HIV Testing Strategies

Implications for Programs Now and in COP21

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Outline

- Overview of HIV Testing Strategies in COP21
- Impact of COVID
- Linking HIV Testing to Other Health Services
- Specifics on Testing Strategies:
  - Self-Testing
  - Index Testing
  - Recency Testing
  - Multi-Disease Testing

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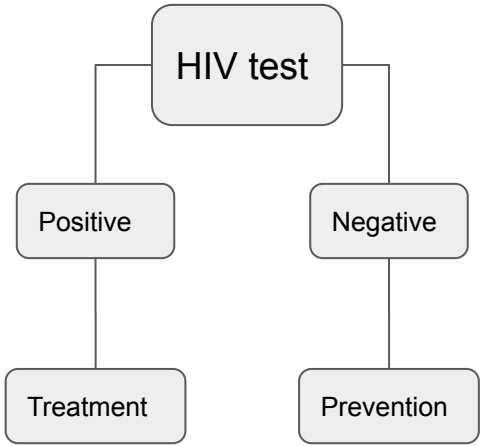
Big picture: why test?



- PEPFAR largely thinks about testing as “case-finding”, or looking for people living with HIV who don’t know their status
- In some PEPFAR prevention programming, testing is also meant to be a link to prevention (DREAMS)
- Good testing programs can be used to do both!

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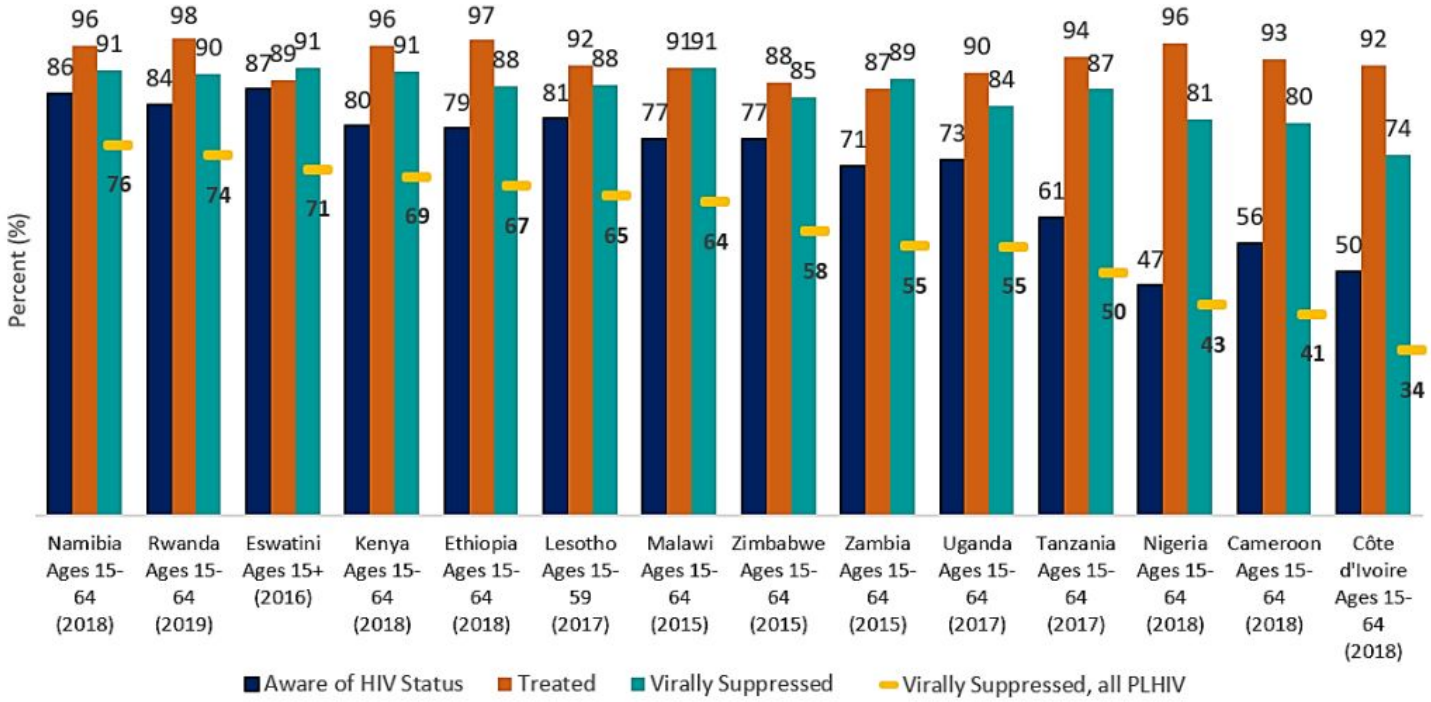
PEPFAR funded household surveys Show Achievements towards the global HIV SDG 90/90/90 Goals



**Data based on self-reported status, ARV metabolites still being analyzed.*

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U.S. President's Emergency Plan for AIDS Relief

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

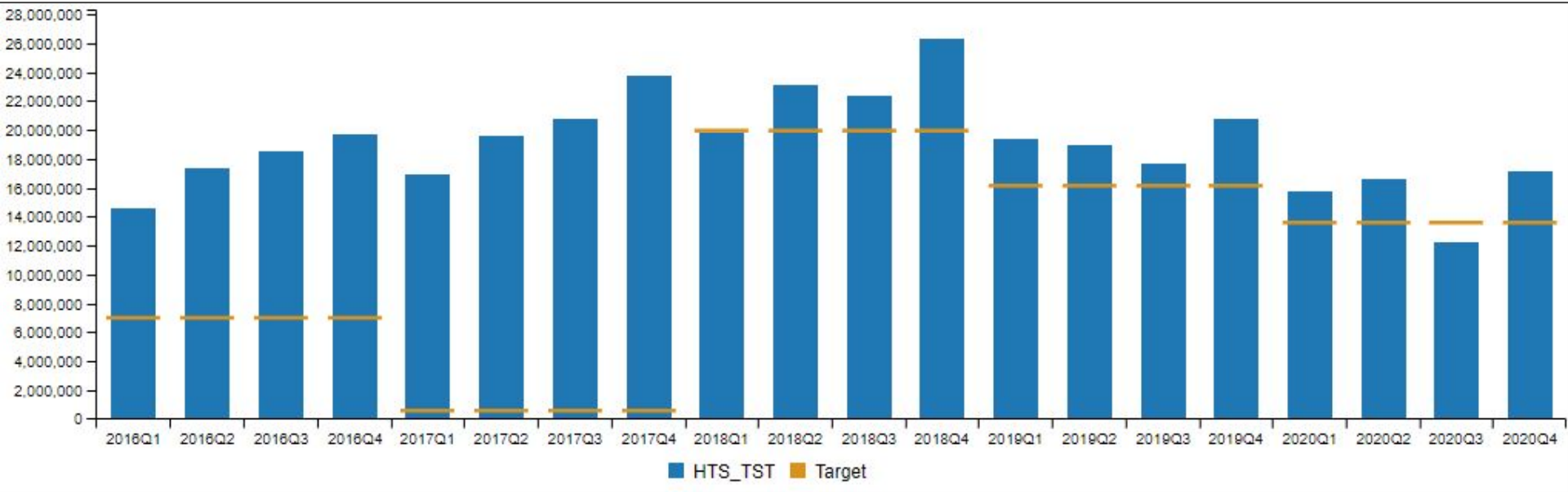
PEPFAR Strategy: Do fewer tests

2018

- Target: 79,792,700
- Result: 91,532,371

2020

- Target: 54,335,654
- Result: 61,717,310



In other words: only do some types of tests

Figure 6.3.4 HIV case finding approaches supported by PEPFAR, based on ART coverage

HIV Case Finding Approaches for COP20 for PEPFAR Support								
ART Coverage (National or subnational)	**Index Testing (facility or community)***	**TB and STI**	**Key Populations**	**Other non-facility based testing**	**PMTCT**	**HIV self testing**	**Other facility-based testing** • Symptom-based • Risk-based • Men 25 to 35 years old	**Percentage of HTS_POS from index testing**
80% or greater	Minimum 15% to 40% yield	Yes	Yes		Yes	Yes	Minimum 10% yield	75%
70-79%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 10% yield	50%
Less than 70%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 5% yield	30%

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Impact of COVID on HIV Testing

Decline in volume of patient visits to health facilities

Fear of COVID-19 may be keeping clients away from HIV testing services

Overwhelmed health-care services may turn people away as resources run short and are diverted to COVID-19.

COVID fixes (telemedicine, MMD, fewer clinic visits) don't help.

COVID-19 screening and testing algorithms could include TB and HIV.

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Chicago EDs Screen for HIV as Part of COVID-19 Evaluation

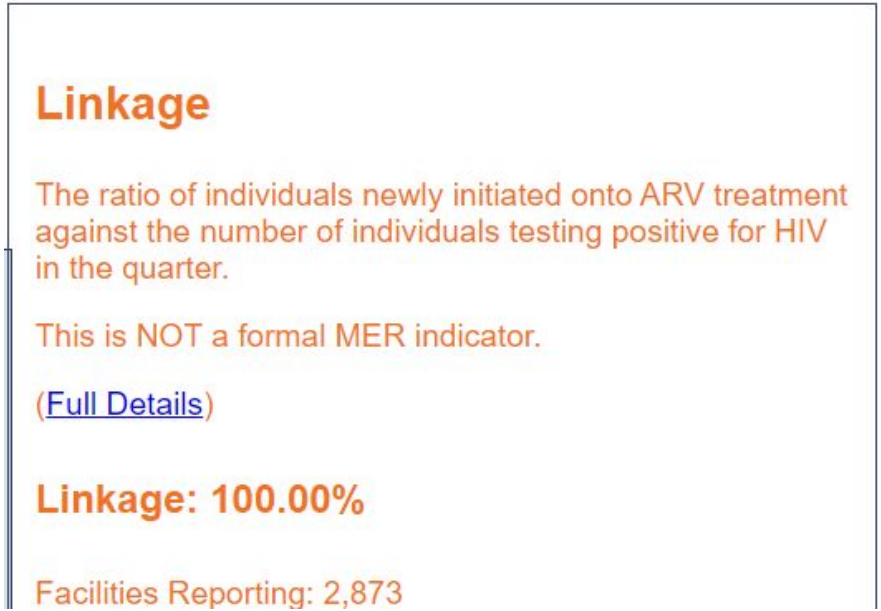
— Hospital identified 12 acute HIV patients being tested for SARS-CoV-2

by Greg Laub, Director, Video, MedPage Today December 23, 2020

Emergency departments in 13 Chicago hospitals experienced a significant increase in the detection of acute HIV infections during the COVID-19 pandemic, according to study results at the virtual IDWeek 2020 meeting.

Linking testing to treatment

- PEPFAR recommends same-day ART initiation
- Within 7 days for those who don't want to start same day
- Innovative models:
  - Community initiation for KPs in Tanzania
- Same day initiation data that PEPFAR presents are usually strong (well over 90%), but what happens next?



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Linkage to Prevention

The Goal: Targeted prevention plans should routine linkage to prevention including PrEP for those individuals testing negative in high HIV prevalence areas either by geography or risk group. Special attention must be paid to women. COP 20/21 Guidance

The Reality: PEPFAR goal to "[a]ddress the rising new infections or slow progress in key population epidemics around the globe …. was before COVID19 and now we are working to maintain and support and accelerate prevention services."

Within the first month of COVID-19 related social distancing parameters some countries are seeing a 90% drop in new PrEP initiations while others are noting increasing demand. 74% fewer VMMCs in Q3; reduced linkage to GBV; Varies by country.

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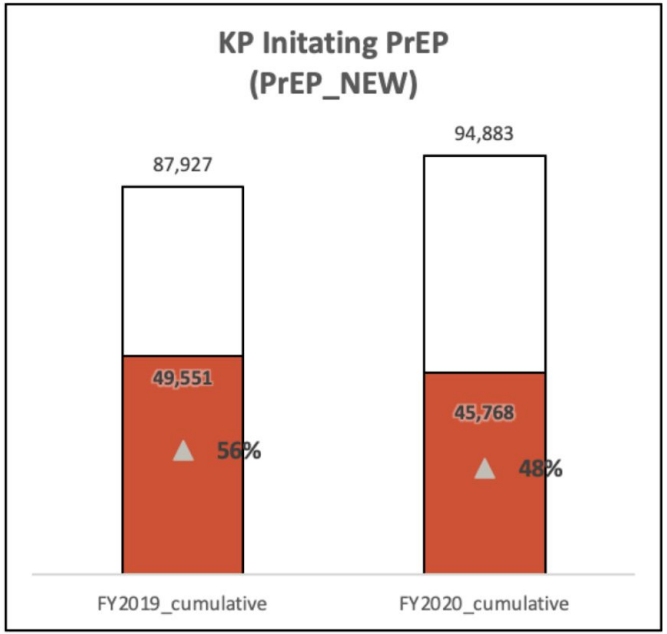
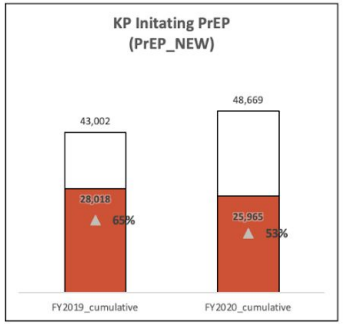
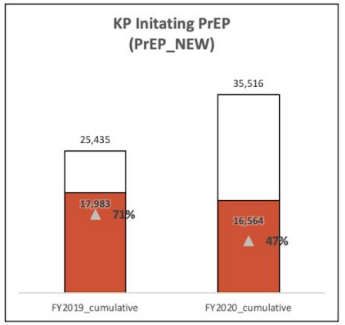
KP Initiating PrEP Results: As of Q2 FY 2020

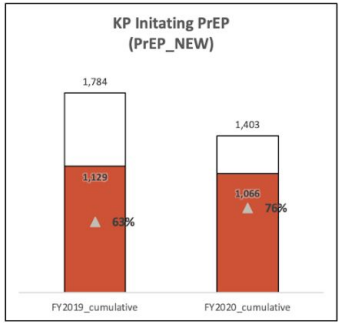




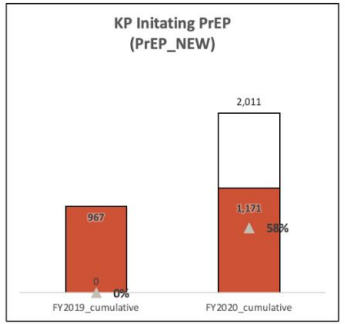
FSW



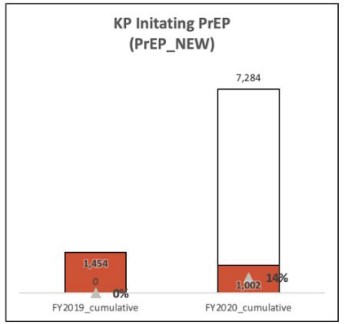
MSM



TG



PWID



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Self Testing

At home or assisted by HCW

Four different tests Chembio Diagnostics HIV self-test; OraQuick HIV self-test kit; INSTI HIV blood-based Self-test; HIVST kit (prequal pending)

Need to be strategically used where men's awareness of their HIV status is under 60% or to screen AGYW and their partners, 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.

HTS_SELF indicator that measures distribution of HIVST kits and, where possible, measures intended use of HIVST.

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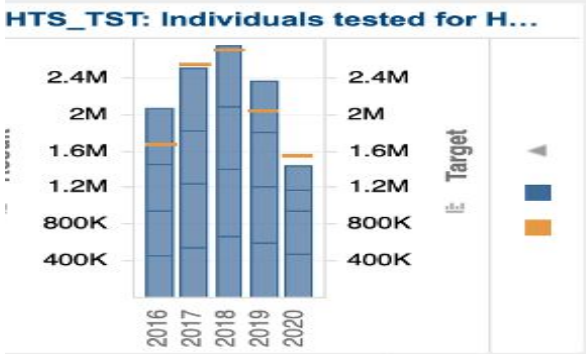
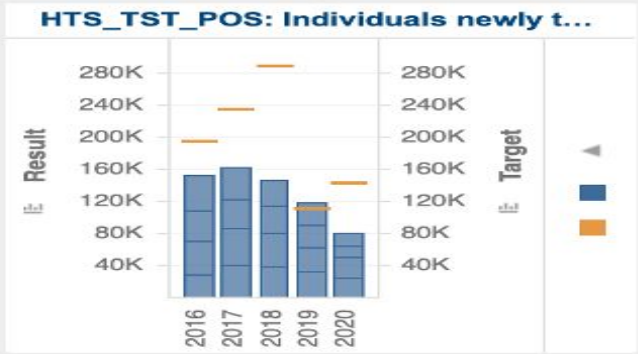
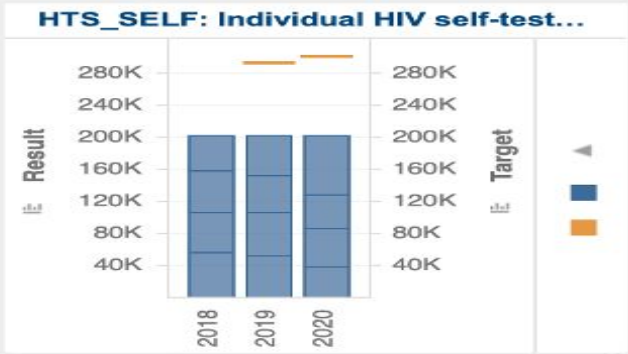
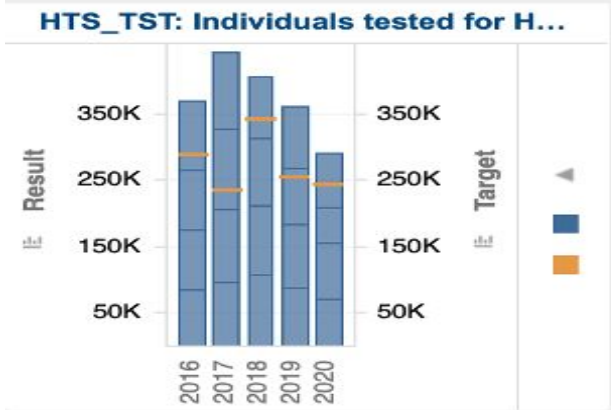
Operating Unit	Sub-National Unit 1	Sub-National Unit 2	Sub-National Unit 3
Zimbabwe	(All)	(All)	(All)

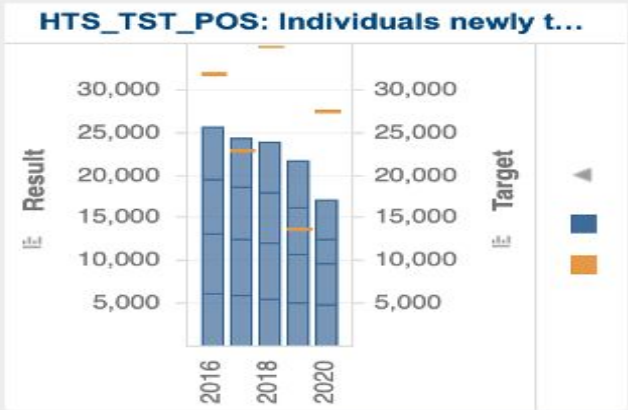


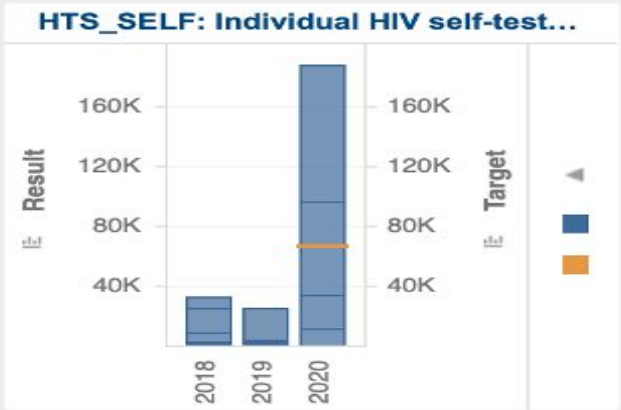




Operating Unit	Sub-National Unit 1	Sub-National Unit 2	Sub-National Unit 3
Eswatini	(All)	(All)	(All)



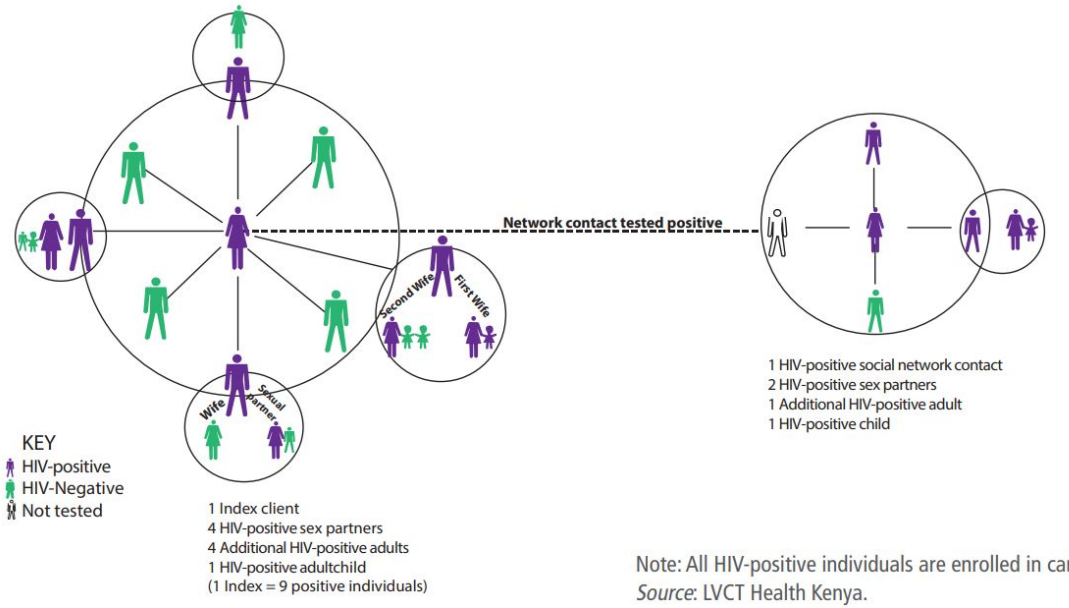




Index Testing

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

-PEPFAR, Guidance for Implementing Safe and Ethical Index Testing Services



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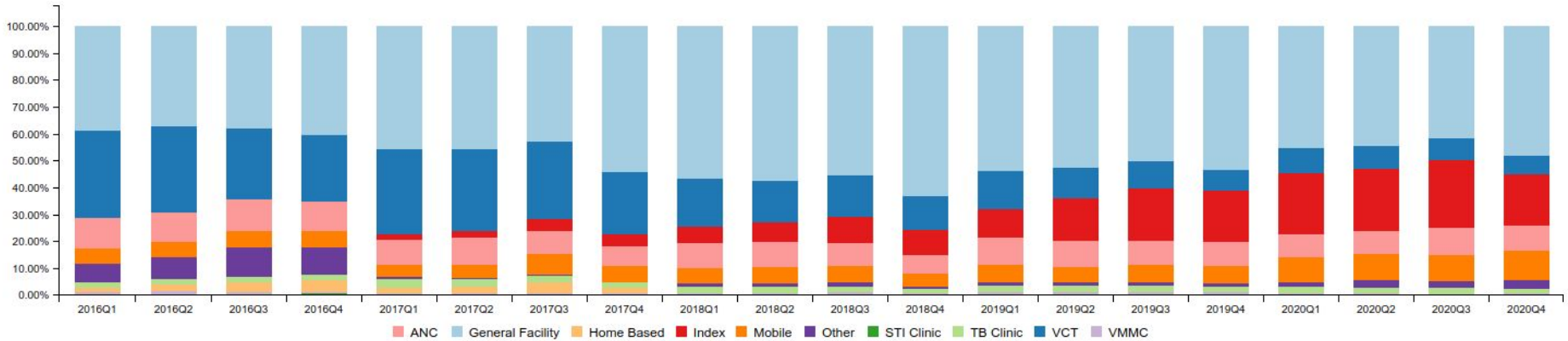
Index Testing

Become a cornerstone of HIV Testing strategies for PEPFAR over the past few COP cycles.

Of all new HIV diagnoses in 2020:

- Overall: ~21%
- Tanzania: ~58%
- Kenya: ~38%
- Zambia: ~33% of all new HIV diagnoses



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Index Testing

Challenges with Index Testing:

- Index Testing Targets
- Informed Consent and Voluntarism
- Confidentiality
- Intimate Partner Violence
- Safety of Key Populations

Figure 6.3.4 HIV case finding approaches supported by PEPFAR, based on ART coverage

HIV Case Finding Approaches for COP20 for PEPFAR Support								
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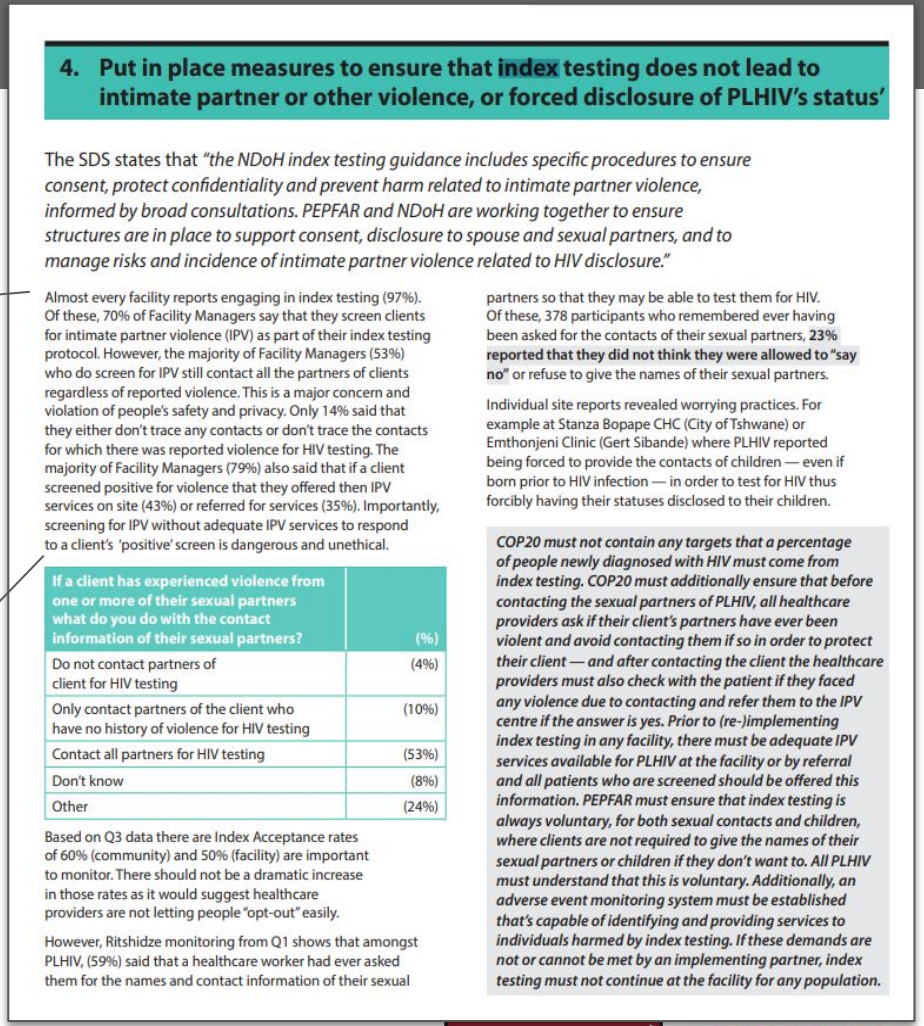
Community Led Monitoring

(South Africa)

70% of Facility Managers say that they screen clients for intimate partner violence (IPV) as part of their index testing protocol. However, the majority of Facility Managers (53%) who do **screen for IPV still contact all the partners of clients regardless of reported violence**.
[...]
Only 14% said that they either don't trace any contacts or don't trace the contacts for which there was reported violence for HIV testing.



4. Put in place measures to ensure that index testing does not lead to intimate partner or other violence, or forced disclosure of PLHIV's status'

The SDS states that *"the NDoH index testing guidance includes specific procedures to ensure consent, protect confidentiality and prevent harm related to intimate partner violence, informed by broad consultations. PEPFAR and NDoH are working together to ensure structures are in place to support consent, disclosure to spouse and sexual partners, and to manage risks and incidence of intimate partner violence related to HIV disclosure."*

Almost every facility reports engaging in index testing (97%). Of these, 70% of Facility Managers say that they screen clients for intimate partner violence (IPV) as part of their index testing protocol. However, the majority of Facility Managers (53%) who do screen for IPV still contact all the partners of clients regardless of reported violence. This is a major concern and violation of people's safety and privacy. Only 14% said that they either don't trace any contacts or don't trace the contacts for which there was reported violence for HIV testing. The majority of Facility Managers (79%) also said that if a client screened positive for violence that they offered then IPV services on site (43%) or referred for services (35%). Importantly, screening for IPV without adequate IPV services to respond to a client's 'positive' screen is dangerous and unethical.

If a client has experienced violence from one or more of their sexual partners what do you do with the contact information of their sexual partners?	(%)
Do not contact partners of client for HIV testing	(4%)
Only contact partners of the client who have no history of violence for HIV testing	(10%)
Contact all partners for HIV testing	(53%)
Don't know	(8%)
Other	(24%)

Based on Q3 data there are Index Acceptance rates of 60% (community) and 50% (facility) are important to monitor. There should not be a dramatic increase in those rates as it would suggest healthcare providers are not letting people "opt-out" easily.

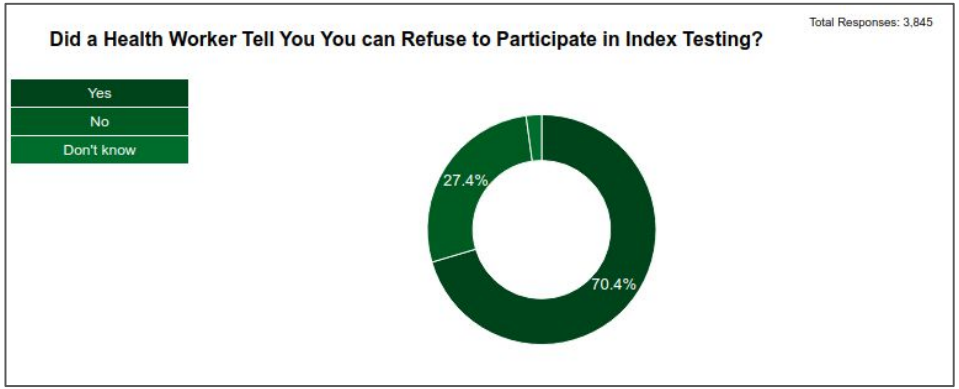
However, Ritshidze monitoring from Q1 shows that amongst PLHIV, (59%) said that a healthcare worker had ever asked them for the names and contact information of their sexual partners so that they may be able to test them for HIV. Of these, 378 participants who remembered ever having been asked for the contacts of their sexual partners, **23% reported that they did not think they were allowed to "say no"** or refuse to give the names of their sexual partners.

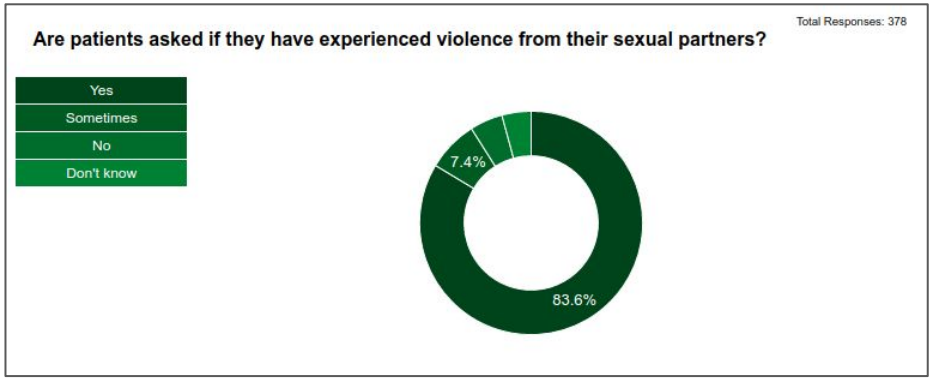
Individual site reports revealed worrying practices. For example at Stanza Bopape CHC (City of Tshwane) or Emthonjeni Clinic (Gert Sibande) where PLHIV reported being forced to provide the contacts of children — even if born prior to HIV infection — in order to test for HIV thus forcibly having their statuses disclosed to their children.

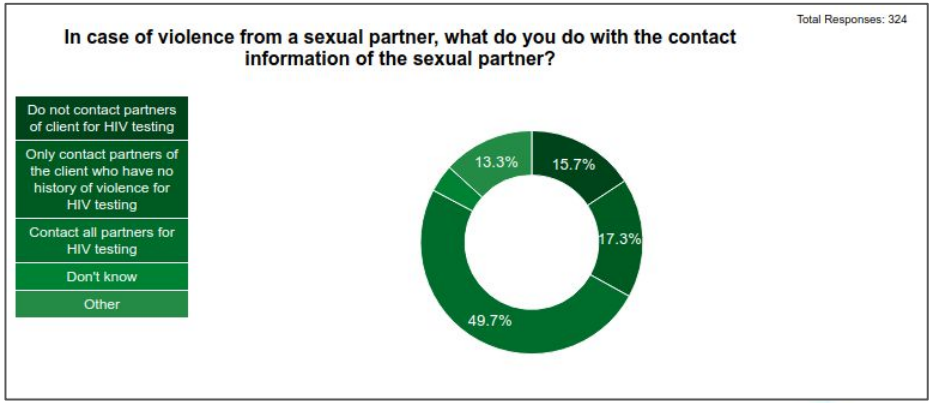
COP20 must not contain any targets that a percentage of people newly diagnosed with HIV must come from index testing. COP20 must additionally ensure that before contacting the sexual partners of PLHIV, all healthcare providers ask if their client's partners have ever been violent and avoid contacting them if so in order to protect their client — and after contacting the client the healthcare providers must also check with the patient if they faced any violence due to contacting and refer them to the IPV centre if the answer is yes. Prior to (re-)implementing index testing in any facility, there must be adequate IPV services available for PLHIV at the facility or by referral and all patients who are screened should be offered this information. PEPFAR must ensure that index testing is always voluntary, for both sexual contacts and children, where clients are not required to give the names of their sexual partners or children if they don't want to. All PLHIV must understand that this is voluntary. Additionally, an adverse event monitoring system must be established that's capable of identifying and providing services to individuals harmed by index testing. If these demands are not or cannot be met by an implementing partner, index testing must not continue at the facility for any population.

Community Led Monitoring

(South Africa)







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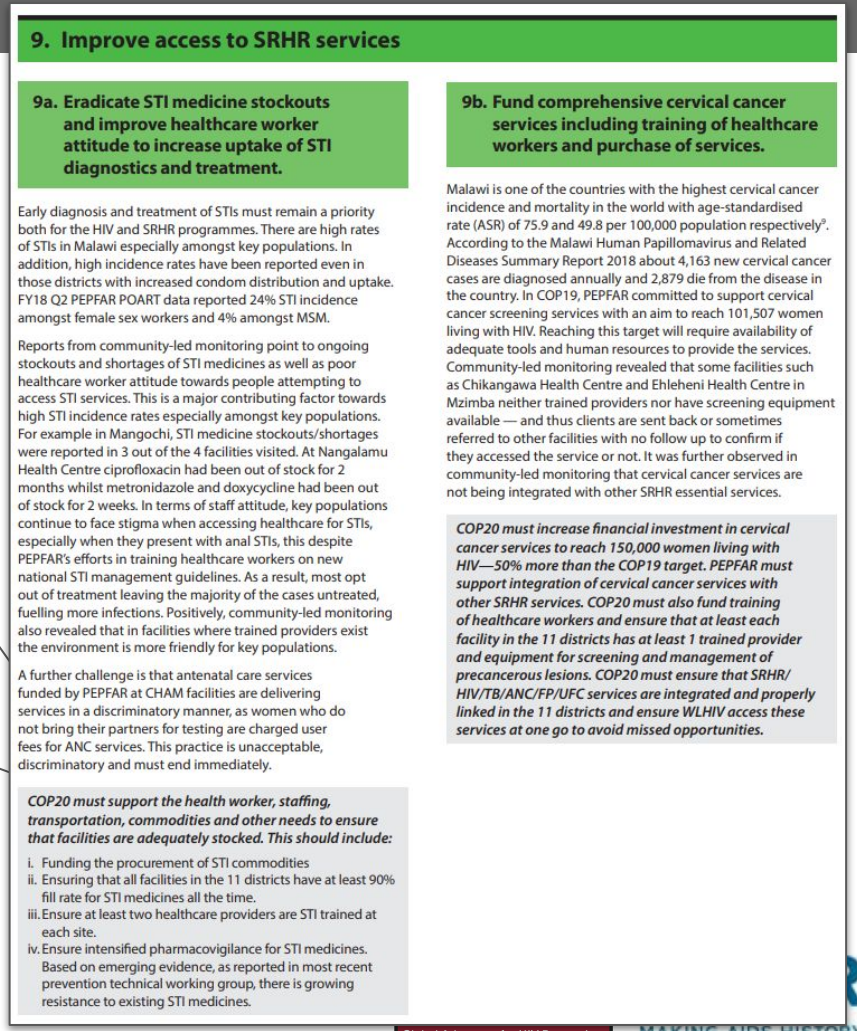
Community Led Monitoring

(Malawi)

A further challenge is that antenatal care services funded by PEPFAR at CHAM facilities are delivering services in a discriminatory manner, as **women who do not bring their partners for testing are charged user fees for ANC services.** This practice is unacceptable, discriminatory and must end immediately.



9. Improve access to SRHR services

9a. Eradicate STI medicine stockouts and improve healthcare worker attitude to increase uptake of STI diagnostics and treatment.

Early diagnosis and treatment of STIs must remain a priority both for the HIV and SRHR programmes. There are high rates of STIs in Malawi especially amongst key populations. In addition, high incidence rates have been reported even in those districts with increased condom distribution and uptake. FY18 Q2 PEPFAR POART data reported 24% STI incidence amongst female sex workers and 4% amongst MSM.

Reports from community-led monitoring point to ongoing stockouts and shortages of STI medicines as well as poor healthcare worker attitude towards people attempting to access STI services. This is a major contributing factor towards high STI incidence rates especially amongst key populations. For example in Mangochi, STI medicine stockouts/shortages were reported in 3 out of the 4 facilities visited. At Nangalamu Health Centre ciprofloxacin had been out of stock for 2 months whilst metronidazole and doxycycline had been out of stock for 2 weeks. In terms of staff attitude, key populations continue to face stigma when accessing healthcare for STIs, especially when they present with anal STIs, this despite PEPFAR's efforts in training healthcare workers on new national STI management guidelines. As a result, most opt out of treatment leaving the majority of the cases untreated, fuelling more infections. Positively, community-led monitoring also revealed that in facilities where trained providers exist the environment is more friendly for key populations.

A further challenge is that antenatal care services funded by PEPFAR at CHAM facilities are delivering services in a discriminatory manner, as women who do not bring their partners for testing are charged user fees for ANC services. This practice is unacceptable, discriminatory and must end immediately.

COP20 must support the health worker, staffing, transportation, commodities and other needs to ensure that facilities are adequately stocked. This should include:

i. Funding the procurement of STI commodities
ii. Ensuring that all facilities in the 11 districts have at least 90% fill rate for STI medicines all the time.
iii. Ensure at least two healthcare providers are STI trained at each site.
iv. Ensure intensified pharmacovigilance for STI medicines. Based on emerging evidence, as reported in most recent prevention technical working group, there is growing resistance to existing STI medicines.

9b. Fund comprehensive cervical cancer services including training of healthcare workers and purchase of services.

Malawi is one of the countries with the highest cervical cancer incidence and mortality in the world with age-standardised rate (ASR) of 75.9 and 49.8 per 100,000 population respectively[9]. According to the Malawi Human Papillomavirus and Related Diseases Summary Report 2018 about 4,163 new cervical cancer cases are diagnosed annually and 2,879 die from the disease in the country. In COP19, PEPFAR committed to support cervical cancer screening services with an aim to reach 101,507 women living with HIV. Reaching this target will require availability of adequate tools and human resources to provide the services. Community-led monitoring revealed that some facilities such as Chikangawa Health Centre and Ehleheni Health Centre in Mzimba neither trained providers nor have screening equipment available — and thus clients are sent back or sometimes referred to other facilities with no follow up to confirm if they accessed the service or not. It was further observed in community-led monitoring that cervical cancer services are not being integrated with other SRHR essential services.

COP20 must increase financial investment in cervical cancer services to reach 150,000 women living with HIV—50% more than the COP19 target. PEPFAR must support integration of cervical cancer services with other SRHR services. COP20 must also fund training of healthcare workers and ensure that at least each facility in the 11 districts has at least 1 trained provider and equipment for screening and management of precancerous lesions. COP20 must ensure that SRHR/HIV/TB/ANC/FP/UFC services are integrated and properly linked in the 11 districts and ensure WLHIV access these services at one go to avoid missed opportunities.

Community Led Monitoring

(Kenya)

In Kenya, our monitoring revealed that health workers only asked questions about violence before they tested the clients, and that **reports of violence were often ignored in favour of targets.** Once contacts were elicited and partners contacted, none of the facilities followed up with clients to track if they had faced violence as a result of reaching out to their partner.

2. Put in place measures to ensure that index testing does not lead to intimate partner or other violence, or forced disclosure of PLHIV's status'.

Civil society in Kenya together with other partners across the world expressed concern that the high targets set for the index testing program, along with expectations of high positivity rates resulting from index testing, violated human rights, confidentiality and put people at risk of violence. Civil society also raised concerns that index testing programs do not have adequate measures in place to prevent and monitor adverse effects associated, including intimate partner violence (IPV).

In Kenya, our monitoring revealed that health workers only asked questions about violence before they tested the clients, and that reports of violence were often ignored in favour of targets. Once contacts were elicited and partners contacted, none of the facilities followed up with clients to track if they had faced violence as a result of reaching out to their partner.

Screening for violence and ignoring responses to a client's capacity to face violence is dangerous and unethical. In COP20, PEPFAR must implement index testing with rules that ensure the rights of people living with HIV are not violated.

"The SDS 2019 states that "Kenya is developing a guidance document for index testing expected in June 2019 that includes consent procedures and confidentiality are protected and monitoring of intimate partner violence (IPV) is ensured through a screening process. We do not test people with a risk of IPV." The guidance is yet to be finalised." Civil society must be involved in the development of the certification processes for restarting index testing and in the implementation of monitoring.

In theory, index testing has the ability to help identify individuals who may have been exposed to HIV earlier, thereby protecting their health and interrupting onward transmission of HIV by enrolling people into effective treatment. It can also be aggressively implemented in ways that can cause harm to individuals, undermine their rights to consent, privacy, safety and confidentiality, and can erode the trust of communities with healthcare providers.

All index testing programs should be immediately paused while risk mitigation and mediation efforts are put in place. Civil society rejects any PEPFAR guidance that only key populations (KP) programs need to deal with this issue or that index testing is only halted for members of KPs. Many KPs test in general population health facilities where disclosing their partners may risk discrimination and violence. Cisgender women and adolescent girls and young women (AGYW) face equally high risk of adverse events related to index testing. Their needs will not be met by KP-specific interventions.

COP20 must not contain any targets that a percentage of people newly diagnosed with HIV must come from index testing. COP20 must additionally ensure that before contacting the sexual partners of PLHIV, all healthcare providers ask if their client's partners have ever been violent and avoid contacting them if so in order to protect their client and after contacting the client's partner the healthcare providers must also check with the patient if they faced any violence due to the partner notification and refer them to the GBV centre if the answer is yes. Prior to (re-)implementing index testing in any facility, there must be adequate IPV services available for PLHIV at the facility or by referral and all patients who are screened should be offered this information. PEPFAR must ensure that index testing is always voluntary, for both sexual contacts and children, where clients are not required to give the names of their sexual partners or children if they don't want to. All PLHIV must understand that this is voluntary. Additionally, an adverse event monitoring system must be established that's capable of identifying and providing services to individuals harmed by index testing. If these demands are not or cannot be met by an implementing partner, index testing must not continue at the facility for any population.

3. Increase funding for healthcare workers to ensure quality programming and better linkage. Fund an additional 6,000 outreach workers, transport reimbursements for community outreach and community support groups.

Trouble with Testing

PEPFAR COP21 Index Testing Minimum Program Requirements:

1. Adherence to WHO's 5Cs (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
2. 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)
3. A site level adverse event monitoring and reporting system
4. Providers trained and supervised on index testing procedures including 5 Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and "do no harm")

See: WHO, Guidelines on HIV Self-Testing and Partner Notification

ALL Facilities implementing Index Testing MUST have adequate, accessible IPV/GBV services available that clients can actually access BEFORE implementing Index testing. **Demand to know how these referral services are being supported and monitored to ensure they are actually accessed!**

Implementing partners are being left to determine HOW to implement adverse event monitoring. Some are as little as comment boxes at the facility. These are inadequate alone. **Many instances of harms won't be reported to the facility, particularly if the facility breached trust already! Demand to know HOW adverse-event monitoring is working and how adverse-events are actually followed-up. NOT just a form!**

See: Index Testing Adverse Event Monitoring System Sufficiency Assessment Tool

Additional Resources:

amfAR/AVAC/CHANGE: New HIV Testing Strategies in PEPFAR COP19:Rollout and Human Rights Concerns

PEPFAR: Guidance for Implementing Safe and Ethical Index Testing Services

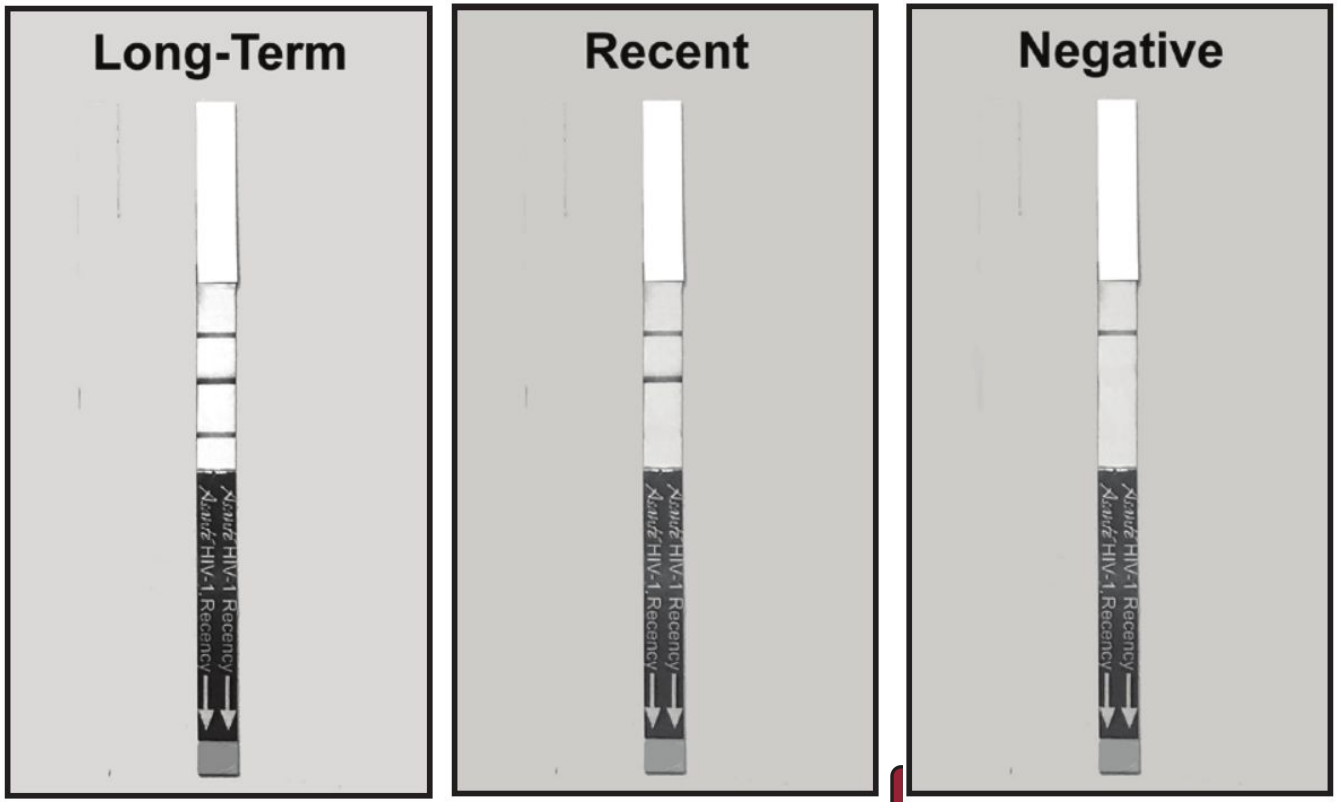
Recency Testing

Recency Testing:

Tests whether an individual acquired HIV “recently”.

Depending on test, could be within the past 6-months or past 12-months

Result is Yes/No - Nothing more specific than yes or no.



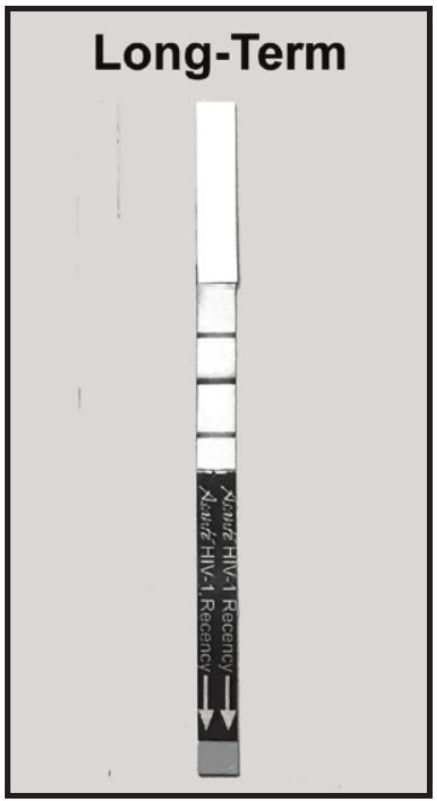
Recency Testing

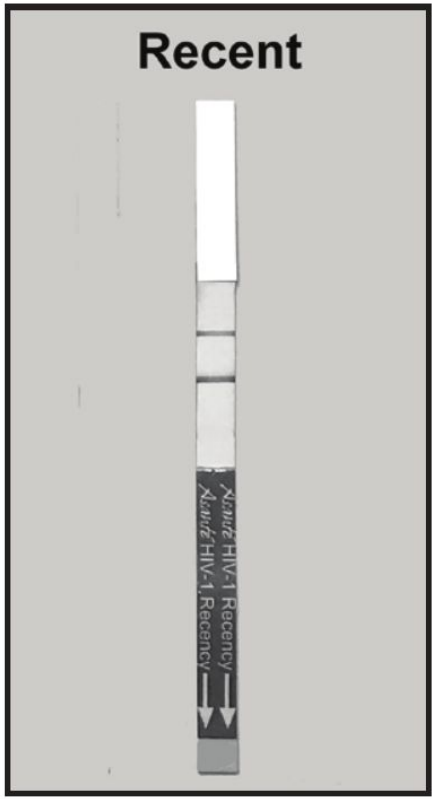
Goals of Recency Testing:

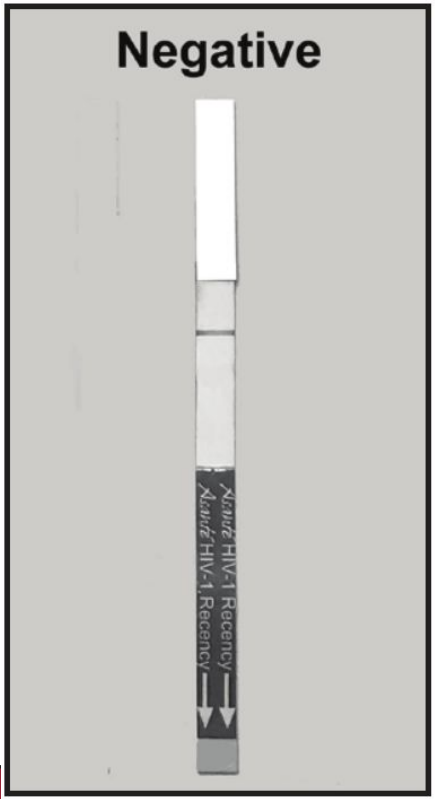
Target Index testing even further

Identify HIV transmission hotspots to target prevention efforts

Understanding HIV transmission epidemiology - Who and why different individuals becoming infected







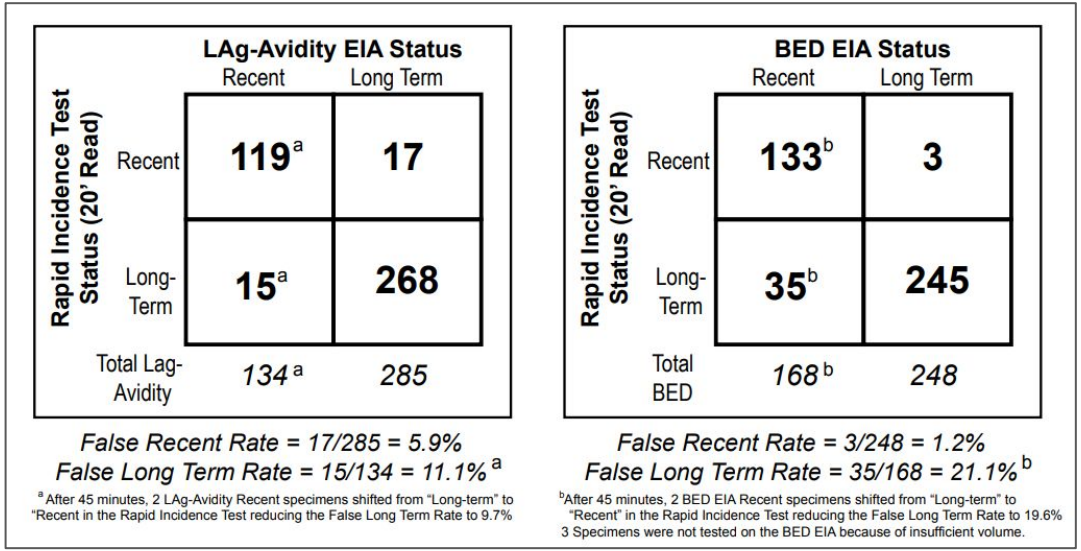
Recency Testing

Challenges:

Rapid recency tests are relatively new and have error rates

Criminalized Populations and HIV Criminalization

Capacity to respond programmatically to the HIV recency test results



AVAC Global Advocacy for HIV Prevention

amfAR MAKING AIDS HISTORY

Diagostics blindspots in the HIV response
& integrated multidisease testing

Sharonann Lynch, HIV & TB Policy Advisor
Stijn Deborggraeve, Diagnostics Advisor
MSF Access Campaign

#1 Diagnostic blindspot: CD4 at baseline

CD4 baseline testing

- Problem: PEPFAR limits CD4 baseline testing to settings/risk groups with AHD prevalence >15% either overall or in specific risk groups
- What should happen: PEPFAR should support CD4 at baseline and re-entry into care regardless of rates of AHD
- Why it's important
  - EVERY PLWHA that is CD4<200 or has AHD needs extra workup and care.
  - CD4 is essential for diagnosing (especially asymptomatic) advanced HIV disease (AHD) as clinical staging/symptom screening alone misses **half of people with AHD** at entry and re-entry into care, including
    - TB-LAM, even in the absence of TB symptoms
    - CrAG testing for cryptococcal meningitis
    - Fluconazole for people CD4<100
- The tests (US$4-80)
  - Rapid POC Omega Visitect AHD
  - Benchtop Abbott PIMA
  - Benchtop BD FACSPresto (more suitable for hospital and central labs)

#2 Diagnostic blindspot: TB LAM

TB-LAM

- Problem: The POC Alere TB-LAM test is available and affordable but **NOT IN FACILITIES and NOT USED**
  - **Also, many countries are not 'in step' with WHO recommendations**
- What should happen: TB-LAM should be in ALL outpatient and inpatient settings
- Why it's important
  - TB-LAM testing increases the diagnosis of TB, particularly at lower CD4 cell counts, and shortens the time to TB treatment with a subsequent reduction of deaths.
  - TB-LAM usage INCREASES overall yield of TB cases
  - A better test that works for ALL PLWHA will be available in early 2022 (estimated)
- The test: Abbott Determine POC TB LAM LFA: US$3.50/test

#3 Diagnostic blindspot: CrAg

CrAg RDT for the diagnosis of cryptococcal meningitis (CM)

- Problem: The CrAg test is not widely available nad not used
- What should happen: PEPFAR and countries should scale-up use for that ALL PLWHA with a symptoms (headache) receive a CD4 and all with CD4<200 receive a CrAg test
- Why it's important
  - Cryptococcal meningitis (CM) is the second-leading killer of PLWHA, second only to TB
  - Early diagnosis and treatment is paramount to reducing CM-related mortality
- The test: POC CrAg LFA (IMMY=US$2.00, Biosynex=US$2.40)

Integrated multi-disease testing

- **Goal**: Technology and implementation to INTEGRATED TESTING (and contact tracing): SARS-CoV-2, HIV, TB, hypertension, diabetes
- **Rationale**
  1. Increase uptake
  2. Reduce stigma
  3. Catch up: Drop in TB and HIV diagnoses and NCD screenings
  4. 'Test and treat' scenario if Covid treatment in early disease progression is viable ('hit early, hit hard')
     - ...Community-based campaigns to help bend the curves

Integrated multi-disease testing (cont'd)

5. Synergies in terms of health programmes and issues (leave something on the table)
   - Getting governments on board
   - Address the testing gaps across comorbidities- where 19% of all PLHIV, less than 50% of people living with diabetes, and 39% of people living hypertension are still not aware of their status

6. Clinical management: Identify comorbidities & risk factors linked to severe Covid disease

7. Existing capacity and experience of community-based testing and Rx distribution and platforms
   - Utilize the point of contact for testing as an opportunity for education awareness and provision of prevention tools
   - Address the leaky cascade/continuum of care, including finding cases, linkage to treatment and prevention (including TPT) and better follow up;
   - It's 2020! Creating silo/vertical efforts is so 2000...

Integrated multi-disease testing in the PIPELINE

Open & multi-disease platforms in the pipeline

- BLINK (Germany): molecular platform in R&D that allows multi-analyte testing (DNA/RNA, antigen, antibody) from the same samples. Proof of concept will be delivered on HCV.
- COVID/TB/HIV integrated testing: need for innotive POC tests that can analyse the same sample at the POC
  (work ongoing at BMGF)

Thank You!

Questions?

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