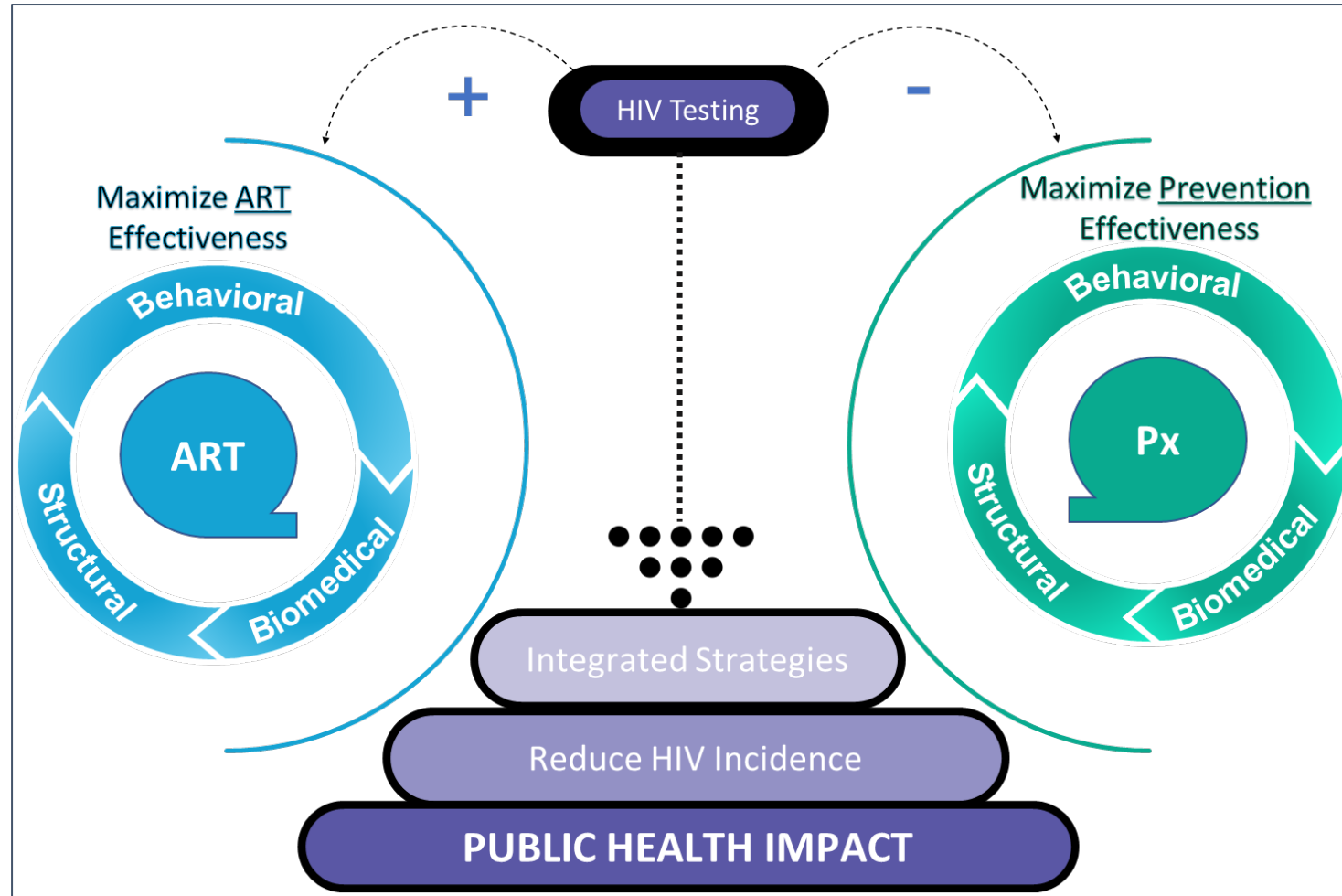


HIV Testing Overview

Test for prevention and treatment

Testing is pivotal to identifying & referring people for services and support – for treatment & prevention



HIV Testing: Quick overview

- HIV testing is a cornerstone of all efforts to address HIV
 - Ensuring that all people can know their HIV status to access appropriate services and support for treatment or prevention
 - Reaching UNAIDS 95-95-95 targets and eliminating AIDS by 2030
- Multiple types and brands of tests are used in settings worldwide for research, screening, diagnosis and monitoring
 - Different test types meet different programmatic needs
 - Rapid tests and self-tests are increasingly important as they help support same day diagnosis and rapid treatment or PrEP initiation
 - WHO processes provide assurance of test quality, performance and operational characteristics
- Testing is central to ARV-based HIV prevention programs
 - Work ongoing on testing recommendations that balance safety with feasibility as services are decentralized and expand into community settings to improve access

Summary of HIV Test Types and Characteristics

Rapid diagnostic tests



Results: 1-20 min, same day results

Specimen: Fingerprick blood or oral fluid taken with swab (measuring antibodies)

How soon to detection: 4 weeks - 3 months after exposure depending on the test

Where: Virtually anywhere (clinics, community level, labs)

Who: Virtually anyone (trained lay providers, healthcare workers, etc)

Other considerations: A negative test result is considered definitive, but a positive result needs confirmation; WHO recommends two confirmatory tests. Recommended by WHO for HIV diagnosis in individuals over 18 months of age. **Dual tests with syphilis** are available.

Self-test



Results: 1-20 min, same day results

Specimen: Fingerprick blood or oral fluid taken with swab (measuring antibodies)

How soon to detection: 3 months after exposure

Where: Virtually anywhere (clinics, community level, etc)

Who: Most anyone (videos/demonstrations can help users)

Other considerations: A positive test requires confirmation; WHO recommends two confirmatory tests. Can expand access and increase privacy. Some countries have been slow to expand. **Dual tests with syphilis** are available.

Other simple assays & Immunoassays



Results: ~30 min–3hrs, turnaround time varies by setting generally next day

Specimen: Blood from vein or fingerprick (measuring antibodies and antigens)

How soon to detection: 14 days- 1 month after exposure

Where: Health facilities (some clinics, but mostly higher level facilities and labs)

Who: Trained facility staff and lab techs only

Other considerations: Also called a 4th generation rapid diagnostic test. More costly and much less widely available than other rapid diagnostic tests.

Nucleic acid techniques (NAT)



Results: ~1hrs–4hrs, turnaround up to 35 days (varies by setting), turnaround time not same day

Specimen: Blood from vein (measuring HIV RNA)

How soon to detection: 10 days after exposure

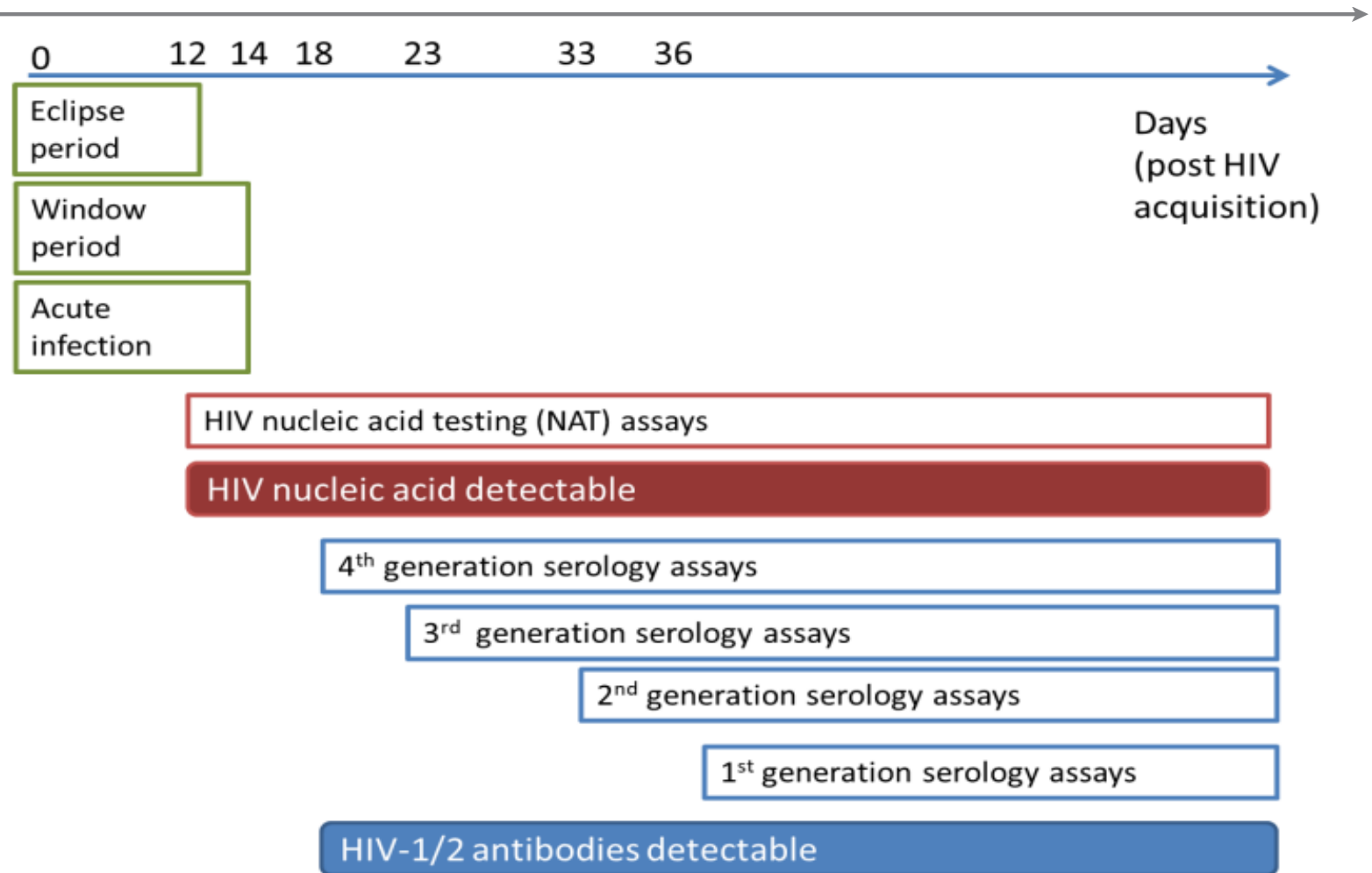
Where: Health facilities (some clinics, higher level facilities & labs)

Who: Trained facility staff and lab techs only

Other considerations: Not in routine use for screening in LMIC. Recommended by WHO for HIV diagnosis in individuals less than 18 months of age. Sometimes used to measure viral load in people living with HIV on ART

How soon after HIV infection can each type of test detect HIV?

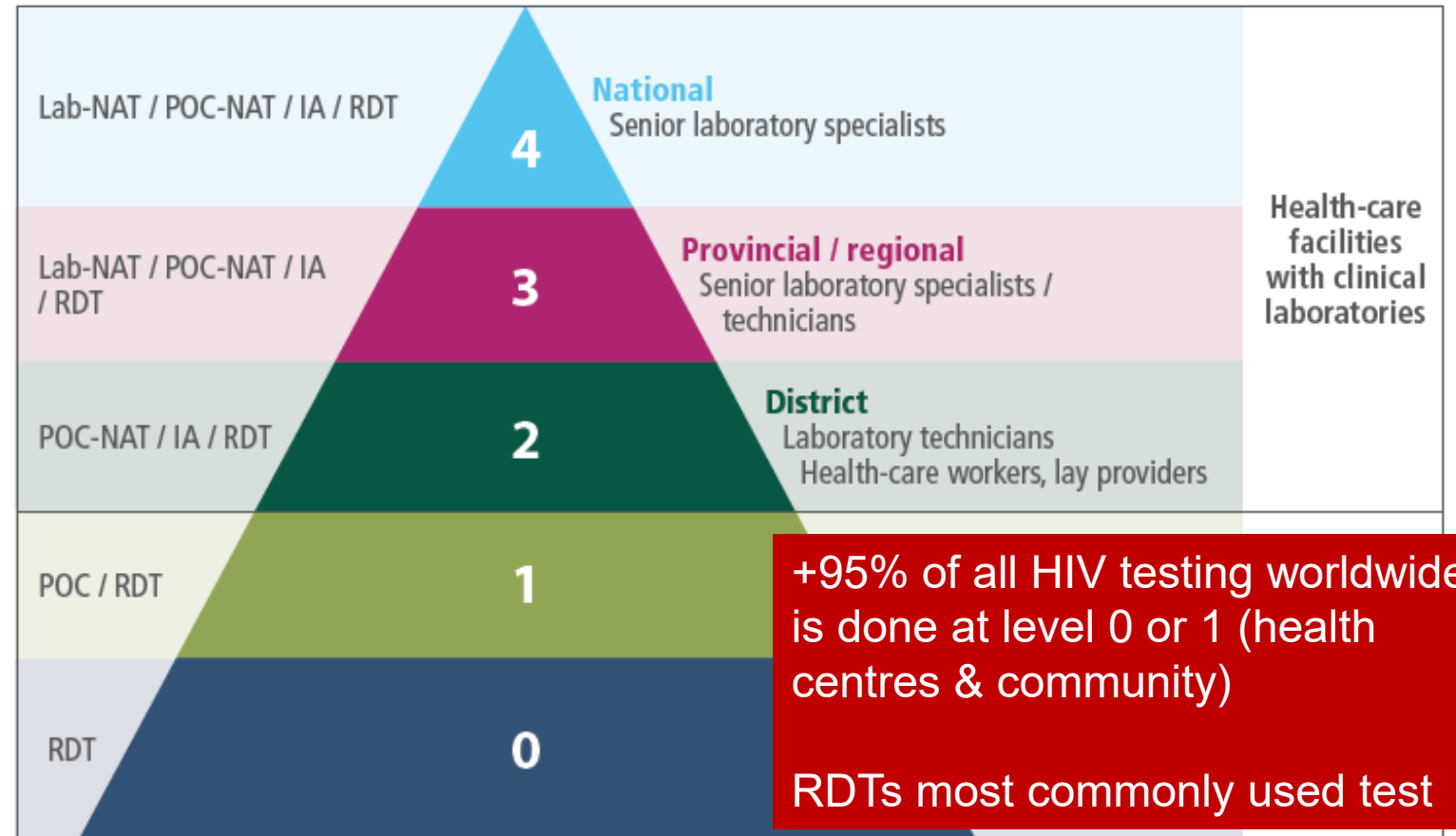
- No rapid tests in routine use in LMIC can reliably detect acute HIV infections
- No test type can detect HIV until 10 days after infection
- Time to detection has shortened with each successive generation of tests developed – but even newer 4th generation antigen/ antibody tests – not widely available in LMIC – cannot reliably detect antigens/ antibodies until 2 weeks after infection
- This means a window period of at least two weeks before HIV can be reliably detected by tests currently in use in LMIC



Sources: Adapted from Delaney KP et al. Time until emergence of HIV test reactivity following infection with HIV-1: implications for interpreting test results and retesting after exposure. Clin Infect Dis. 2017 Jan 1;64(1):53–59. Epub 2016 Oct 12.
Rosenberg NE et al How can we better identify early HIV infections? Curr Opin HIV AIDS. 2015 Jan;10(1):61–8. doi: 10.1097/COH.000000000000121.

Test types, settings and capacity needs in LMIC

- WHO recommends settings for conducting different categories of tests, including the service and provider type and capacity requirements.
- Rapid diagnostic tests can be used in primary care and community settings, and can be administered by health care workers, lay providers and community workers.
- NAT is only feasible in referral district level health care settings and above that have laboratory capacity.



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.

WHO Recommendations for HIV Testing

- WHO's recommended testing strategy uses a combination of rapid diagnostic tests (RDTs) and/or enzyme immunoassays (EIAs). The RDTs can be based on oral or blood samples.
- The HIV testing algorithm of three consecutive reactive (positive) tests should meet the standard of at least 99% combined sensitivity, or less than one false positive per 100 people diagnosed with HIV
- All individual tests should meet WHO standards of at least 99% sensitivity and 98% specificity
 - Sensitivity = the ability of the test to detect a true positive result
 - Specificity = the ability of test to detect a true negative result
- First tests administered should be highly sensitive, and second and third tests highly specific
- Verification of specific combinations of tests in the algorithms is important to ensure products selected work best together
- HIV self-testing is advised for triage and to support greater access and implementation
 - Self-tests require confirmation for HIV diagnosis
 - Self-testing recommended for initiation, re-initiation and continuation of PrEP

WHO Guidelines on HIV Testing and PrEP

Recommendations for HIV Testing for PrEP Delivery

- HIV testing prior to and during PrEP use is recommended to decrease risk of developing drug resistance.
- WHO currently recommends HIV testing before starting or re-starting PrEP, and regularly (currently every 3 months) during PrEP use
 - Testing after one month can detect acute infection that may have been present but undetectable at initial screening
- HIV self-testing can be used to initiate, re-initiate, continue PrEP
 - HIVST can be used for PEP, as well as oral PrEP and DVR
 - Research ongoing on the role of HIVST for CAB for PrEP

[WHO Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring \(2021\)](#)

[WHO Recommendation on Use of HIV Self-testing for PrEP \(2023\)](#)

HIV Testing and Injectable CAB for PrEP

- Injectable cabotegravir (CAB for PrEP) is proven effective as PrEP in clinical trials
- Some concern emerged on the potential for resistance arising from acute (early) HIV infections in CAB for PrEP users that are not detectable by HIV tests in wide use in LMIC
- [WHO guidelines for CAB for PrEP implementation](#) recommend using national testing algorithms
- Guidance from the US Food and Drug Administration and the Centers for Disease Control and Prevention recommend NAT testing for PrEP initiation and continuation
- NAT testing is not widely available or in routine use in LMIC
 - Requiring NAT testing would add cost and complexity to CAB for PrEP, likely severely limiting or curtailing its availability in LMIC
- Global health stakeholders are considering whether other HIV test strategies could address concern about resistance with CAB for PrEP such as testing pooled samples with NAT to determine whether resistance is emerging at a population level

[*Predicted effects of the introduction of long-acting injectable cabotegravir pre-exposure prophylaxis in sub-Saharan Africa: a modelling study*](#)

Resources and more information

- [WHO Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach \(2021\)](#)
- [HIV Testing: What's involved \(Avert\)](#)
- [WHO Implementation Tool for PrEP of HIV Infection: Module 10 Testing Providers \(2017\)](#)
- [HIV Self Testing Research and Policy Hub](#)