

Guidance for Implementing Safe and Ethical Index Testing Services

Updated July 13, 2020

Packet of Materials Available

- This slide deck is part of a packet of materials on Safe and Ethical Index Testing available on PEPFAR's SharePoint site: <u>https://www.pepfar.net/sites/indextesting/Shared%20Documents/Forms/AllItems.aspx</u>
- The packet of materials includes:
 - This slide deck in PDF form
 - All forms and tools referenced in this slide deck (as zipped files). See next slide for inventory
- These materials were developed and reviewed by the interagency PEPFAR Index and Key Populations (KP) Communities of Practice



Inventory of Tools and Implementation Forms

Folder	Tools	Implementation Forms
1. Minimum Standards	CDC REDCap; USAID REDCap	NA
2. Consent	NA	Consent Form
3. IPV Risk Assessment and Response	NA	IPV Assessment Questions; LIVES Materials
4. Adverse Events (AE) Monitoring and Reporting	NA	AE Investigation Form, AE Reporting Form, Customer Complaint Form, Index Testing Sample Register, Patient Rights Poster
5. Quality Assurance and Accountability	GBV Quality Assurance Tool; SIMS Standards	Supportive Supervision Form



Overview of Index Testing Services in PEPFAR

- Index testing (aka partner notification or contact tracing): is a case-finding approach that focuses on eliciting the sexual or needle sharing partners and biologic children of HIV-positive individuals and offering them HIV testing services
- All HIV testing services, including index testing, must meet **WHO's 5C standards:** consent, counseling, confidentiality, correct test results, and connection to HIV prevention, care, and treatment services
- Index testing is a completely voluntary service offered to people living with HIV to assist them with getting their partner(s) and child(ren) tested for HIV. They are free to accept or decline this service.
- Index testing should be client-centered and focused on the needs and safety of the index client and his or her partner(s) and children
- All recently testing HIV-positive or with recent unsuppressed viral loads must be provided with all available HIV prevention, care and treatment services, regardless of their decision to participate in partner notification services
- Services MAY NEVER be withheld from clients and clients MAY NEVER be pressured into disclosing the names and contact information of their partner(s)



Overview of Index Testing Services in PEPFAR (cont'd)

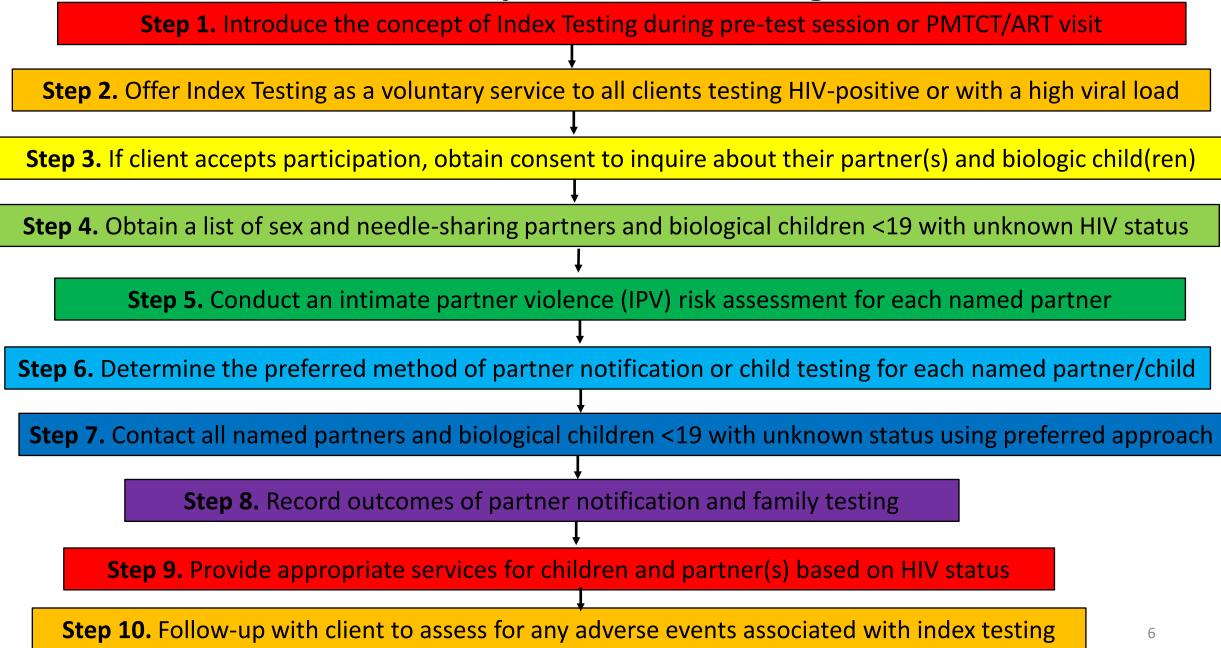
- All providers conducting index testing must be trained on index testing procedures including Intimate Partner Violence (IPV) screening and adverse event monitoring and reporting
- A secure environment (e.g. lockable cabinets) must be in place to store patient information
- While community organizations may play a role in monitoring index testing, the Implementing Partner is responsible for and required to have an adverse-event monitoring system in place at all facilities that are funded implemented through program resources.

Note: See Section on Quality Assurance and Accountability for monitoring and reporting requirements





10 Steps of Index Testing



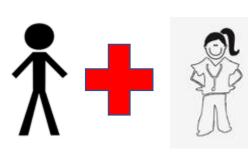
Options for Notifying Partner(s) and Child(ren) about HIV Testing



Provider Referral = A counsellor or other health care provider will call or visit your partner and offer them HIV testing services.



Client Referral = You tell your partner about your HIV and encourage him or her to come to the health facility for an HIV test.



Contract Referral = You and the counsellor will work together to notify your partner. You will have 14 days to tell your partner. After which, the counsellor will contact your partner and offer them HIV testing services.



Dual Referral = The counsellor/provider will sit with you and your partner and support you as you tell your partner about your HIV.

What are the Minimum Standards for Safe and Ethical Index Testing?

All PEPFAR-supported sites must comply with the following minimum standards for safe and Ethical index testing:

- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- ✓IPV risk assessment and provision of "first line" response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
- A site level adverse event monitoring and reporting system
- ✓ Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')



Implementing Safe and Ethical Index Testing Services

- There is no such thing as zero risk; all HIV testing programs involve some risk
- This level may be increased for index testing due to possibilities for accidental disclosure of confidential information regarding the client and his/her partners(s), violations of consent, and other adverse events
- All PEPFAR-supported programs should take steps to implement safe and ethical index testing services by:
 - 1. Monitoring site and provider-level **compliance with minimum standards** for index testing
 - 2. Obtaining **informed consent** prior to the elicitation interview and before contacting partners
 - 3. Conducting an **IPV risk assessment** for each named partner and providing appropriate services for clients experiencing violence
 - 4. Implementing a robust mechanism for detecting, monitoring, reporting, and following up on any **adverse events** associated with index testing services
 - 5. Utilizing **quality assurance and accountability** to remediate any gaps in the provision of index testing services





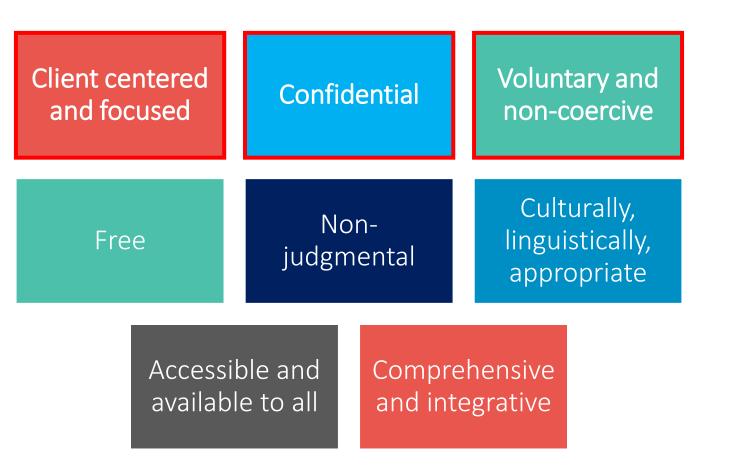
1. Monitor Compliance with Minimum Standards



Index Testing Services Must meet WHO 5Cs

Minimum Standards for Safe and Ethical Index Testing include:

- Meeting the WHO 5Cs by being consensual, confidential, and include counseling, correct test results and connection to treatment or prevention services AND
- Adhering to core principles of HIV testing services listed on the right





.7 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

Index Testing Services Should Always be Voluntary

- Index testing is a completely voluntary service offered to people living with HIV to support them in getting their partner(s) and children tested for HIV
- Index testing should be client-centered and focused on the needs and safety of the index client and their partner(s) and children
- All HIV testing clients, including index clients, should be provided with all available HIV prevention, care and treatment services, regardless of whether or not they provide details about their partners.
 - Services may **NEVER** be withheld under any circumstances.
 - Clients may **NEVER** be pressured into sharing the names of their partner(s)
 - Clients' should be informed of their right to decline participation in index testing services throughout the process, not just during the elicitation interview.
- Clients may opt-out of index testing services FOR ANY OR NO REASON. Clients do not need to provide a reason for not participating in index testing services.



Index Testing Services Must Remain Confidential

- **Confidentiality** = protection of personal information
- Both the confidentiality of the index client and all named partners and children should be maintained at all times.
- The name of the index client should never be shared with the partner and the partner's HIV status should never be shared with the index client (unless consent is obtained from both parties).
- Programs MUST have confidentiality protections in place prior to the start of index testing services (including safe storage of data)
- Full information about the potential risk for unintended disclosure of the client's identity **MUST** be discussed with the client as part of obtaining informed consent for index testing services





Index Testing Services Must Protect the Confidentiality of Index Clients and Contacts

- Whenever possible, names of contacts other than biological children (e.g. sex and needle-sharing partners) should be kept separate from the names of index clients to prevent accidental breaches in confidentiality
 - One method for doing this is to assign all index clients a unique ID number. This number can be written in the "comments" section of the HTS register
 - This ID number can then be used in place of the client's name in the index testing register
- Programs may also consider having separate index testing registers for family testing (spouse and biologic children) and partner notification (extramarital partners, same sex partners, needle sharing partners, etc.)
- Under **NO** circumstances should the name of the index client be shared with community organizations notifying partners out in the community.
 - Only information required to contact the partner should be shared with these organizations



REMINDER: Minimum Standards for Index Testing

All PEPFAR-supported sites must comply with the following minimum standards for safe and Ethical index testing:

- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- ✓IPV risk assessment and provision of "first line" response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
- A site level adverse event monitoring and reporting system
- ✓ Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')



Meeting Minimum Standards for Index Testing (cont'd)

- PEPFAR requires all sites and personnel, involved directly or indirectly with index testing, to meet minimum standards for safe and ethical index testing
- All IPs serving all populations including general populations must verify that each facility and/or community site providing index testing meet these minimum standards
- COP20 guidance states that ALL sites must be assessed and meet minimum standards by Oct 1, 2020*
- PEPFAR will work with country teams to ensure that either: (1) existing data confirm that current HTS provision at sites meets minimum standards or (2) sites are brought up to standards and assessed using vetted and valid tools

*Given the COVID-19 pandemic, we are aware that site visits may be limited. As per the official COIVD-19 Technical Guidance posted on state.pepfar.gov, all country teams are under chief of mission authority and movements may be limited. In addition, all IPs and USG staff must exercise and abundance of caution re: site visits. As such, the October 1 deadline is not a strict requirement. Country teams should keep their S/GAC Chair/PPM and relevant Agency HQ POCs posted on assessment plans and progress.



Meeting Minimum Standards for Index Testing (cont'd)

- Assessing whether sites meet minimum standards for safe and ethical Index Testing can be done online or using a paper-based version of the REDCap tool (REDCap is a free and secure, Web-based application)
- Note that the REDCap tool is not intended for site certification
- Instead, this tool is designed to assess whether sites are meeting minimum standards (Section 1 of the tool) and to identify program gaps, remediation and training needs (Sections 2-5 of the tool)





Meeting Minimum Standards for Index Testing (cont'd)

 There is no requirement that site assessments must be completed only by USG staff. Assessments may be completed by one individual and/or a team of individuals (e.g. someone from USG, IP, and CSO).

• PEPFAR programs are also encouraged to include Ministry of Health and other stakeholders (e.g. Civil Society, community organizations, etc.) as part of the assessment process, including conducting assessments, sharing gaps, and identifying solutions.

• Summary data from the assessments should be shared with Ministry of Health and other key stakeholders.



Assessing Minimum Standards Using REDCap

- REDCap online tool should be completed for each PEPFAR supported site (facility and community)
 providing index testing services
- All questions should be administered as written. The only changes permitted include:
 - Using country specific terminology to refer to 'index testing services'
 - Adding questions to the existing assessment tool
 - Any changes should be reviewed and approved by your HTS ISME/HQ POC
- Each site will receive a score based on the assessment of minimum standards included in Section 1
- Sections 2-5 will not be scored instead information gathered will be used to further inform quality improvement efforts for index testing services
 - Assessors will need to upload SOPs, job aids, etc. that will be reviewed by IP, HTS in-country POC and HTS ISMEs



Assessing Minimum Standards Using REDCap (cont'd)

- The Index and KP Communities of Practice, along with GBV technical experts, developed an online Minimum Standards Checklist tool in REDCap (Section 1)
 - CDC's REDCap tool is available here: https://is.gd/indextestingcert
 - USAID is available here: https://redcap.link/64a2cet8
- The REDCap Tool can be printed should sites want to fill out on paper before entering electronically
- IPs can use this tool for the assessment or create their own Excel or paperbased tool
 - <u>However</u>, any tool created should include the same minimum standards (see Section 1 of the REDCap tool) <u>and</u> should be approved by the Chair/PPM in consultation with HTS ISME prior to use at sites



Assessing Minimum Standards Using REDCap (cont'd)

At the Start of the Site Assessment:

- Ensure both the assessor(s) and staff who are answering questions are the most knowledgeable about index testing services at that site
- Emphasize that the site assessment is designed to optimize quality of index testing services

At the End of the Site Assessment:

- Site staff should always be provided same-day feedback that includes:
 - Specific areas of optimal performance/best practices and areas for improvement
 - Significant breaches of policy or procedure that were observed should be brought to the attention of site and IP leadership
 - Informing staff that a remediation plan will be developed to address any minimum standards that are not achieved
 - Sharing copy of completed assessment with the site



- Section 1: Minimum Standards Checklist*
- Section 2: Index Testing Training and Post-Training Evaluation
- Section 3: Intimate Partner Violence/Gender-Based Violence Training
- Section 4: Community Engagement
- Section 5: KP, PLHIV and Young People Considerations

*Assesses compliance against Minimum Standards for Safe and Ethical Index Testing



5)

Section 1: Checklist (33 questions)

Site Assessment Tool for Index Testing Minimum Program Standards

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Section 1: Minimum Standards Checklist

All HIV testing services must meet WHO's 5Cs minimum standards. For index testing, index clients have already received a correct diagnosis so the other 4 Cs must be met. In addition to the 5Cs, other minimum standards for index testing include conducting an intimate partner violence (IPV) risk assessment, providing training and supportive supervision, and adverse event monitoring and response. Section 1 assesses whether a site is meeting these minimum standards for index testing.

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	Save & Return Later	

- 1.1. Counseling 4 questions
- 1.2. Informed Consent 5
- 1.3. Confidentiality 6
- 1.4. Connection to Services 2
- 1.5. IPV Risk Assessment 6
- 1.6. Training and Supportive Supervision 4
- 1.7 Adverse Events Monitoring and Response 6

How many providers/counselors have been formally trained in index testing at?			
What index testing training curriculum was used?			
If available, please upload a file containing index training materials (e.g. agenda, slides, etc).	C	Upload document	
Do not attach documents containing patient personally identifiable information.			Documents can be uploaded I the assessor. All documents from a facility will be stored ir
In what format was the index testing training provided?	 In-person group In-person individual 		one file together with the fina survey answers.
(check all that apply)	 Online individual Online group 		Survey answers.
	Other		
How many hours of index testing training did providers/counselors receive?			

Implementing partner name: Facility name:	
Facility name:	
Name of individual conducting the site assessment:	
Email of person conducting the assessment:	
Date the assessment was conducted:	
Name of facility point-of-contact assisting w/ the assessment:	
Number of HIV testing services providers/counselors that work in?	
Number of providers/counselors at that provide index testing:	
Next Page >> Save & Return Later	

Assessor can return to the tool at any time.

REDCap Tool Summary

Checklist score out of 33:	0	
If checklist score < 33, the minimum requirements at this facility/site have not been met. Please briefly describe specific correction actions planned in order to achieve the minimum standards. Include a timeline and person responsible for each proposed action.	Expand	
Please describe any additional gaps (beyond those identified in the minimum standards checklist) at the facility related to index testing that should be addressed.		

- A minimum standards score will be given at the end of the questionnaire
- If checklist score < 33, the minimum requirements at this facility/site has not been met.
- A remediation plan must be developed to achieve the minimum standards. Be sure to include a timeline and person responsible.
- Survey data can also be saved and downloaded in PDF.

Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need the survey link to this survey.

Survey link for returning

You may bookmark this page to return to the survey, OR you can have the survey link emailed to you by providing your email address below. If you do not receive the email soon afterward, please check your Junk Email folder.

Enter email address

Send Survey Link

Your email address will not be stored

Or if you wish, you may continue with this survey again now.

Continue Survey Now

What if sites do NOT Meet Minimum Standards for Safe and Ethical Index Testing?

- Sites not meeting all minimum standards must take immediate steps to ensure they are able to meet these standards by the end of fiscal year 2020
- In coordination with the USG point of contact (POC), the IP will establish a remediation plan that is actionable and timebound
- If the issue is specific to individual provider(s), the implicated provider(s) should not conduct index testing/counseling until they have been re-trained and the issue or issues are corrected.
- It is possible that a provider will not be allowed to conduct index testing/counseling at all if remediation proves unsuccessful

See final Section on Quality Assurance and Accountability



2. Obtain Informed Consent



Informed Consent Must Be Obtained Prior to Eliciting the Names of Contacts and Before Partner Notification

Sections

Instructions: Health care worker should use this script to obtain consent for index testing services

What Are Index Testing Services?

If they agree to participate, we will ask the names and contact information of their partner(s) and child(ren)

They can choose one of four options to get their partner(s) and child(ren) tested for HIV

They can choose different options for different partner(s)

Key Messages

Instructions:

The counselor or health care worker should use this script to obtain informed consent from the index client prior to eliciting the names and contact information of sex/drug-using partner(s) and biological children. While index testing services should be offered to all index clients, they have the right to decline these services without any impact on their ability to receive other health services, including anti-retroviral treatment.

What are Index Testing Services?

It is important that your partner(s) and biological children are tested for HIV. If they are negative, we can provide them with information and services to help them remain free from HIV. If they are positive, we can start them on anti-retroviral treatment so they can live long, healthy lives. At this facility (or site), we are offering index testing services to help you get your partner(s) and biological children tested for HIV. We are offering these services because we know it can be difficult to tell your partner(s) and children about your HIV. Participation in index testing services is voluntary. It is a service we offer if you want to access it. If you don't want to participate it will not affect any other health services, including treatment, that you will receive from us.

If you agree to participate, I will ask you to give me the names and contact information of people you have:

- Had sex with in the past year, including anyone you had sex with just one time and even if you used a condom;
- Shared needles or injection equipment with; or
- Given birth to who are under the age of 19 years.

We offer four options for assisting you to get your partner(s) and child(ren) tested for HIV:

- Client referral where you tell your partner about your HIV and encourage him (or her) to come to the facility (or site) for an HIV test.
- Dual referral where a counsellor will sit with you and your partner and support you as you tell your partner about your HIV. We will then offer your partner an HIV test.
- Provider referral where a counselor will call or visit your partner and offer them an HIV test. This
 approach does not require you to tell your partner about your HIV.
- Contract referral where you will have 14 days to tell your partner about your HIV and bring him (or her) in for an HIV test. After 14 days, the counselor will call or visit your partner and offer them an HIV test.

You are free to choose different options for different partner(s).

Informed Consent Must Be Obtained Prior to Eliciting the Names of Contacts

Sections

Index Testing Services Are Completely Voluntary

Index Testing Services Are Confidential

What Are the Risks Associated with Index Testing?

Kev Messages

Index Testing Services Are Completely Voluntary.

You can choose <u>whether or not</u> to participate in index testing services. This means that you do not have to provide the names and contact information of your partner(s) and child(ren) if you feel uncomfortable sharing this information with us. You are free to say "no" without giving us a reason for why you do not want to participate. It is enough just to say "no". You will still receive anti-retroviral treatment and other health services at this facility (or site), regardless of whether you choose to participate in index testing services. You are also free to change your mind at any time. This means you can say yes to index testing services now, but later decide you do not want to participate.

Index Testing Services Are Confidential

We are committed to protecting your personal information. All the information you share with us will be kept in strict confidence. This means that we will not reveal your name to your partner(s). It also means that we will not be able to tell you whether your partner tested for HIV or his or her HIV status, unless we get consent from both you and your partner(s). We may share your partner's name and contact information with a community organization that helps us conduct HIV testing out in the community. However, your name will not be shared with this organization and they will not know who gave them the information about your partner. In this way, they will not be able to reveal your name to your partner. All information you provide us will be kept in locked cabinets, accessible only to health care workers and counselors providing index testing services.

What Are the Risks Associated with Index Testing?

Although we will keep your identity a secret when we notify your partner, there is a risk that your partner may be able to determine that you were the one who provided his or her contact information. This is particularly true if you are the only person your partner has had sex with in the past year. If you are concerned that your partner might hurt you, please let us know. We can review different ways of notifying your partner that may protect your safety. However, we will not notify your partner if we cannot protect your safety.

If you choose to notify your partner by yourself, there is a risk that your partner may react badly when you tell him or her about your HIV status. However, the counselor will review strategies for how to tell your partner about your HIV, including how to answer his or her questions and deal with any negative emotions, as part of the counseling session. In addition, you can bring your partner to this facility (or site), and a counselor can help you tell your partner about HIV.

Informed Consent Must Be Obtained Prior to Eliciting the Names of Contacts

Sections

What Are the Benefits Associated with Index Testing?

Provide an Opportunity to Ask Questions

Obtain Consent for Participating in Index Testing Services

Key Messages

What Are the Benefits Associated with Index Testing?

By sharing the names and contact information of your partner(s) and child(ren), we can help you to get them tested for HIV. If they are positive, we can start them on treatment so they can remain healthy and strong. If they are negative, we can provide them with information and services to help them to stay negative.

What Questions do You Have about Index Testing?

Please let me know if you have any questions about index testing. We want you to have enough information to make an informed decision about whether to participate in these services.

Consent to Participate in Index Testing

Do you understand the objectives, risks, and benefits of index testing services?	[_] Yes	[] No
Have all your questions been answered?	[_] Yes	[] No

Do you agree to participate in index testing services? Remember that even if you consent now, you can always change your mind <u>at a later time</u>.

Note: Consent can be verbal or written, depending upon your national guidelines

Obtain Consent to Contact Partner if Client Chooses Contract or Provider Referral

- **Contract referral**, "I plan to tell my partner about my HIV and refer him (or her) to this facility (or site) for HIV testing within 14 days of today's date. If I am unable to do this within 14 days, I give permission for the counselor to telephone my partner and offer them an HIV test. I understand that while all services are confidential and my partner will not be given my name, there is a risk of accidental disclosure or that my partner will attempt to guess my identity."
- **Provider referral,** "I give consent for the counselor to telephone (or visit) my partner and offer them an HIV test. I understand that while all services are confidential and my partner will not be given my name, there is a risk of accidental disclosure or that my partner will attempt to guess my identity."

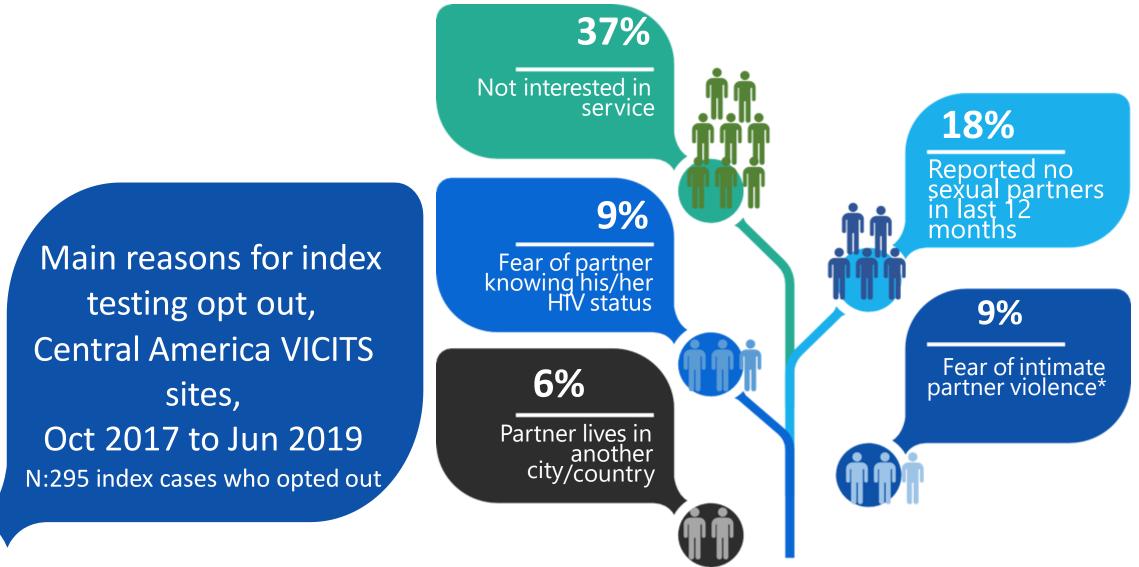


Track Reasons Why Clients Decline Index Testing Service

- Programs should track why clients decline index testing services, but keep in mind that clients are NOT required to provide a reason (as described in example consent form)
- Some reasons, to adapt as needed, include:
 - Declined to answer/no reason given
 - No time for elicitation interview
 - Do not believe services are confidential/afraid partner will learn my identity
 - Afraid of intimate partner violence/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_



Example from PEPFAR/Central America



*This represents 3% of all index cases in the reported period. 13-Jul-20

3. Conduct IPV Risk Assessments and Provide Appropriate Services



REMINDER: Minimum Standards for Safe and Ethical Index Testing

All PEPFAR-supported sites must comply with the following minimum standards for safe and Ethical index testing:

- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- ✓IPV risk assessment and provision of first line response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
- A site level adverse event monitoring and reporting system
- ✓ Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')



Why Do We Conduct Intimate Partner Violence (IPV) Risk Assessment?

- Screening for IPV risk <u>and</u> provision of immediate response to any disclosure of violence is a standard operating procedure for index testing services
- The **primary goal of the IPV risk assessment is to ensure no harm** comes to the index client, their partner(s), or family members as a result of index testing services
- The IPV risk assessment also allows us to identify and link PLHIV experiencing violence to GBV response services. This can help improve adherence and retention among these clients





How Do We Conduct IPV Risk Assessment?

- Clients should be asked about their experience or fear of violence for each named partner
- You can use the introductory script below to introduce the topic:

"Many people experience problems with their spouse or partner, or someone else they live with. This may include violence. Violence from a partner can negatively affect your health and because I care about your health, I want to ask you the following questions before we talk about partner notification. I want you to know that I will keep anything you tell me between us, unless you give me permission to share it."



How Do we Conduct IPV Risk Assessment? (cont'd)

- The provider asks about violence using a standard set of IPV screening questions.
- A sample tool (below) using WHO validated questions can be found at: <u>https://www.pepfarsolutions.org/tools-</u> <u>2/2018/4/11/index-and-partner-notification-</u> <u>testing-toolkit</u>

SCREEN FOR INTIMATE PARTNER VIOLENCE (IPV)

Because your safety is very important to us, we ask all clients the following questions:

- 1. Has [partner's name] ever hit, kicked, slapped, or otherwise physically hurt you? □ Yes □ No
- 2. Has [partner's name] ever threatened to hurt you?

🗆 Yes 🛛 No

3. Has [partner's name] ever forced you to do something sexually that made you feel uncomfortable?

🗆 Yes 🛛 No

- Country teams should feel empowered to develop and validate their own IPV screening questions based on their data and context
- For example, if a team wants more focus on emotional IPV, they could use questions from the Violence Against Children and Youth Surveys (VACS), validated by CDC:

Has [partner's name] ever done any of these things to you:

- insulted, humiliated, or made fun of you in front of others?
- *kept you from having your own money?*
- tried to keep you from seeing or talking to your family or friends?
- *kept track of you by demanding to know where you were and what you were doing?*



What If the Client Says Yes to a Screening Question?

- A client's safety is the most important factor in determining if they should participate in index testing services
- If any client discloses violence, the first priority is to provide a compassionate first line response, including safety checks and referrals to GBV-related services
- All decisions about partner notification should ultimately be up to the client
- However, providers should recommend to the client that partner notification not proceed in cases where there is a risk of violence



Offer First-Line Support if the Client Discloses Violence

- First-line support is a practical, survivor-centered, empathetic counseling approach. It is the immediate care given to an index client who has experienced violence upon their first contact with the health or criminal justice system.
- First-line responds to the client's emotional, physical, safety and support needswithout intruding on their privacy, and is also a component of clinical post-violence care.
- Often, first-line support is the most important care that you can provide. Even if this is all you can do, you will have greatly helped your client.
- First-line support has helped people who have been through various upsetting or stressful events, including anyone subjected to IPV.



The WHO defines first-line support using the acronym "LIVES":

L	ISTEN	Listen closely with empathy, no judgement
I	NQUIRE	Assess and respond to the client's needs and concerns – emotional, physical, social, and practical
V	ALIDATE	Show the client you believe and understand them
Ε	NHANCE SAFETY	Discuss how to protect the client from further harm
S	UPPORT THROUGH REFERRALS	Help connect the client to appropriate services, including social support. <i>For KPs, this should only include KP-friendly services</i>

Adapted from WHO Clinical Handbook (2014)



How to Assess Client Safety If the Client Discloses Violence

- The following questions can be used by the provider to assess the client's safety:
 - Has the physical violence happened more often or gotten worse over the past 6 months?
 - Has that person(s) ever used a weapon or threatened you with a weapon?
 - Is that person(s) violently and constantly jealous of you?
 - Has that person(s) threatened to kill you?
 - Do you believe that person(s) could kill you?
 - [For female clients], has that person(s) ever beaten you when you were pregnant?
- If the client responds yes to any of these question, it may not be safe for the client to return home.
- The provider should make appropriate referrals and help the client to make a safety plan
 - Referrals can include shelter or safe housing
 - The safety plan should include a safe place where the client can go (such as a friend's home or church).
- The provider's response should not cause further trauma to the client; the client's decision on whether or not to involve the police or accept a referral should be respected at all times





Role of the Index Testing Provider



- Providers should be trained in LIVES and how to ensure respectful, sensitive communication with clients
- The client is the expert on their situation. Explore the client's options and respect their wishes
- Speak to the client respectfully with kindness and empathy, not blame
- Empower the client to ask for support
- Have a list of referral services available to support index clients who have experienced violence
 - When possible, include location of referral, proximity to the facility and information on transport support options
- Know the resource a client is being referred to quality matters

Adapted from WHO Clinical Handbook (2014)

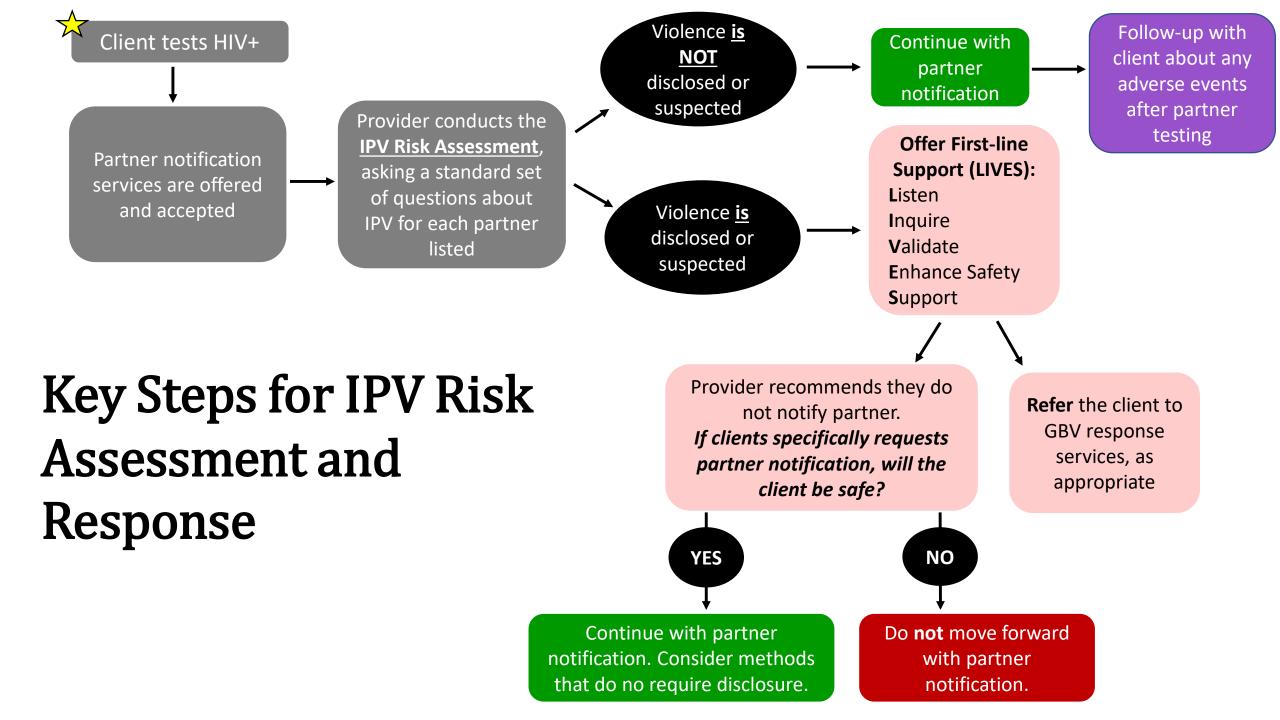


Index Testing Should <u>NOT</u> Be Offered if the Site Is Unable to Inquire about IPV and Respond Appropriately

- Minimum requirements for the IPV Risk Assessment include:
 - A private setting, where confidentiality is ensured
 - Index training providers have been trained how to ask about IPV and how to respond
 - A protocol or standard operating procedure is in place which outlines the roles and responsibilities of site staff if an index client discloses violence
 - A standard set of questions for asking about IPV
 - Index testing providers have the ability to provide first-line support: Listening, Inquiring, Validating, and Enhancing safety and Support through referrals
 - A system for referrals is in place for clients experiencing violence
- If any of these minimum requirements is not met, then the site does not have the ability to conduct the IPV risk assessment and index testing services should not be offered.

Also see final section on Quality Assurance and Accountability





4. Implement an Adverse Event Monitoring and Reporting System



REMINDER: Minimum Standards for Safe and Ethical Index Testing

All PEPFAR-supported sites must comply with the following minimum standards for safe and Ethical index testing:

- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- ✓IPV risk assessment and provision of "first line" response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
- A site level adverse event monitoring and reporting system
- ✓ Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')



- Adverse Event = an incident that results in harm to the client or others as a result of their participation in index testing services.
- 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.



Adverse Event Categories

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/or 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)



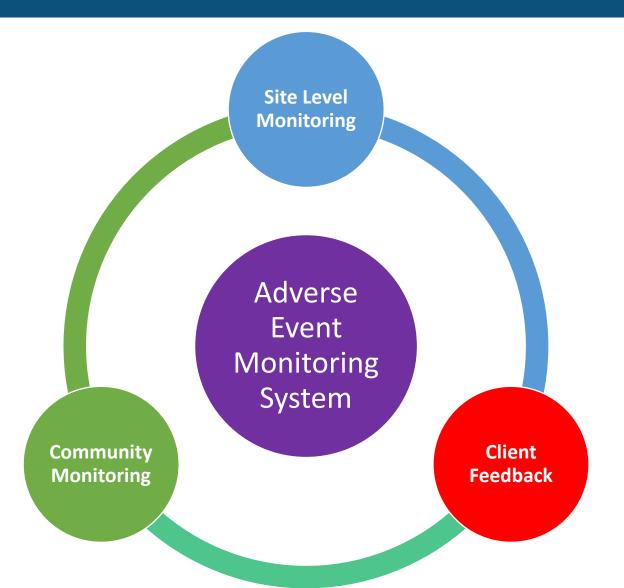
Monitor Consent, IPV and Other Adverse Events (AE)

- Ensure forms are available at the facility or site for staff to document and monitor consent, IPV, and frequency of AEs
- Flag sites with unusually high acceptance of index testing services for a supportive supervision monitoring visit to ensure index testing is being offered as a voluntary service
- Actively monitor reasons for refusing index testing services, prevalence of IPV and other AEs (e.g. confidentiality breaches, stigmatization, coercive tactics, etc.) for improvement
- Investigate each reported AE and follow-up





What is Included in an Adverse Event Monitoring System?





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Site Level Monitoring

- Facilities should routinely ask index clients if they experienced any adverse events following participation in index testing services
 - Suggested question, "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?"
- This follow up should be done during the client's first 2-3 clinic appointments OR through follow-up (phone or otherwise) 4-6 weeks following testing of client's contact(s). Note: an unintended negative outcome as result of HIV disclosure could still occur in the future and, as such, follow up should occur while all contacts are being actively traced
- All reports of adverse events should be documented

Adverse Event Report Form for Index Testing Services

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 2-4 business days of this form being completed.

Note: Partners include both sexual and needle-sharing partners

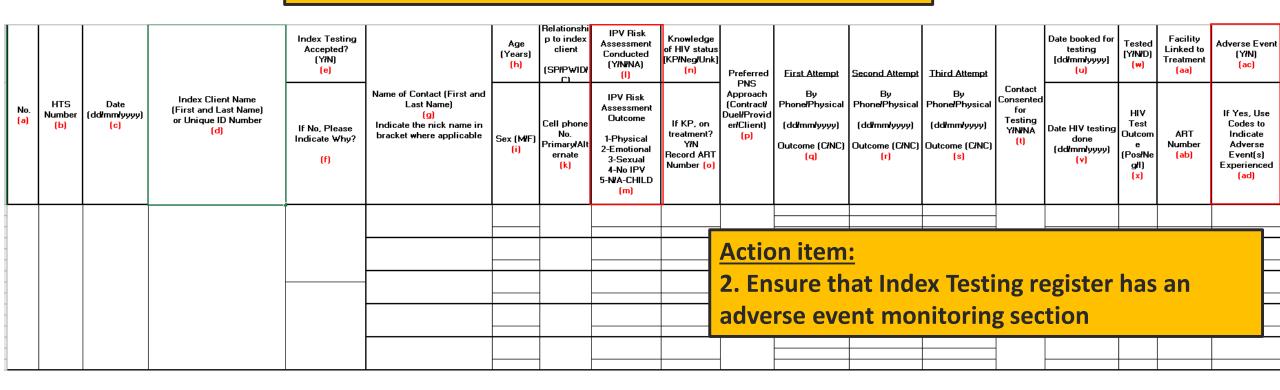
	I. Procedural Information:								
Date For	Date Form Completed:								
Facility o	r Site Name:								
Facility T [,]	ype (circle one): 1) MOH 2) Key	Population 3) Private	4) Other:						
Date and	Time Adverse Event Occurred:								
Name Ti	tle, and Phone Number of Person	Completing This Peport:							
Name, II	ue, and Phone Number of Person	completing this keport.							
	II. Pa	rticipant Information:	-						
Client's N	lame or ID Number:	Client's Age:	Client's Gender:						
		-							
Participant Type (circle one):									
	of HTS site 2) Client of ART site		r 4) Other:						
1) Client	of HTS site 2) Client of ART site	3) Community membe	r 4) Other:						
1) Client	of HTS site 2) Client of ART site III. went (Please circle all that apply)		r 4) Other:						
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1) Client Type of E 1) Se a. b. c. d. e. 2) Se a.	of HTS site 2) Client of ART site III. vent (Please circle all that apply) evere Threats of physical, sexual, or ec members, or the index testing p Occurrences of physical, sexual, family members, or the index te Withholding treatment or other Forced or unauthorized disclosu Abandonment/forced removal f erious	Event Information: conomic harm to the ind rovider or economic harm to th sting provider services re of client or contact's i rom home for children <	ex client, their partner(s) or famil e index client, their partner(s) or name or personal information : 19 years old ng and/or for notifying partners						

3) Other, Specify



Action item:

1. Ensure that Index Testing register has an IPV Risk assessment section for each named contact



Action item:

3. Use this information to track number of contacts not tested/traced due to IPV risk concerns and number and type of adverse events associated with index testing services

Notify Index Testing Clients of Their Right to Receive Quality Services

- Sites should notify clients of their right to receive quality index testing services
- They should also be informed of their ability to make a complaint if these rights are violated
- This can be done through posters in waiting/exam rooms, patient handouts, and other educational materials



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, risk behavior, 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 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 it on your own.



Establish Channels for Client Feedback

Index clients should be provided multiple pathways for issuing concerns or complaints regarding index testing services. These include:

- Suggestion boxes within health facilities
- Hotlines
- Online submissions
- Client surveys

III:	structions: You have the right to receive HIV services that respect your needs as a person and that
ar	e free of discrimination. If you feel like your rights have not been respected or that you received
ina	adequate health services, we ask that you complete this form so that we can improve our services
Yo	u can choose to make your complaint anonymous or confidential.
	Anonymous = You choose not to share any personal information with us. This means we will n be able to identify you.
	Confidential = You share your name and phone number with us. We may use this information t
	contact you and ask additional questions about your complaint. We will keep this informatio
	safe. This means we will not share it with anyone not involved in handling your complaint.
-	INFORMATION ABOUT YOU
Do	You Want This Complaint to Be? Confidential Anonymous (please skip to next section)
Yo	ur <u>Name:</u>
Yo	ur Address:
Yo	ur Phone <u>Number:</u> Your Email (if you have one):Your Email (if you have one):
\geq	
	INFORMATION ABOUT YOUR COMPLAINT
Da	te Incident Occurred Time Incident Occurred
Pla	ace Where Incident Occurred:
Na	ame of Healthcare Workers Involved (if known):
DI.	ease Tell Us about What Happened:
PI	ease Tell Us about What <u>Happened:</u>
_	
_	
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5	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



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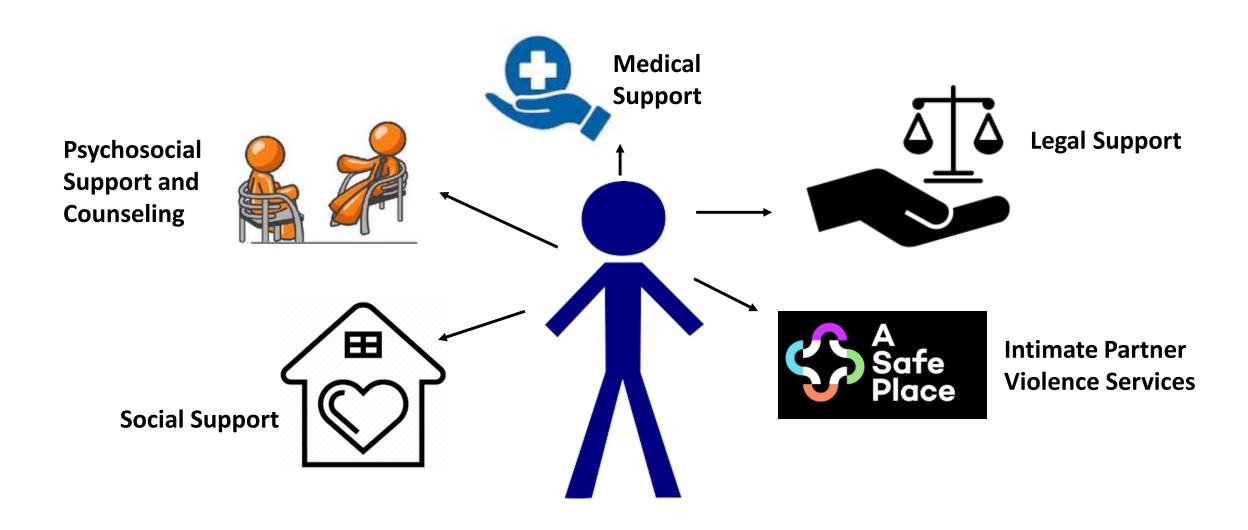
THANK YOU! Please Place This Completed Form in the Drop Box by the Registration Desk

Community Advisory Boards Can Assist Clients Make Complaints

- Community Advisory Boards (CABs) are made up of community leaders and people living with HIV. They can act as a liaison between the community and facility
- The CAB can make an adverse event complaint on the client's behalf if the client does not feel comfortable making the complaint alone
- USG and IPs should consider establishing CABs to support quality improvement and adverse event monitoring



Clients Who Experience Adverse Events Should Be Linked to Appropriate Services





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Investigating Reports of Adverse Events

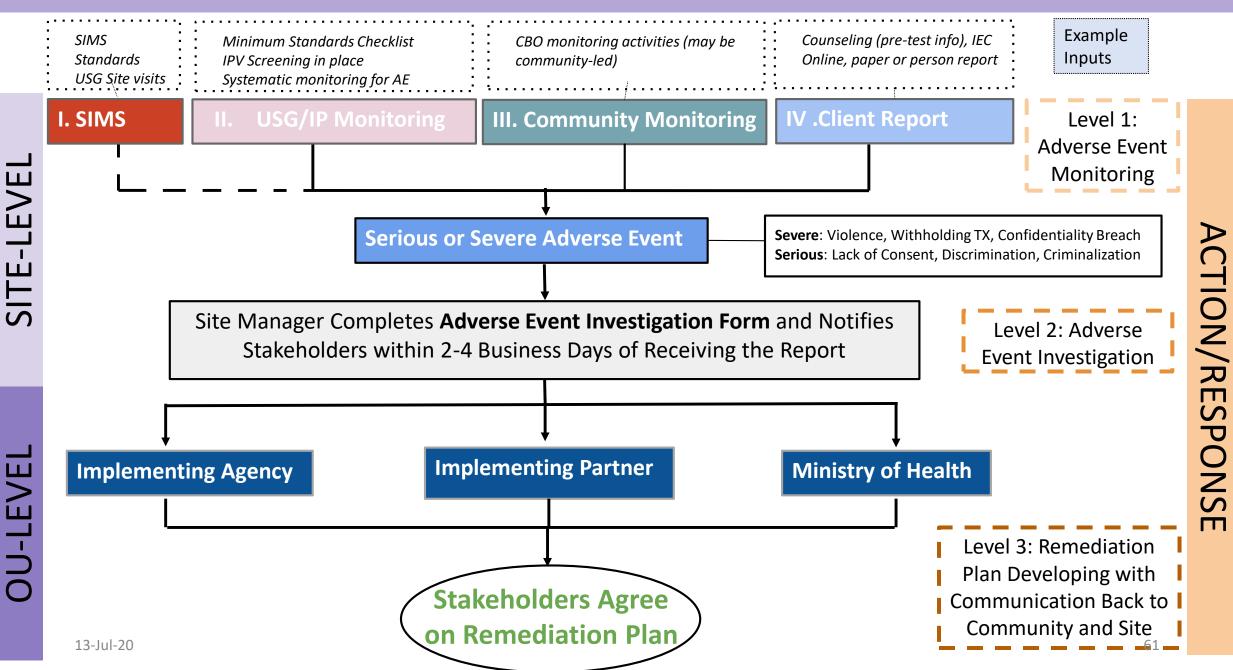
- All reports of serious or severe adverse events (from site monitoring, community monitoring, and/or client feedback) **MUST** be investigated
- Follow-up steps and actions should be identified to prevent similar adverse events from occurring in the future
- Investigations into IPV should not be investigated like other adverse events due to confidentiality and existing laws/policies that may require specific legal steps to be taken (including forensic exams). Instead, investigations should **focus on whether all procedures were followed** (e.g. risk assessment, LIVES, appropriate referrals, etc.) to protect the safety of the client.
- If an adverse event is determined to be a result of a provider's failure to abide by the minimum standards for index testing, he or she should immediately stop offering services until remedial actions can occur

	a. Date Investigation Completed: b. Facility or Site Name: c. Facility type (circle one): 1) MOH 2) 4) Other: d. Name, Title, and Phone Number of Pers II. Summary of Adve	Key Population 3; on Completing This rse Event That Led t	Private Form: o This Investigation						
b. Facility or Site Name: c. Facility type (circle one): 1) MOH 2) Key Population 3) Private 4) Other: d. 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	b. Facility or Site Name: c. Facility type (circle one): 1) MOH 2) 4) Other: d. Name, Title, and Phone Number of Per: II. Summary of Adve III. Brief Summar	rse Event That Led t	Form: o This Investigation						
c. Facility type (circle one): 1) MOH 2) Key Population 3) Private 4) Other: d. 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	c. Facility type (circle one): 1) MOH 2) 4) Other: d. Name, Title, and Phone Number of Pers II. Summary of Adve	rse Event That Led t	Form: o This Investigation						
4) Other:	4) Other: d. Name, Title, and Phone Number of Pers II. Summary of Adve	rse Event That Led t	Form: o This Investigation						
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IV. Corrective Actions Taken	IV. C								
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IV. Corrective Actions Taken	IV. C								
IV. Corrective Actions Taken	IV. C								
		IV. Corrective Actions Taken							

Also see final section on Quality Assurance and Accountability



Example Framework for Monitoring and Reporting Adverse Events



5. Quality Assurance and Accountability



REMINDER: Minimum Standards for Safe and Ethical Index Testing

All PEPFAR-supported sites must comply with the following minimum standards for safe and Ethical index testing:

- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- ✓IPV risk assessment and provision of first line response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
- A site level adverse event monitoring and reporting system
- ✓ Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')



Quality and Accountability in Safe and Ethical Index Testing Services

Define minimum quality standards for index testing services

Ensure compliance with minimum standards to demonstrate that index testing services meet international quality standards

Proactively monitor providers and sites on an ongoing and routine basis (incl. MER and SIMS) to identify and remediate concerns

Review and act on data in a routine and timely manner for improvement and to promote accountability

Encourage a multidisciplinary team approach to problem-solving, integrated data use and quality assurance



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Tools for Quality Monitoring, Accountability and Action

No single data source provides the complete picture on quality and accountability of index testing services. As such, tools referenced here and included in packet, include:

- Minimum Standards Checklist for Providers and Sites (see previous section)
- Supportive Supervision and Mentoring Tools for Index Testing
- GBV Monitoring and follow-up action tool
- Adverse Events Monitoring and Reporting Tools (see previous section)
- Monitoring Evaluation and Reporting (MER) Indicators
- Site Improvement Through Monitoring System (SIMS) Core Essential Elements (CEEs) or Standards
- Community-monitoring (using mystery shoppers, beneficiary interviews etc.)



Monitoring Quality Through Supportive Supervision

- IPs should directly observe the elicitation interview and provider notification field visits at least every 6 months to ensure that counselors are conducting these services in a safe and ethical manner
- Providers should be given immediate feedback, with suggestions for improvement
- Providers failing to offer quality services should be re-trained and/or reassigned other duties

SUF	PORTIVE SU	JPERVISION TO	OLS	
	Interview Ob	oservation Form	ı	
ite of Observation: /				
ow did the Index Testing Provider	nerform in the fo	lowing areas?		
rite N/O (not observed) if the inter			observe the skill.	
	Not Observed/ Not Applicable	Needs Improvement	Satisfactory	Excellent
reparation				
Reviews Medical Record (Diagnosis, Other Pertinent Info)				
ntroduction of Self & Purpose of nterview remonstrates Professionalism Velcomes Client and Introduces Self				Field Visit Observation Form Date of Observation: /
learly Explains the Purpose of the nterview				Not Observed/ Needs Satisfactory Excellent
mphasizes Confidentiality				1. Organization
nformation about the index client will ot be shared with the partner iformation about the partner's HIV tatus will not be shared with the inder				A. Reguest for thome Visit (Clearly Documented in Index Register
				2. Projected Professional Image During the Field Visit
				3. Confidentiality A. Verified Patient's Identity B. Chose Confidential Location for Conversation
				4. Delivery of Health Risk Information
				A. Conveyed Information in a Conveyed Information in a Conveyed Information and Conveyed Information Based Conveyed Information Conveyed Commitment for Testing
				5. Delivery of HIV Testing Services

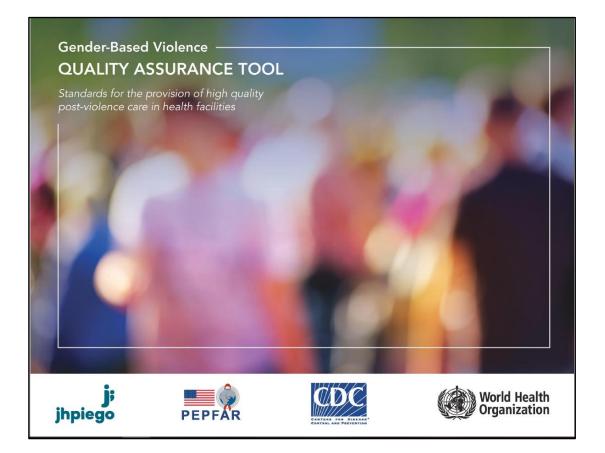


Best Practices for Accountability in Supportive Supervision

- Having trainees "shadow" an experienced counsellor for 2-4 weeks for on-site learning opportunities
- Using experienced counsellors to mentor counselors who are struggling
- Routinely observing index testing providers and providing feedback on their performance, including completeness of their records
- Offering daily, weekly or monthly opportunities for counsellors to share difficult cases and learn from each other (case conferences either in-person or virtually)
- Rotating counsellors experiencing burn-out back to regular counselling duties



Monitoring Quality and Accountability Through GBV QA Tool



Name of Facility	Date
Name of Person Completing This Form	
Title of Person Completing This Form	
Basic structure of the tool	
to start, strengthen or expand post-GBV health services through Centers for Disease Control and Prevention (CDC) and the Worl the President's Emergency Plan for AIDS Relief (PEPFAR), an arr	offers health care providers, facilities, and program planners a straightforward way the use of 28 evidence-based standards. It was developed by Jhpiego, the U.S. Id Health Organization (WHO), with reviews and input from gender/GBV partners at ay of international organizations, GBV health providers and ministries of health. The oviders and program planners, and has been adapted, piloted and refined in severa
gender/GBV partners at the President's Emergency Plan for AID	sease Control and Prevention (CDC) with reviews of resources and input from IS Relief (PEPFAR), World Health Organization (WHO), an array of international ease read the full background and instructions in the Facilitation Guide prior to
what it means to be a man or woman, boy or girl. The most common forms are sexu osychological abuse, threats, coercion, arbitrary deprivation of liberty, and economic	verson's biological sex, gender identity or expression, or perceived adherence to socially-defined expectations o al assault, intimate partner violence against women and child abuse, but GBV also includes physical and deprivation, whether occurring in public or private life. GBV is rooted in gender-related power differences, l abuse of physical, emotional, or financial power and control. GBV takes on many forms and can occur across
Magna of Varification: D. Direct character de later in	w providers or facility managers, R: Review of records, guidelines, documents, etc.



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Monitoring Quality Through SIMS Core Essential Elements

Using existing and new SIMS Core Essential Elements to monitor and improve quality of services related to minimum standards for safe and ethical index testing

Existing CEEs

- Site Level
 - Confidentiality of services
 - Partner Services
 - Patient Rights
 - Supportive Supervision
 - Patient Rights, Stigma and Discrimination
 - Client-Centered Services (e.g. services are stigma-free)
 - Post-GBV Care Provision

New CEEs Added

- Above Site
 - Index Testing in HTS National Guidelines
- Site Level
 - Index Testing Training and Supportive Supervision
 - Monitoring Adverse Event from Index Testing
 - Secure Handling and Storage of Index Testing Data
 - Intimate Partner Violence Risk Assessment and Support

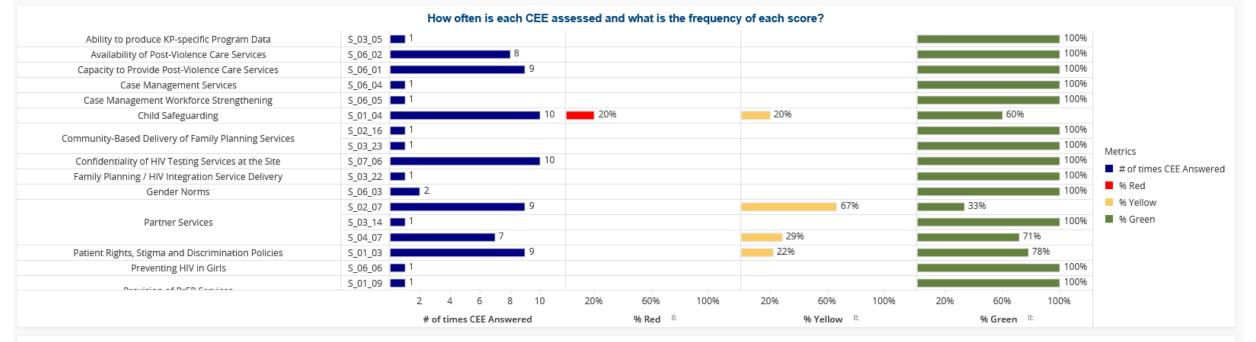


Routinely Integrating SIMS and MER data

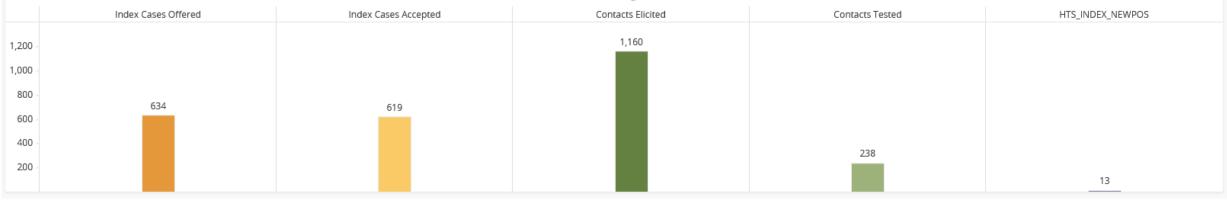
- Example integration of site level SIMS and site level MER data is provided in the next two slides (from PEPFAR Panorama – available beginning in FY20 Q2)
- This demonstrates how detailed site level data about quality standards (measured through SIMS) can be analyzed against MER HTS_INDEX cascade data for those same sites
- Such analysis can contextualize MER and SIMS data, and reveal gaps and areas for remediation and improvement



Ex: Monitoring Safe and Ethical Services Through SIMS and MER



What is the extent and scale of index testing at sites where CEEs are assessed?

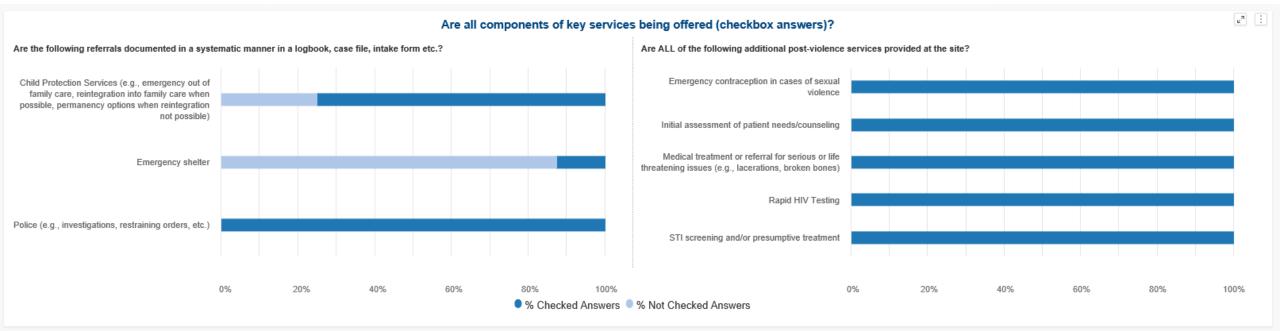


Available in PEPFAR Panorama in FY20 Q2



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Ex: Monitoring Safe and Ethical Services Through SIMS and MER



What is the scale and quality of index testing services at sites where above assessments occured?

	Index Cases Offered	Index Cases Accepted	Contacts Elicited	Contacts Tested	HTS_INDEX_NEWPOS	
1,000 - 800 - 600 - 400 - 200 -	578	565	1,077	221	10	Metrics Index Cases Offered Index Cases Accepted Contacts Elicited Contacts Tested HTS_INDEX_NEWPOS

Available in PEPFAR Panorama in FY20 Q2



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Accountability for Implementing Partners

- The IP should assign an **index testing point of contact** (POC) within their team to oversee index testing services across all supported sites
- The IP POC serves as the main counterpart responsible for:
 - ensuring all PEPFAR-supported sites meet **minimum standards for index testing**
 - monitoring and reporting any adverse events to the USG Testing Advisor within 2-4 business days
 - liaising with community organizations about index testing services at the facility/site level
- While community organizations may play a role in monitoring index testing, the IP and IP POC is responsible for and required to have an adverse-event monitoring system in place at all facilities that are funded implemented through program resources.





Community Led-Monitoring Can Be Another Important Component for Monitoring the Quality of Index Testing Services

- Monitoring and improving the quality of Index Testing services is the responsibility of USG and IPs
- However, where resources and community interest allow, PEPFAR teams should work with civil society organizations and PLHIV networks to monitor index testing services to ensure they meet the needs of beneficiaries
- See <u>PEPFAR Solutions</u> Platform for example tools and frameworks

Accountability, Review and Action

- IP Work Plans: Inclusion of minimum standards for safe and ethical Index Testing and concurrent monitoring plan in IP-level work plans
- Rapid action: USG and IPs will develop rapid action and time-bound remediation plans to address any site level challenges identified through REDCap assessments AND on-going monitoring/QA activities
- Frequent Engagement among IPs, USG staff, CSOs and Sites: PEPFAR teams will review all relevant monitoring, remediation and implementation data with all stakeholders at least monthly
- Quarterly Reporting on POART calls: USG teams will provide summary data on POART calls, focusing on use of these data for action through follow-up and remediation





Thank you!