The Diagnostic Needs of Women: Overview of WHO recommendations

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Diagnostic Needs

- HIV testing
- Infant diagnosis
- Co-infections
- Advanced HIV disease
- Virologic Treatment monitoring

Self Care Solutions
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
HIV self-testing for increased case-finding

- 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.*
Differences in coverage of testing for HIV and syphilis in pregnant women visiting ANC in 10 countries, 2016–2018
**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**
Virologic Treatment Monitoring

High viral suppression rates across countries

86%
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 is defined as CD4 count < 200 cells/mm³ 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. 

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)*
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:

Further trials may indicate additional necessary tests for patients with advanced disease (i.e. pneumocystis, toxoplasmosis, severe bacterial infections, etc.)
Prevalence of cervical cancer in women living with HIV
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 end of the period at risk for transmission
### Impact of POC testing – on identification and treatment initiation

**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).

<table>
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<tr>
<th>Country</th>
<th>Setting</th>
<th>Device/ Sample</th>
<th># of sites</th>
<th>n</th>
<th>% result return to caregiver</th>
<th>TAT result return</th>
<th>% ART initiation</th>
<th>TAT ART Initiation</th>
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<tr>
<td>Mozambique (Maputo, Sofala)</td>
<td>cRCT</td>
<td>AlereQ, WB</td>
<td>SOC - 8</td>
<td>1876</td>
<td>0.32% 0%</td>
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<td>12.8% NA</td>
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<td></td>
<td></td>
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<td>98.7% 98.2%</td>
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<td>89.7% NA</td>
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<tr>
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<td>Observational pre/post</td>
<td>AlereQ, WB</td>
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<td>963</td>
<td>18.1% 0%</td>
<td>56</td>
<td>41.9% 43.8%</td>
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<tr>
<td></td>
<td></td>
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<td>7 post</td>
<td>789</td>
<td>100% 99.5%</td>
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</table>
Call for diagnostic integration

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.
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