The Diagnostic Needs of Women: Overview of WHO recommendations

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WHO Geneva

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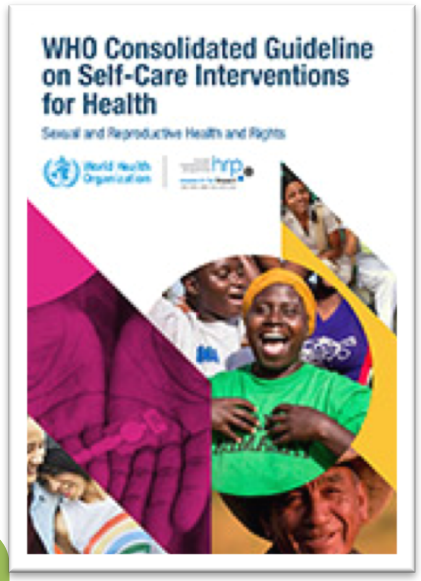
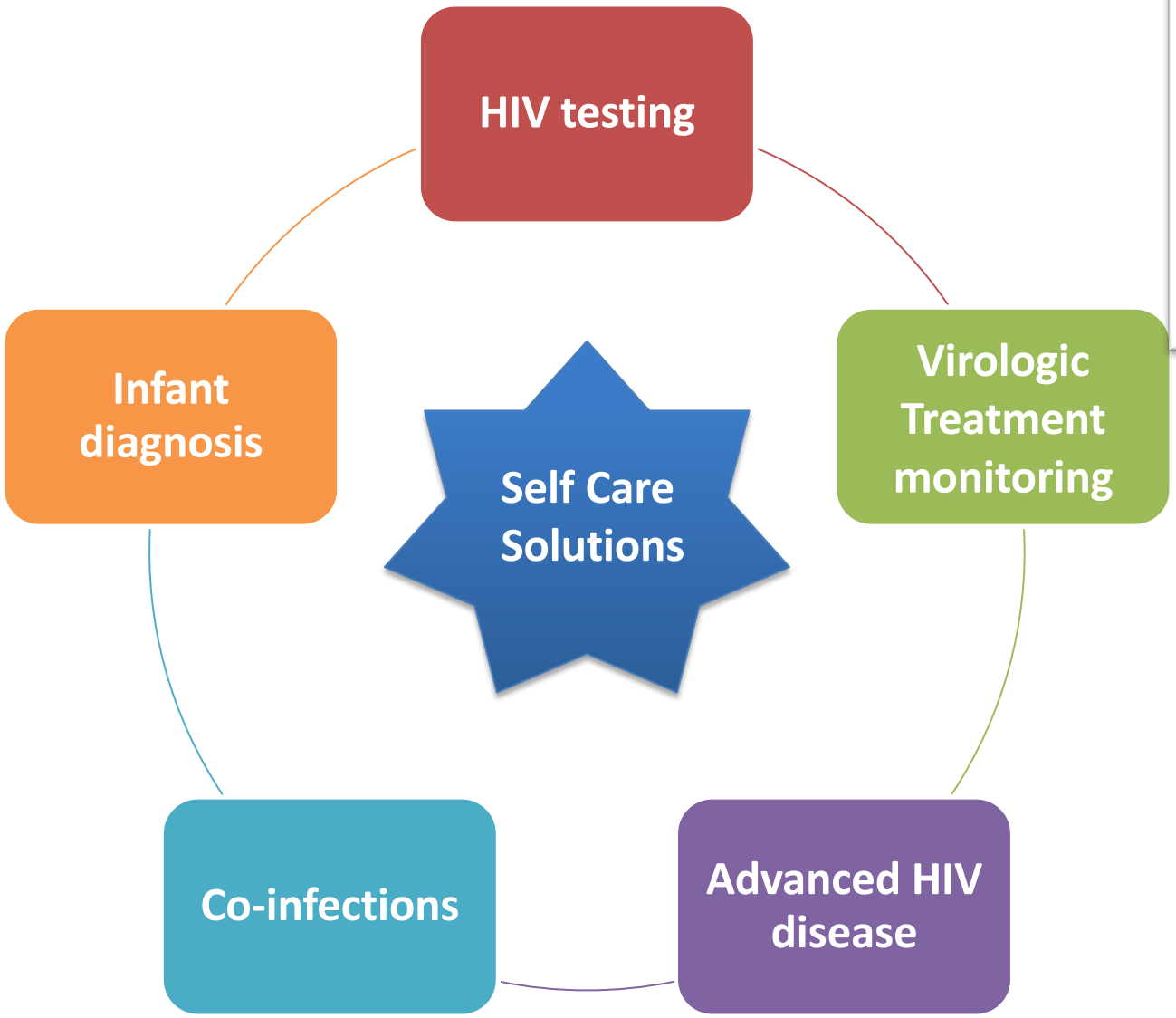
World Health Organization

Diagnostic Needs





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HIV testing

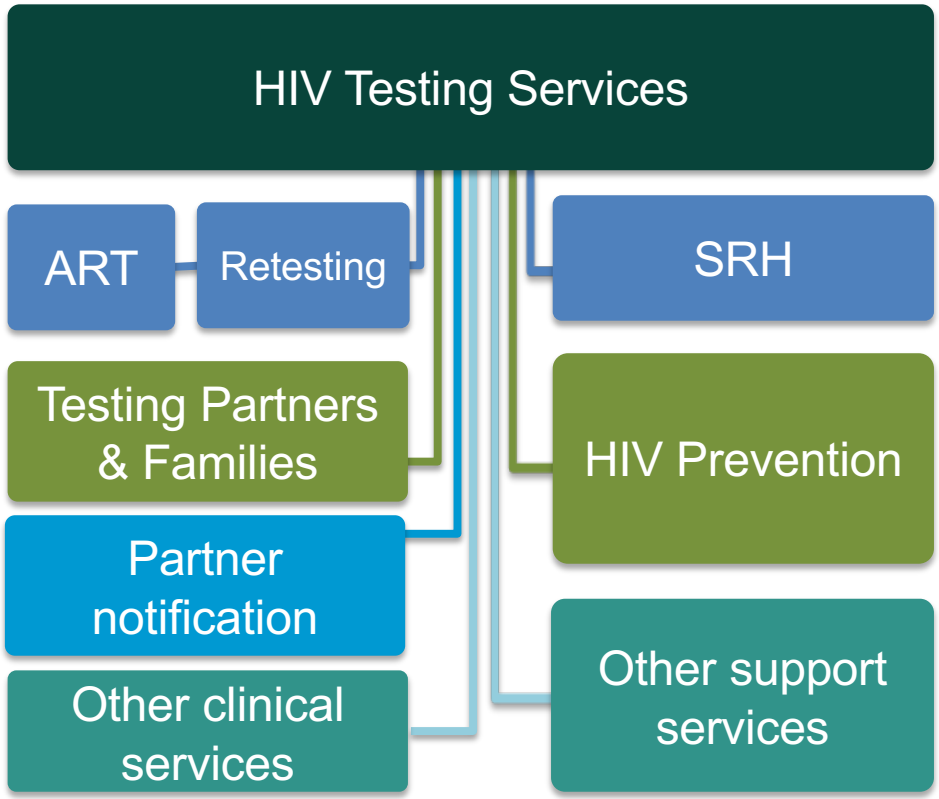
Important gateway to treatment and prevention for individuals, couples, and partners and families

Facility-based: Offering HIV testing in a facility, e.g. VCT, in-patient and out-patient clinics, ANC, TB, STI.

Community-based: Offering HIV testing in natural setting of the community, e.g. outreach, CBOs, workplace, clubs, bars.

Assisted partner notification: Assisting individuals with HIV by contacting their sexual and/or drug injecting partners and offering them HIV testing services.

HIV self-testing: Offering self-test kit for individual, and/or their partner, enabling them to collect their sample (oral or blood), perform test, and interpret results in private. **All reactive results need confirmation.**



Source: WHO 2015; WHO 2016, WHO 2019

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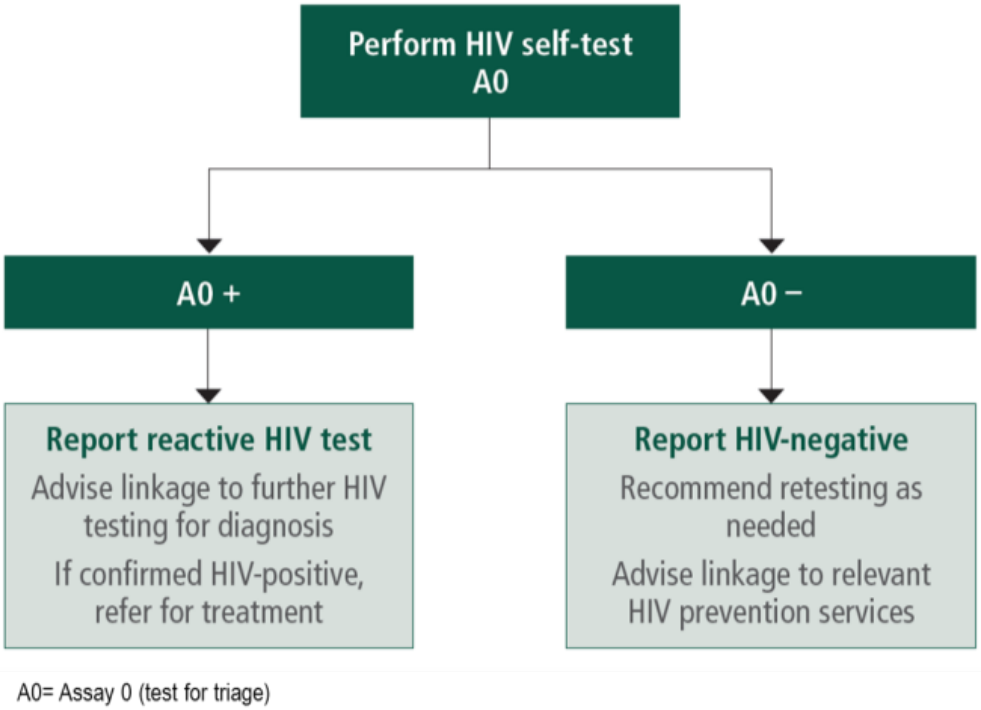
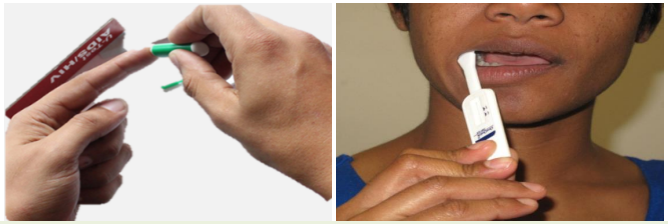
HIV self-testing for increased case-finding



A0= Assay 0 (test for triage)



- HIVST requires self-testers with a **reactive** (positive) result to receive **further testing** from a trained provider using a validated national testing algorithm.
- All self-testers with a non-reactive test result should retest if they might have been exposed to HIV in the preceding six weeks, or are at high ongoing HIV risk.
- HIVST is **not** recommended for people taking anti-retroviral drugs, as this may cause a false non-reactive result.

*Any person **uncertain** about how their self-test result, should be encouraged to access facility- or community-based HIV testing

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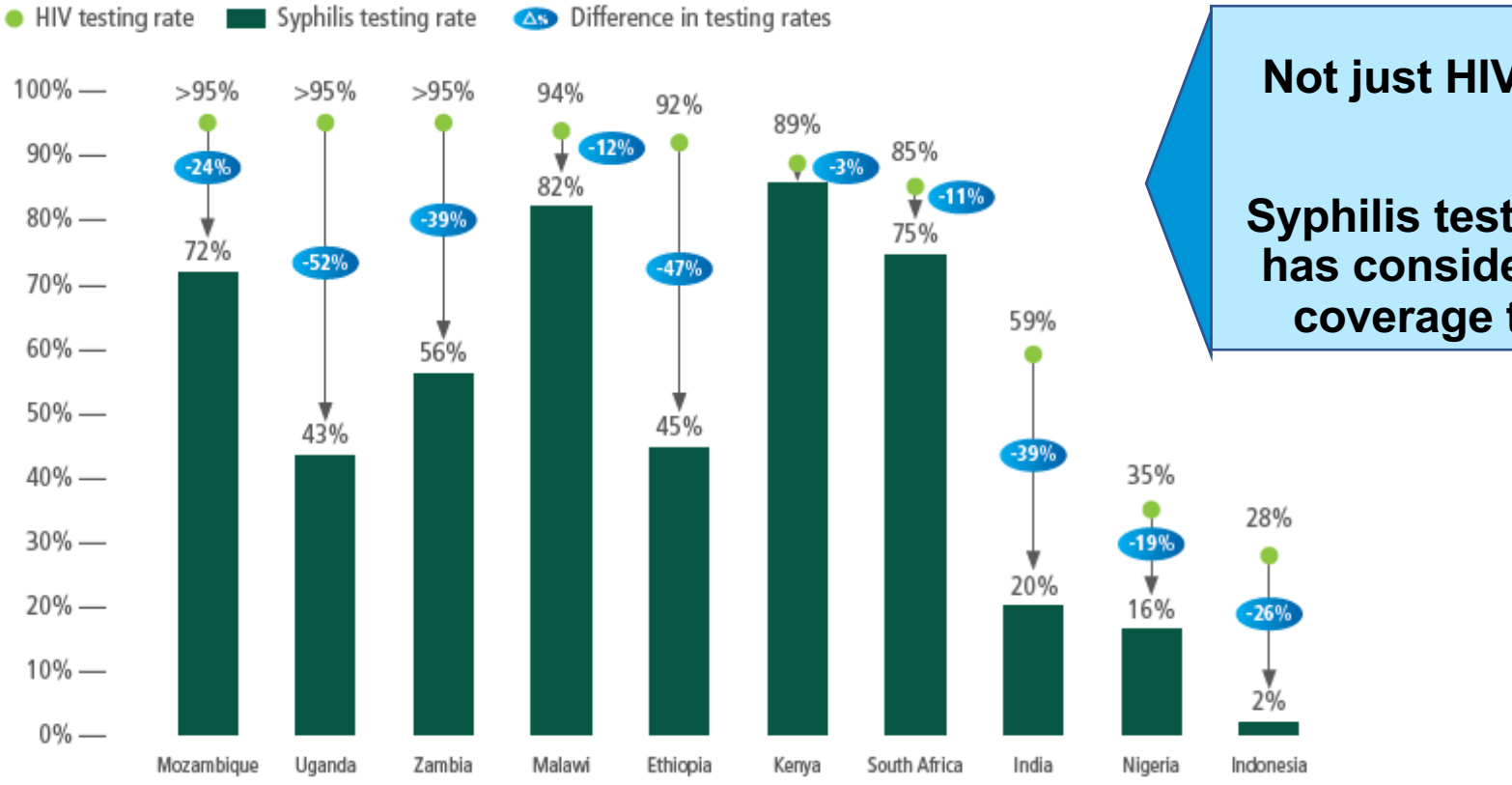
Dual HIV-Syphilis Test



Prevalence	Mozambique	Uganda	Zambia	Malawi	Ethiopia	Kenya	South Africa	India	Nigeria	Indonesia	
HIV	15.0%	7.3%	14.3%	11.7%	1.2%	6.2%	23.7%	0.2%	3.0%	0.3%	Women between 15–49 years
Syphilis	4.6%	2.9%	3.5%	1.0%	1.1%	1.4%	2.0%	0.38%	0.8%	3.2%	% ANC attendees positive for syphilis

ANC = antenatal care

Source: Storey A, Seghers S, Pyne-Mercier L, Peeling R, Newman Owiredu M, Taylor M. Syphilis diagnosis and treatment during antenatal care: the potential catalytic impact of the dual HIV and syphilis rapid diagnostic test. Lancet Glob Health. 2019; 7(8): e1006-e1008.

Not just HIV, but STIs

Syphilis testing, which has considerably low coverage than HIV

Differences in coverage of testing for HIV and syphilis in pregnant women visiting ANC in 10 countries, 2016–2018

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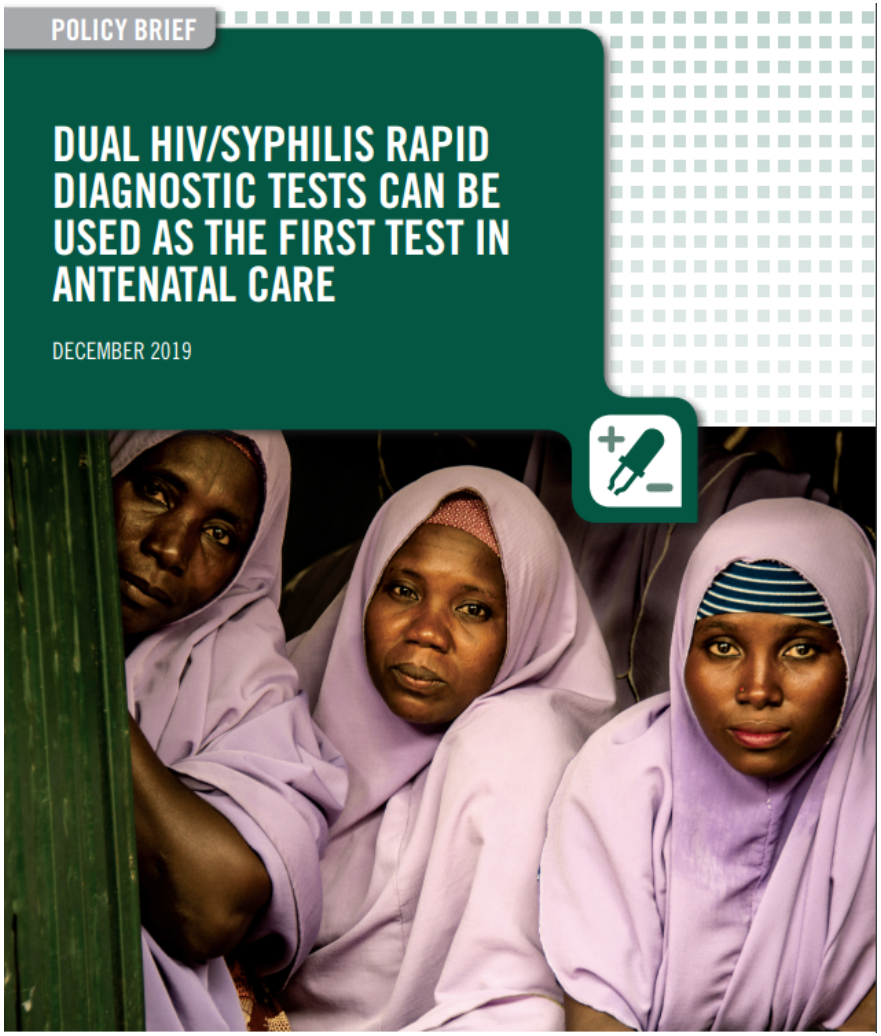
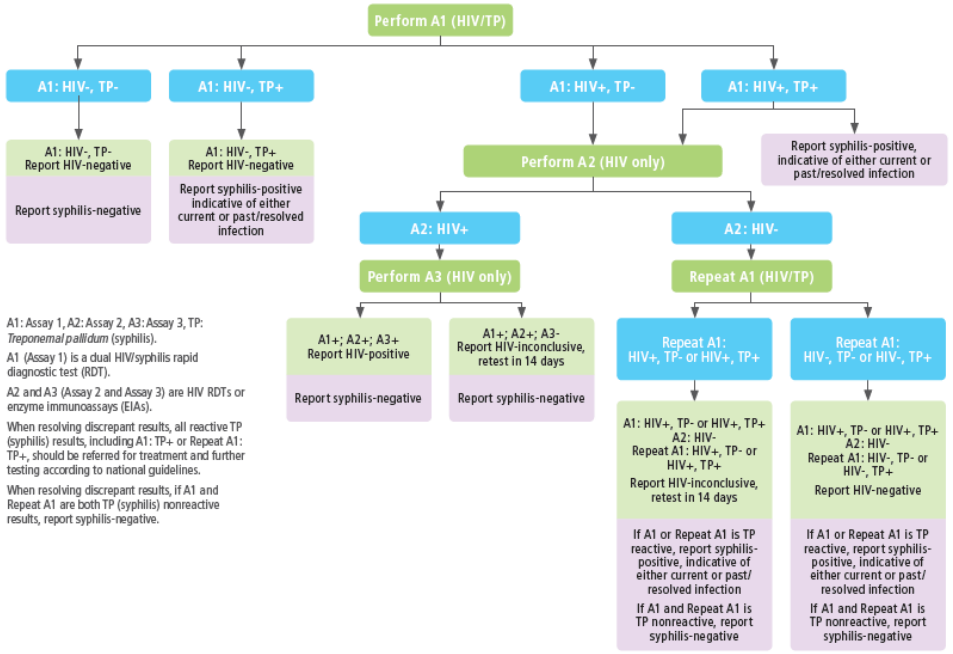
Dual HIV-Syphilis Test





- Cost-savings in high and low HIV burden settings
- **Dual HIV/syphilis RDT can be first test for ANC**
- Important to ensure integrated services for maximum impact
- Not for retesting women on ART or diagnosed with syphilis during pregnancy

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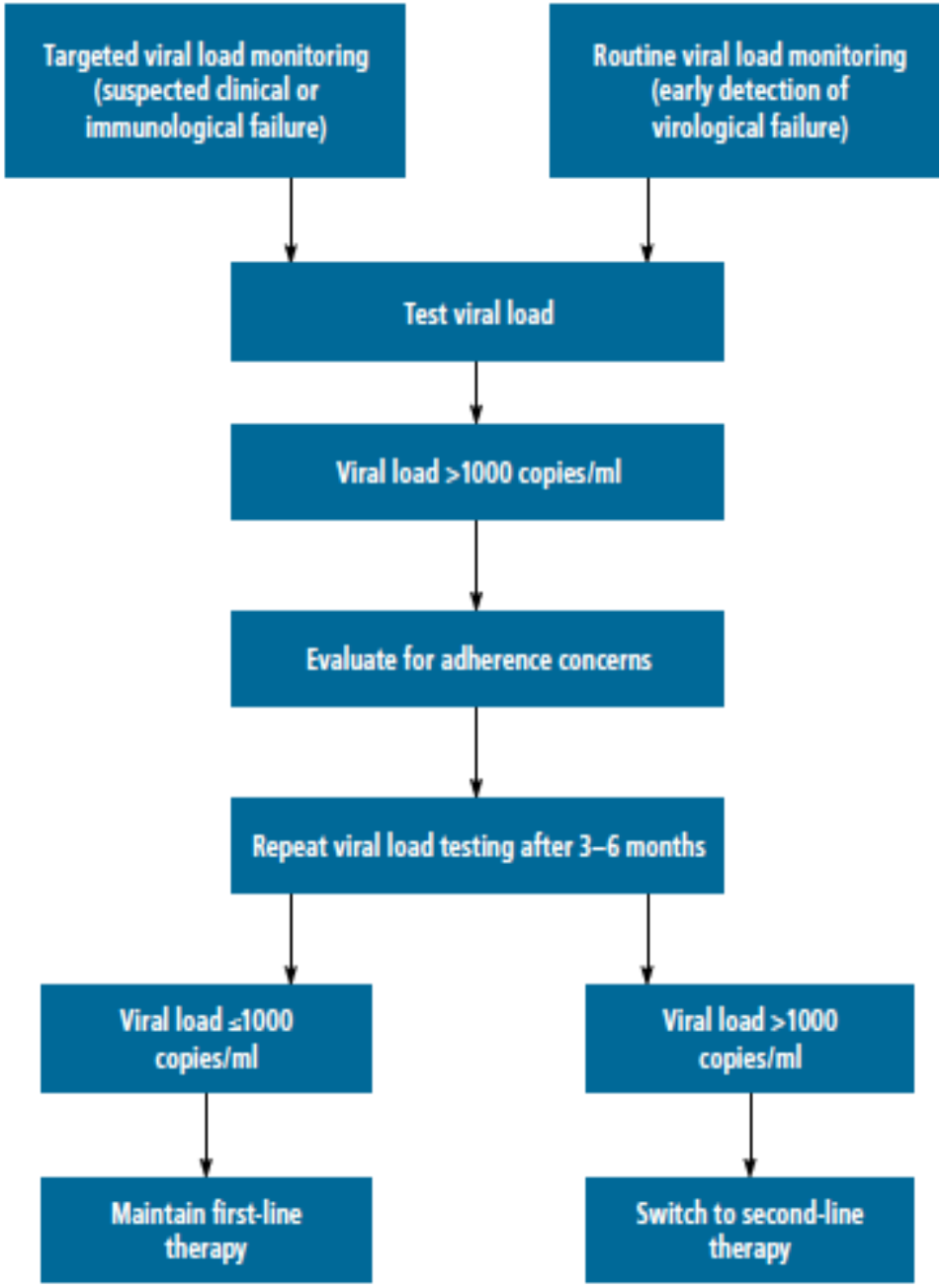
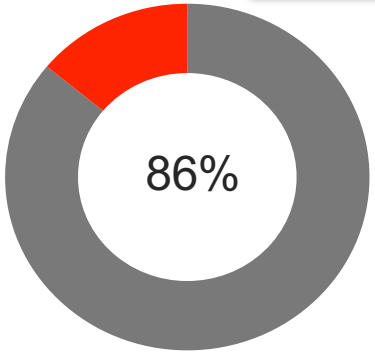
Virologic Treatment Monitoring





High viral suppression rates across countries

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Molecular testing pipeline

Available on the market






Centralized — POC

Pipeline products

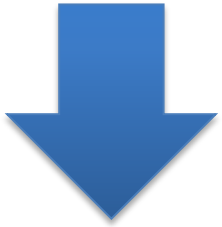

Technologies listed by WHO prequalification

Multiplex/polyvalent technologies that can or will likely be able to test for HIV and another disease assay (ie. TB, HCV, HPV, etc)

Advanced HIV disease guideline

Advanced HIV disease is defined as CD4 count < 200 cells/mm^3 or WHO clinical stage 3 or 4.
(All children < 5 years old are considered having advanced disease.)

- In a study from Kenya, Malawi, Uganda and Zimbabwe, almost half (47%) the people with CD4 count < 100 cells/mm3 were classified as having WHO clinical stage 1 or 2 disease. Hakim NEJM 2017



Management of advanced HIV disease

A package of interventions including screening, treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation and intensified adherence support interventions should be offered to everyone presenting with advanced HIV disease.

(Strong recommendation, moderate-quality evidence)

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Supportive tests for management of advanced HIV disease

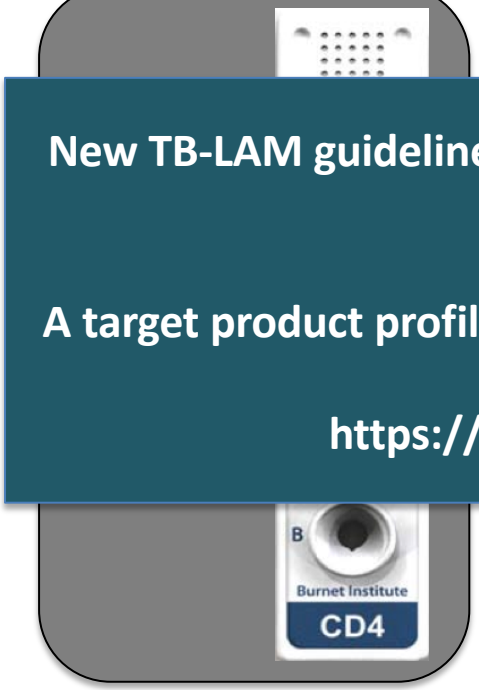
CD4

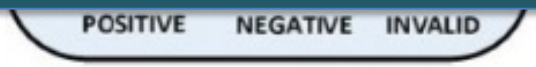
CrAg

TB

New TB-LAM guidelines have been released recently to expand access to more people living with HIV.

A target product profile for a device-free point-of-care CD4 technology is now open for public comment:
https://www.who.int/in-vitro-diagnostic/innovation/en/





BD

Alere

Further trials may indicate additional necessary tests for patients with advanced disease (ie. pneumocystis, toxoplasmosis, severe bacterial infections, etc.)

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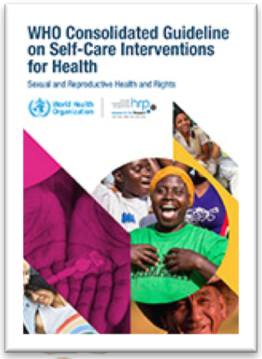
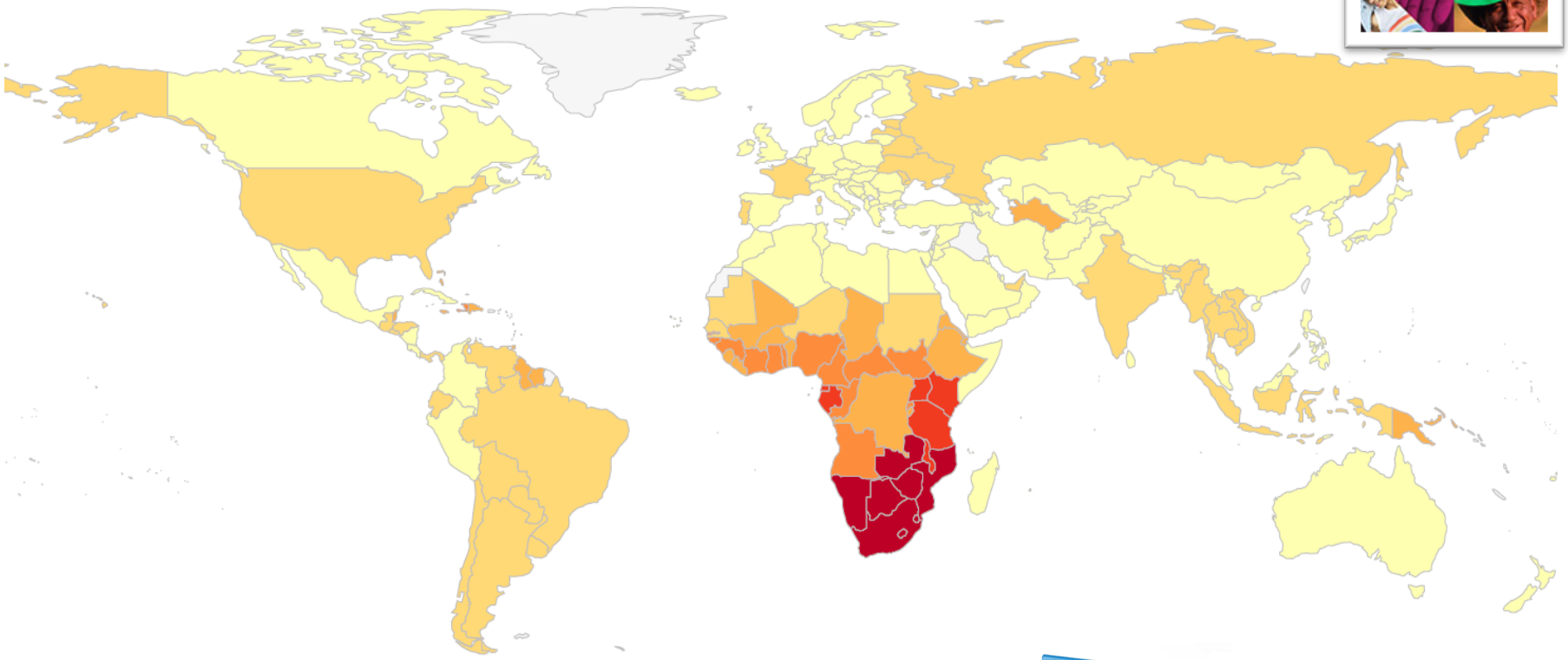
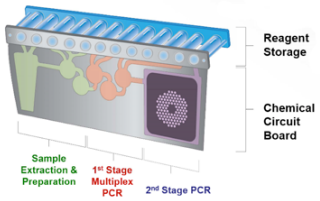
Prevalence of cervical cancer in women living with HIV







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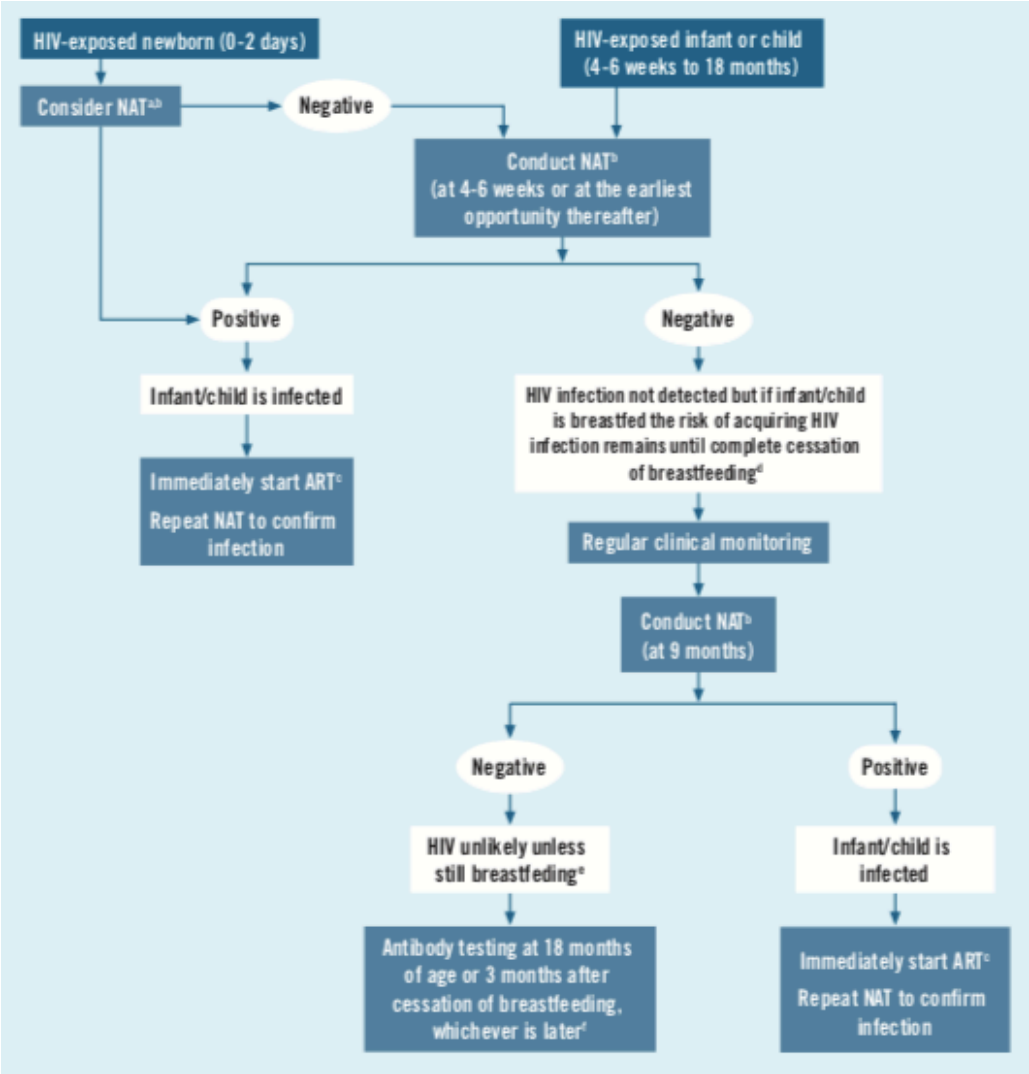
Infant diagnosis



- Moving to a multi-HIV NAT algorithm
  - Birth (where of value)
  - 6 weeks
  - 9 months
  - Any time HIV exposed infants present sick
- Ensuring confirmatory testing of a positive NAT result is undertaken
- Diagnosis is not completed without “final diagnosis” at the of the period at risk for transmission

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Impact of POC testing – on identification and treatment initiation

HIV testing to CD4 testing 1.21 (1.15-1.27)

Recommendation

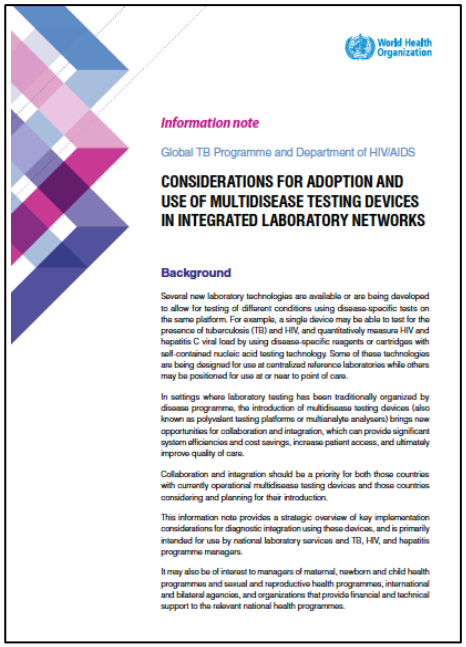
Nucleic acid testing (NAT) technologies that are developed and validated for use at or near to the point of care can be used for early infant HIV testing (conditional recommendation, low-quality evidence).

0.- 0.- 1.- 1.- 2.-

Risk ratio (95% CI)

Country	Setting	Device/ Sample	# of sites	n	% result return to caregiver		TAT result return	% ART initiation		TAT ART Initiation
					≤ 30# days	Same day		≤ 60 days	Same day	
Mozambique (Maputo, Sofala)	cRCT	AlereQ, WB	SOC - 8	1876	0.32%	0%	125	12.8%	NA	127
			POC - 8	2034	98.7%	98.2%	0	89.7%		0
Malawi	Observa-tional pre/post	AlereQ, WB	7 pre	963	18.1%	0%	56	41.9%	43.8%	38
			7 post	789	100%	99.5%	0	91.1%	70.7%	0

Call for diagnostic integration



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Information note

Global TB Programme and Department of HIV/AIDS

CONSIDERATIONS FOR ADOPTION AND USE OF MULTIDISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS

Background

Several new laboratory technologies are available or are being developed to allow for testing of different conditions using disease-specific tests on the same platform. For example, a single device may be able to test for the presence of tuberculosis (TB) and HIV, and quantitatively measure HIV and hepatitis C viral load by using disease-specific reagents or cartridges with self-contained nucleic acid testing technology. Some of these technologies are being designed for use at centralized reference laboratories while others may be positioned for use at or near to point of care.

In settings where laboratory testing has been traditionally organized by disease programme, the introduction of multidisease testing devices (also known as polyvalent testing platforms or multianalyte analysers) brings new opportunities for collaboration and integration, which can provide significant system efficiencies and cost savings, increase patient access, and ultimately improve quality of care.

Collaboration and integration should be a priority for both those countries with currently operational multidisease testing devices and those countries considering and planning for their introduction.

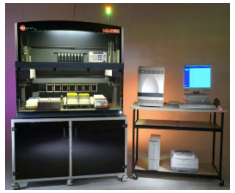
This information note provides a strategic overview of key implementation considerations for diagnostic integration using these devices, and is primarily intended for use by national laboratory services and TB, HIV, and hepatitis programme managers.

It may also be of interest to managers of maternal, newborn and child health programmes and sexual and reproductive health programmes, international and bilateral agencies, and organizations that provide financial and technical support to the relevant national health programmes.

Cepheid

Abbott

Abbott



Roche

HOLOGIC

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MULTI-DISEASE DIAGNOSTIC LANDSCAPE FOR

INTEGRATED MANAGEMENT OF HIV, HCV, TB AND OTHER COINFECTIONS

JANUARY 2018

As of 31 December 2017, a total of 9,449 GeneXpert instruments (comprising 42,392 modules) had been *cumulatively* procured in the public sector in 130 of the 145 countries eligible for concessional pricing.

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Conclusions

- Optimizing and broadening HIV testing is essential to achieve the first 90
- Scale-up and improved access is critical and necessary across a number of diagnostics for people living with HIV, much of this scale-up can be supporting through diagnostic integration
- Women in particular require additional care, including for cervical cancer and infant diagnosis