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ISSUE BRIEF

New HIV Testing Strategies in PEPFAR COP19: Rollout and Human Rights Concerns

Introduction

Between 2016 and 2018, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supported more than 252 million HIV tests in the 35 countries and regions in which it implements programs. HIV testing is the most crucial component of HIV programs as it is the gateway by which people who are positive are able to know their status and be linked immediately to treatment and care services to protect their own health and prevent transmission of HIV to their partners. It also allows HIV-negative individuals to be linked to HIV prevention interventions and provides them with the knowledge they need to remain negative. Despite the very low individual cost of testing, the aggregate cost can be substantial. Between 2015 and 2018, PEPFAR spending on HIV testing services grew from $141 million to $436 million per year. This has raised concerns about the sustainability and feasibility of the existing testing campaigns.

To improve testing efficiency and uptake among harder-to-reach populations such as youth and younger men, PEPFAR is revising or introducing testing interventions including provider-initiated testing and counseling (PITC) optimization, HIV recency testing, HIV self-testing, and index testing and/or partner notification services. It is important to understand that PEPFAR's approach to testing is almost exclusively focused on initiating people on treatment, not on aiding downstream prevention activities or simply enabling people—especially HIV-negative people—to know their status. The implementation of these strategies, the complexity of their rollout, and their implications are issues for civil society organizations in each PEPFAR country to engage with, monitor, and improve both during the upcoming country operational plan (COP) reviews in Johannesburg, South Africa, and going forward.

Where We Are with Diagnosis: PHIAs and Programmatic Data

Over the past few years, PEPFAR has funded population-based HIV impact assessments (PHIAs).[1] The PHIAs are intended to assess country level progress on HIV diagnosis, treatment, and viral suppression—mirroring UNAIDS 90-90-90 goals—and to estimate HIV prevalence and incidence. PHIAs have been completed in 11 countries, with several additional studies underway.

Key Takeaways and Recommendations

- Targeted HIV testing is an essential component of the PEPFAR Country Operational Plan (COP) 2019 Guidance and the fight against HIV.
- Core strategies in COP19 include:
  - Optimized provider-initiated testing and counseling
  - Index testing and partner notification services
  - Recency testing
  - HIV self-testing
- Aggressive rollout of these testing strategies with targets can threaten:
  - Patients' rights to informed consent
  - To expose patients to intimate partner and gender-based violence
  - Criminalization of exposure/transmission, particularly among key populations (men who have sex with men, sex workers, transgender individuals, and people who use drugs).

Current COP Guidance sets thresholds and goals around testing uptake of these services for each program, but does not adequately address HOW to monitor for adverse events and the standards, metrics, and reporting frameworks for such events.

In most countries, diagnosis remains the point in the HIV treatment cascade with the lowest uptake. However, as countries approach higher coverage of HIV diagnosis, the efficiency of existing testing strategies is lowered and it becomes more important to offer testing services to individuals who have thus far opted out of, or been excluded from, current testing priorities and options. Establishing new or revised testing strategies that successfully reach these individuals is an essential component of how PEPFAR must move forward, but it raises serious concerns about human rights, informed consent, safety, and the effectiveness of reducing some testing strategies in favor of others.

Table 1. PHIA Results

Country	HIV Diagnosed	On Treatment	Virally Suppressed
Cameroon	46.9%	91.3%	80.0%
Cote d'Ivoire	37.2%	88.1%	75.9%
Ethiopia	72.0%	98.6%	89.6%
Eswatini	84.7%	87.4%	91.9%
Lesotho	77.2%	90.2%	88.3%
Malawi	76.8%	91.4%	91.3%
Namibia	86.0%	96.4%	91.3%
South Africa[2]	84.9%	70.6%	87.5%
Tanzania	52.2%	90.9%	87.7%
Uganda	72.5%	90.4%	83.7%
Zambia	67.3%	85.4%	89.2%
Zimbabwe	76.8%	88.4%	85.3%

This brief provides an overview of the current state of testing policies and guidance from PEPFAR and the concerns associated with each.

Provider-Initiated Testing and Counseling

In FY2018, the testing modality "Other Provider-Initiated Testing and Counseling" was the most frequent testing modality in almost every PEPFAR country program.[3] PITC is a catch-all term for testing in outpatient departments throughout a health facility, but doesn't include testing in tuberculosis (TB), prevention of mother-to-child transmission (PMTCT), sexually transmitted infection (STI), or voluntary medical male circumcision (VMMC) wards and clinics. In FY2018, the yield, or percentage of tests that were positive, in many PITC wards was very low. From PEPFAR's perspective, low yields are indicative of inefficient testing as individuals who test negative are not part of the 90-90-90 cascade and PEPFAR's programming is not designed to offer most HIV-negative individuals additional prevention services.

To combat low yields and bring down the overall cost of testing to the program, PEPFAR COP 2019 Guidance (COP Guidance) includes prescriptive guidelines about which testing approaches will be supported by PEPFAR. The major change from years past is that, in countries or regions with over 70% antiretroviral therapy (ART) coverage of all people living with HIV (PLHIV), community and mobile testing will no longer be supported, and facility-based testing will only be supported if it is targeted in a way that produces a 10% yield (see table 2).[4] COP Guidance specifically identifies Burundi, Eswatini, Ethiopia, Kenya, Namibia, Rwanda, and Zimbabwe as countries where PEPFAR will no longer support universal testing.[5] Yields of 10% or more can be achieved by pre-screening patients prior to testing to determine if they are at sufficient risk to warrant conducting an HIV test, but the proportion of facilities meeting this standard is small. Across all PEPFAR sites in 2018, only 7.4% of facilities had HIV testing yields over 10% for the year, including high-yield testing sites such as TB, STI, and key populations (KPs) programs. In the countries identified above, only 1.5% of facilities met this standard. This does suggest there is room for improvement in these countries, but it is not without risks.

Table 2. HIV Case-Finding Approaches for COP19 for PEPFAR Support

ART Coverage: National or subnational	Index testing through facility or community (biological child of HIV positive parent or sexual contact, partners of those on ART but unsuppressed)	TB and STI	Testing key populations	Other community or mobile	PMTCT	HIV self-testing	Other facility-based testing: *Symptom-based *Risk-based *Men over 25
70% or greater	Minimum 20% to 40% yield	Yes	Yes	No	In high-burden areas	Yes	Minimum 10% yield
Less than 70%	Minimum 20% to 40% yield	Yes	Yes	Targeted to specific populations and in high-burden areas	Yes	Yes	Yes

Overly restrictive screening tools targeting 10% yields risk turning away asymptomatic HIV-positive individuals from testing (and subsequently treatment). Symptoms-based testing alone could make it more difficult to find patients who only recently contracted HIV if they are prevented from testing. Risk-based screening relies on high levels of trust between patients and providers to accurately convey risk factors, especially among key populations whose risk factors are likely criminalized or stigmatized.

Most importantly, in addition to being the dominant mode of testing, PITC continues to identify the plurality of positives. In Kenya, for example, despite increases in index testing, Q4 results show 45.9% of newly identified positives came from PITC.[6] While this is down from 54.6% in Q1, the shift did not lead to an increase in individuals being newly diagnosed.[7] Indeed, Kenya's target for new diagnoses in FY2018 was higher than for FY2017, but overall results were marginally lower year on year.

The 2019 COP Guidance suggests that strategic shifts from low-yield strategies like PITC to high-yield strategies like index testing can increase the number of people diagnosed, or at least reduce the cost associated with providing a diagnosis. As the Kenya example shows, this is not guaranteed. In fact, an analysis of PEPFAR FY2018 facility performance data reveals that through Q3, large testing sites that provided fewer tests on average found fewer positives, but did increase their yield. Ideally any such decreases in case identification should be made up for in other testing strategies such as index testing, but it remains to be seen whether this will be the case.

More work is needed to understand whether the proposed testing strategy shift can result in greater case identification. In addition, the higher-yield strategies slated for scale-up, like index testing, require far more resources per test than traditional facility-based testing. Unless implemented with extreme care, the proposed testing shift runs the risk of both decreasing case identification and increasing spending on testing.

Index testing

Among the minimum program requirements in the 2019 COP Guidance for continued PEPFAR support is "Scale-up of index testing and self-testing, and enhanced pediatric and adolescent case finding, ensuring consent procedures and confidentiality are protected and monitoring of intimate partner violence (IPV) is established (required in COP18)."[9]

Index testing is a method of testing whereby the partners and biological children of an individual who has tested positive for HIV (the "index patient") are solicited and specifically recruited for HIV testing. Index testing generally has higher yields than other testing modalities and may also enable outreach to individuals unlikely to seek testing services on their own, especially younger men.

Forms of Index Testing[8]

Index testing is a form of HIV testing in which a person diagnosed with HIV serves as an "index patient" to identify family members, partners, and other individuals at higher risk of being HIV positive who are then proactively offered HIV testing services as a result of their association with the index patient. In addition to partner notification services, index testing also includes testing services for biological children and the parents of young children. Partner notification can be done in several different ways:

Partner notification services (PNS): Trained providers ask people diagnosed with HIV about their sexual and/or drug injecting partners, and then, if the HIV-positive client agrees, offers these partner(s) HIV testing services. Partner notification is provided using passive or assisted approaches.

Assisted partner notification: Trained providers help HIV-positive clients disclose their status to their partner(s) and/or they help the clients provide information enabling the provider to anonymously disclose to a partner that they may have been exposed to HIV and should seek HIV testing services. Types of assisted partner notification include contract referral, provider referral, dual referral, and anonymous client notification services, and are detailed in the COP guidance.

Passive referral: With encouragement from a trained provider, HIV-positive clients disclose their status to their sexual and/or drug injecting partners by themselves, and also suggest HIV testing services to the partner(s).

Index testing is not a new method of HIV testing, but the 2019 COP guidance has expressly included aggressive scale-up of index testing as a core component of the epidemic control strategy. The 2019 COP Guidance states:

> *For many of the PEPFAR countries, the main bottleneck to achieving 95-95-95 is the low case-finding of specific populations. In order to improve case-finding, we require innovative and more effective outreach and testing strategies, and the right mix of testing strategies tailored to the local epidemiology and ART coverage of specific populations. [...] The most important strategy, however, is voluntary partner or index testing – which should be done routinely and in all programs. It is essential that all testing and treatment partners are doing index partner identification and testing thoroughly and well.*[10]

Further, COP Guidance states that planning letters for each country—letters that inform PEPFAR country teams of country funding levels and specific program requirements—will set "[t]he target proportion of PLHIV identified through index testing."[11] Such aggressive scale-up of index testing raises three main urgent human rights concerns: 1) Intimate partner and gender-based violence (IPV/GBV); 2) Target setting that de-emphasizes patient autonomy and informed consent; and 3) Index testing in the context of criminalization and particular concern for the safety of adolescent girls and young women (AGYW) and KPs.

On IPV, asking PLHIV to disclose their sexual partners and biological children is a known risk for increasing their vulnerability to violence.[12] Index testing has the potential to increase IPV if safeguards and patient protections are lacking. This requires skilled screening for GBV, linkages to GBV services, and proper adherence to patient's wishes. Initially, even quality IPV screening is prone to false negatives when patients are not comfortable disclosing violence (often due to lack of provider training and/or lack of comfort with material).[13,14] This may be exacerbated for key populations for whom disclosure of partners carries the risk of stigmatization and criminalization, not only of the index client but also their partners.

While provider training and scripts that prioritize informed consent are required, IPV screening still cannot be relied on as the only way to determine if a relationship is safe enough for index testing. Patients, including male patients, must be able to opt out based on broader concerns even if they do not specifically report violence, and providers must reiterate throughout the process that health services—especially treatment—are not contingent on participating in index testing or disclosing partners.

The 2019 COP Guidance recognizes these concerns, stating:

> ***Each setting where women will be offered index testing and partner notification, or counseled and prescribed PrEP, should have the following: 1) counselors given basic training on what IPV is and how it affects women's lives [Counselors must also be trained on how to ask about IPV and how to respond (listening, inquiring, validating, ensuring safety, and support through referrals).]; 2) protocol or [standard operating procedures] on IPV; 3) private setting with confidentiality ensured; 4) a system for referrals [to IPV services] in place; and 5) a robust mechanism for detecting, monitoring, reporting, and following up on any adverse events potentially arising from index testing and partner notification services.[15]***

While some training materials and tools are available from PEPFAR, they fail to address several key factors identified here. Nothing in the COP Guidance or available materials sets a standard or metric to assess the adequacy of referral to IPV or GBV services. The WHO's global recommendations for IPV screening clearly state that an adequate system for referrals must be in place, without which IPV screening can lead to serious patient harm. In the absence of such standards, partners are likely to develop inconsistent and incomplete assessments on their own while under pressure to complete the rollout of index testing across their facilities and programs. Critically, most IPV and GBV services are targeted at women, but preliminary data from Uganda demonstrate that Index testing also results in GBV against men.[16]

> "Programs which do not monitor the number of adverse events (e.g., GBV or IPV) to index clients are not useful for understanding whether the program is a net benefit."
>
> *— 2019 COP Guidance, page 365.*

Likewise, there is no detailed guidance on the metrics, systems, and standards partners are expected to implement for adverse event tracking, reporting, and follow-up services. Such guidance is urgently needed to prevent the development of ad hoc, inconsistent, and inadequate protocols. Included in such guidance must be thresholds for adverse events above which a worker, facility, partner, or country program as a whole will be temporarily stopped from doing index testing until an evaluation is conducted and modifications made. PEPFAR's Site Improvement through Monitoring System (SIMS) tools—which at present detail no assessment of whether facilities are ensuring consent, confidentiality, and tracking adverse events from index testing[17]— are an opportune location to add such assessments, including the proximity of IPV/GBV services to which patients screening positive or experiencing IPV can be referred.

Appropriately, COP Guidance is clear about the need to protect patient confidentiality in index testing. However, while patient confidentiality protocols are essential, it must be recognized and communicated to patients that even if providers have agreed not to use the index client's name when making contact with partners, inadvertent disclosure may be inevitable. Patients must be made expressly aware of this probability.

Finally, the guidance must be cognizant of the dynamics between prime partners and sub-partners, as well as between prime partners and health care workers employed in the public sector but implementing index testing protocols developed by PEPFAR. These concerns are compounded by an aggressive, target-driven rollout without adequate time and training for

providers and program staff. Any targets that require a certain percentage of positive test results to be from index testing raise immediate concerns about the pressure put on programs and providers to meet those targets. It incentivizes de-emphasizing consent safeguards and pressuring disclosure even where such disclosure is unsafe. At present, there are no metrics proposed nor standards against which providers or implementing partners are held accountable if consent procedures are not adequately followed. There are metrics and consequences if testing targets are not met. This unbalanced relationship, the urgency to test, and the de-emphasizing of a client's ability to decline, is reflected throughout PEPFAR training and planning documents and may only serve to erode trust in the HIV testing centers, with people fearful of getting tested if they believe they will be forced to reveal their sexual network.[18]

HIV Recency Testing

HIV recency testing has existed for many years, but COP 2019 marks the first time PEPFAR has begun aggressively rolling out HIV recency assays for anyone newly testing HIV positive. As the name suggests, recency assays measure how recently a person contracted HIV. New point-of-care tests such as the Asanté HIV-1 Rapid Recency Assay (Asanté 1) have made the prospect of rapidly responding to results possible. However, recency tests are not highly specific and only provide an estimate, depending on the test, as to whether an infection took place within the past six months to one year or not.

The purpose of recency testing from PEPFAR's perspective is stated in the 2019 COP Guidance:

> ***Recency testing should be incorporated as surveillance and for early detection of transmitting networks, not as research. [...] This will help countries detect recent HIV infections among all newly diagnosed individuals in real time; linking this activity to case-finding modalities will help increase HIV-positive yield. By characterizing recent HIV infections with respect to person, place, and time, countries are able to mount a rapid public health and programmatic response to prevent further transmission from all newly diagnosed persons including recently infected individuals.***[20]

In short, recency testing is meant to help country teams identify areas where new infections are taking place, and track networks of individuals in order to intervene as early as possible in any continued transmission. While recency testing can help serve this purpose, it is not clear at present that there is ample and available capacity to make use of the data in the way the 2019 COP Guidance suggests. Additionally, there are several concerns about the rollout of recency testing, including whether the results are communicated to patients and the implications of informing patients of such results.

Implications of Index and Recency Testing on HIV Criminalization and Criminalized Populations

Criminalization of HIV exposure/transmission, either through specific HIV laws or general criminal statutes, as well as criminalization of key populations (men who have sex with men [MSM], sex workers, people who inject drugs [PWID], and transgender individuals), increases the potential for adverse events associated with index testing, recency testing, and HIV self-testing.

Targeted testing strategies must always be implemented in a manner cognizant of the criminalized environments in which they exist. Index and recency testing in particular compound the risk of personal and state violence against PLHIV, especially key populations and AGYW. Both testing programs **must** aggressively avoid any language suggesting causation, such as "Everyone exposed to HIV by the index case."[19] Such language is inaccurate, stigmatizing, and legally problematic. Any suggestion that index or recency testing is about causation will harm individuals living with HIV, as well as the credibility of the program. "Who exposed who" cannot, and should not, be reflected in these protocols.

PEPFAR also needs to clarify how it intends policy and police protocols to interact with index and recency testing. Where testing strategies ask people to disclose partners (MSM, sex workers, transgender individuals, youth, and PWID) in criminalized contexts, protocols must be prescriptive about what confidentiality means and what policies protect or harm them. Neither index nor recency testing disclosures and results must ever be allowed to inform criminal complaints about transmission.

Sensitizing the police is not sufficient; rather, it's a matter of changing the regulations and evidentiary standards in those regulations, training of judges, and the removal of HIV-specific criminal laws. As there is significant overlap between key populations and "general populations," **all** index and recency testing programming **must** be implemented cognizant of the particular risks criminalization poses for key populations and AGYW.

Initially, it should be noted that HIV recency test results have no direct clinical benefit to the individual patient. HIV treatment guidelines do not differentiate clinical treatment—which treatment regimen to start, when to start treatment, or how treatment should be monitored over time—based on how recently a patient became infected.[21] The 2019 COP Guidance expressly acknowledges this, stating:

> *While [recency] tests are not meant to be used clinically or on an individual basis (the specificity is limited), the data are useful for targeting interventions.*[22]

Subjecting patients to testing that is not clinically beneficial to the individual patient—especially if the results of such tests will be linked to the identity of the patient—raises ethical concerns. While intuitively, patients should be entitled to any information that forms part of their medical records, testing that serves a purely epidemiological purpose must carefully balance the rights of patients and the potential harms that can come with such testing, specifically a false sense of certainty and potential misuse as evidence of transmission in criminalized settings. While health surveillance programs routinely test blood samples drawn for other purposes, these test results are generally not linked to the individual unless they serve a clinical benefit. Additionally, while an HIV recency assay like the Asanté 1[23, 24] can serve as a confirmatory HIV test, its use for recency has not been approved by the U.S. Food and Drug Administration. Indeed, Sedia Biosciences, the manufacturer of Asanté 1 and another recency test, LAg AVIDITY, requires U.S. purchasers of the test to sign a use agreement that prohibits informing patients of the results.[25, 26]

If HIV recency testing is intended to serve a purely epidemiological purpose, it also suggests that linking the results directly to individual patients is inappropriate over the long term. While programs in the midst of conducting individual outbreak investigations could appropriately use linked result information in the short term, the scope of such identifiable data should be limited to that context, and not attached to a patient's larger medical record or used outside the scope of an outbreak investigation.

Finally, recency testing as an intervention will only improve programmatic outcomes if the data are developed and used in an actionable way. While identifying hotspots of HIV transmission will be valuable for determining how best to allocate resources, the collection of data must be followed by affirmative implementation of a programmatic response. The 2019 COP Guidance is vague in the expectations for partners given the uncertainty of the results.

Phylogenetic Testing and Directionality

While HIV recency testing does not provide evidence of the direction of transmission, other testing methodologies currently under development do attempt to document the directionality of transmission (i.e., who infected who). Similar to recency testing, phylogenetic testing allows the dynamics of transmission and evolution of the virus in communities to be studied for epidemiological and public health purposes. This has the potential to allow implementers to evaluate drug resistance, transmission networks, and the efficacy of prevention interventions.

The advantages of the use of HIV phylogenetic testing and mapping for improved programming must be weighed against the potential harms faced by those who are identified as "drivers" of the epidemic. Identifying traits of persons likely to be involved in transmission may be useful in designing programs, but it is dangerous to those already marginalized and stigmatized, including those facing criminalization by reason of sexual orientation, sex work, and drug offenses.

HIV Self-Testing

HIV Self-Testing (HIVST) is being expanded in COP 2019 and is now a minimum requirement for continued PEPFAR support.[27] HIVST serves as a screening test but is not sufficient in itself to confirm an HIV diagnosis. It is best thought of as a test to recruit people to then take a determinative diagnostic HIV test. Once a person tests positive through HIVST, he or she still must go through the standard HIV testing protocol just as someone who has not conducted an HIVST.

HIVST has the potential to reach individuals and populations that have not accessed standard HIV testing services. As described in COP Guidance:

> *HIVST continues to be an emerging approach for expanding access to HTS [HIV testing services] among men and underserved, or disenfranchised populations. It is particularly valuable in in key populations and in areas where men's knowledge of their HIV status is under 60%.*
>
> *[...]*
>
> *HIVST should be part of the HTS portfolio especially in high-burden settings, and should be strategically deployed to screen AGYW and their partners, male partners of ANC [antenatal care] clients, sex workers and their clients, KPs and their partners, and other priority populations (e.g., refugees, prisoners, young at-risk men) that face high levels of stigma and discrimination.*[28]

HIVST is also part of the new Faith Based Organization (FBO) programming to offer education programs in communities of faith to increase testing among men. The introduction of testing by FBOs among key populations may be a serious concern in some settings given public attitudes of some FBOs toward key populations and family planning services for AGYW.

While HIVST holds significant promise, there are questions about whether testing can become coercive when done outside of the health care context (i.e., individuals forcing their partners to test in their presence). While such concerns have not been strongly documented,[29] self-testing kits have not been distributed as widely as is now planned so that some continued monitoring of adverse events is warranted, and indeed suggested in the COP Guidance.[30]

From a programmatic perspective, HIVST is challenged by low rates of linkage to care. General population HIVST programs in Sub-Saharan Africa have found linkage rates around 50—60%.[31] More targeted testing programs aimed at AGYW, MSM, and male partners of women in antenatal services have had higher linkage rates, particularly when combined with other outreach services. The design of HIVST campaigns must critically assess how outreach and linkage services will be implemented alongside HIVST. Importantly, while linkage rates may be low in some instances, HIVST may still be a worthwhile investment if programs are recruiting people to test who would not have taken up other testing services.

Recommendations

The policies highlighted here share a common theme: They are intended to help find HIV-positive people who have not been identified by other testing programs and link them to treatment. Intensified focus on reaching vulnerable populations is necessary for continued progress and achieving epidemic control. But vulnerable populations are hard to reach because they are vulnerable, and policies that exacerbate their vulnerability will only serve to drive individuals further from the health care system. Each of these testing methodologies offers critical opportunities, if implemented with fidelity to a human rights based-approach respectful of patient autonomy.

Provider-Initiated Testing and Counseling:

- Ensure optimization strategies align with the overall goal of diagnosing and linking as many people to treatment as possible. Over-screening and complicating HIV testing can undermine patient access to care and treatment services and ultimately deny people access to needed testing services even while testing yields increase.

Index Testing:

- All training and scripts for soliciting contacts from index clients **must** repeatedly emphasize that participation is voluntary, can be withdrawn at any point, and will in no way affect access to health care services such as access to treatment.
- IPV/GBV services must be reasonably available by referral in **all** facilities implementing index testing services. If IPV/GBV services are not reasonably available to the index patient either because of lack of services or services that don't cater to the patient (e.g., GBV services for MSM), index testing should not be implemented in that facility until IPV/GBV services are available.
- **Standards for monitoring adverse events from all index clients must urgently be developed.** Screening for IPV/GBV does not guarantee the safety of index clients. As such, specific metrics for how implementing partners are to monitor, assess, and follow up with index clients in tracking safety and outcomes is critical.
- Remove all targets for "percent of new positives coming from index testing." Setting targets against which partners, nurses, and community health workers are measured incentivizes overruling consent and safety screening. Likewise, targets for contacts per index client must be removed.
- Modify SIMS (Site Improvement Monitoring System) tools to monitor access to IPV/GBV services, voluntariness and informed consent, and monitoring of adverse event outcomes.

HIV Recency Testing:

- Work with ministries of justice to set regulatory standards that prohibit the use of recency testing results in courtrooms as evidence of transmission.
- Clearly establish guidance on the circumstances under which recency test results are made available to the patient.

HIV Self-Testing:

- Standards for monitoring adverse effects of self-testing must be developed, including specific metrics for how implementing partners should monitor safety outcomes.

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16. PEPFAR, *Partner and Family-Based Index Case Testing*, slide 150, available at: https://static1.squarespace.com/static/5a29b53af9a61e9d04a1cb10/t/5bcf3f4324a69482bb98d34f/1540308814679/Index+Testing+SOP+slides+_v12+October+10+2018.pdf
17. PEPFAR SIMS Facility tool.
18. Multiple points in the guidance and training materials create minimum expectations for coverage of index testing. See, e.g. COP Guidance, page 362 (stating: "The proportion of HTS_TST_POS identified from index-testing is expected to be greater than 30% to 50% based on ART coverage. In all cases, index testing is expected to have a yield of 20-40% in adults."), COP Guidance, page 365 (stating: "With appropriate counseling and support, most (~80%) of clients will agree to index testing."), COP Guidance, page 365 (stating: "Programs should demonstrate (with data) the capacity for reaching beyond the index's principal sexual partner to other sexual contacts by demonstrating that the average number of adult contacts elicited per adult index client exceeds one. Furthermore, programs should track the proportion of elicited index contacts who are actually reached for testing. Failure to reach high (e.g., ≥80%) rates should warrant programmatic review to ensure index testing is implemented with the appropriate fidelity, scale and quality."), COP Guidance, page 366 (stating: "Index client services should be integrated with other innovative HTS approaches that are complementary, including recency testing, social network testing, and performance-based incentives for clinic or community testing personnel, related to linkage to treatment, including retention and adherence.") PEPFAR Solutions, *Index and Partner Notification Testing Toolkit*, https://www.pepfarsolutions.org/tools-2 (While the tools include a three-question IPV assessment as part of screening, none of the materials proactively address case studies of clients experiencing IPV and protocols detail IPV screening to take place only after partners are solicited.)
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23. See: http://www.sediabio.com/products/asante-rapid-hiv-1-recency-assay
24. See https://www.pepfarsolutions.org/emerging-technologies-innovations/2018/7/11/surveillance-of-recent-hiv-infections-using-point-of-care-recency-tests-to-rapidly-detect-and-respond-to-recent-infections
25. See: http://www.sediabio.com/LiteratureRetrieve.aspx?ID=136419 stating: "[N]either the institution [purchaser] nor its employees shall divulge the results obtained with the Asanté™ HIV-1 Rapid Recency™ Assay to research subjects, patients or their physicians, and that the Asanté™ HIV-1 Rapid Recency™ Assay shall not be used on samples from patients as a diagnostic or patient monitoring tool that may impact patient therapy and management." While individual countries may have approved the use of recency testing beyond its use by U.S. institutions, many countries rely on U.S. FDA and European regulation of drug and medical devices to set appropriate standards.
26. See: http://www.sediabio.com/LiteratureRetrieve.aspx?ID=122960
27. 2019 COP Guidance, Page 35
28. 2019 COP Guidance, Page 369
29. Kumwenda M, Munthali A, Phiri M, et al. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS Behav 2014; 18 Suppl 4:S396–S404.
30. "In addition, country teams should attempt to track adverse events associated with HIVST, including instances of self-harm, and including events related to secondary distribution where possible." 2019 COP Guidance, Page 371.
31. WHO, Guidelines on HIV Testing Services, HIV Self-Testing, and Partner Notification, page 20