should be tested for HIV three months after the assault. Select "not applicable" if there was no risk of HIV with the assault. Select "not tested" if there was a risk of HIV but no test. Select "tested negative" or "tested positive" if a test was conducted and a result was shared. Select "unknown" if it is unknown whether a test was conducted.

Q29 – If other actions, not captured in Q26, were taken to support the survivor, document those here. This includes any issues with referral services (such as reasons for incomplete referrals). If the survivor pursues legal action, please document any legal outcomes, including the date of those outcomes. If the survivor needed services that were not available or the survivor was not able to access services due to cost, please note here.

Part 3 – This portion of the form should be filled out ONLY if an adverse event related to index testing occurred. It should be completed by the facility/site point of contact for adverse events. If the abuse was not an adverse event related to index testing, leave this section blank. Investigations related to IPV should focus ONLY on whether all procedures were followed (e.g., risk assessment, LIVES, appropriate referrals, etc.) to protect the safety and confidentiality of the client.

Q30 – If the abuse was related to index testing (Q18), write the name and title of the facility staff person who will conduct the investigation.

Appendix F. Patient Rights Poster

This poster from PEPFAR can be adapted to your context.

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 treatments 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 healthcare service at this 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, sexual orientation, or any other personal characteristic.)
- ✓ **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 private and secure and not shared with anyone outside of the healthcare 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 **Patient Complaint Form** and place it in the secure drop box by the registration desk. You can also call the Community Advisory Board at XXX-XXX-XXX. They can make a complaint on your behalf if you do not feel comfortable doing so on your own.

Appendix G. Customer Complaint Form

This form is an adaptable example provided by PEPFAR.

Customer Complaint Form for HIV Services

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 can 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 not share your personal information 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 next section)

Your Name:_____

Your Address:_____

Your Phone Number:_____**Your Email (if you have one):**_____

INFORMATION ABOUT YOUR COMPLAINT

Date Incident Occurred_____ **Time Incident Occurred**_____

Place Where Incident Occurred: _____

Name of health care 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 would like to see happen: _____

_____

_____

THANK YOU! Please place this completed form in the drop box by the registration desk.

Appendix H. Implementer Security Incident Log

Implementer security incident log			
	Question	**How to Answer**	**Response**
1	Security incident number	Begin with number 1 and continue; the numbering allows security incidents to be linked to one another (see question #14)	
2	Date of incident	Type as YEAR-MONTH-DAY (e.g., 2019-02-17 for February 17, 2019) in order to organize this security event log by date	
3	Time of incident	Specific time of day (if known), or more general (morning, afternoon, evening, night)	
4	Perpetrator	If known and safe to list, or use a more general term such as "law enforcement officer"	
5	Affected organization	Name of HIV program implementing partner (i.e., community-based organization's name)	
6	Target	Specific person or type of staff, physical space (e.g., name of a specific hot spot), website, database, etc. Do not name individuals here unless you have their permission to do so.	
7	Where incident occurred	Physical address, online, by phone, etc.	
8	Believed motivation of aggressor (if known)	For example: intimidation, to stop programming, to deflect attention from other local issues	
9	Description of security incident	For example: Facebook posts on project page said "paste specific message here;" or peer educators were arrested without charge when distributing condoms to a group of MSM during a mobile HIV testing event	
10	Programmatic consequences of security incident	For example: implementing partner will conduct only online outreach until physical outreach is considered safe to conduct	
11	Description of actions taken to respond to security incident	For example: on YEAR-MONTH-DAY implementing partner targeted in Facebook post decided that it is not safe to conduct outreach activities for a two-week period and implementing partner filed a complaint with the police.	

		On YEAR-MONTH-DAY local Ministry of Health officials held a meeting with power holders and local law enforcement; they discussed threats to the implementing partner and created a WhatsApp group that can be used to notify and activate allies immediately as needed. Please include dates of actions taken (and continue to update this row as actions are taken).	
12	Was the security incident related to index testing?	Select one: Yes or No or Unsure	
13	Was the security incident related to COVID-19?	Select one: Yes or No or Unsure	
14	Which other security incidents is this related to? (if any)	Note whether this incident was related to other security incidents by listing other security incident numbers here.	
15	Incident resolution (if any)	For example: on YEAR-MONTH-DAY peer educators were released from state custody and provided with mental health support.	