

DUAL HIV/SYPHILIS RAPID DIAGNOSTIC TESTS CAN BE USED AS THE FIRST TEST IN ANTENATAL CARE

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WHO recommends that pregnant women receive testing for HIV, syphilis and hepatitis B (HBsAg)* at least once during pregnancy, preferably in the first trimester. Dual HIV/syphilis rapid diagnostic tests (RDTs) can be used as the first test for pregnant women as part of antenatal care (ANC). These simple tests can be used at the point-of-care and are cost-saving compared to standard testing in ANC. They enable more women to be diagnosed with HIV and syphilis so that they can access treatment and prevent transmission to their children.

*Particularly in settings with a $\geq 2\%$ HBsAg seroprevalence in the general population.

Rationale

Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis is a global health priority. It is estimated that there are 1.4 million new maternal HIV infections and 988 000 new maternal syphilis infections every year.

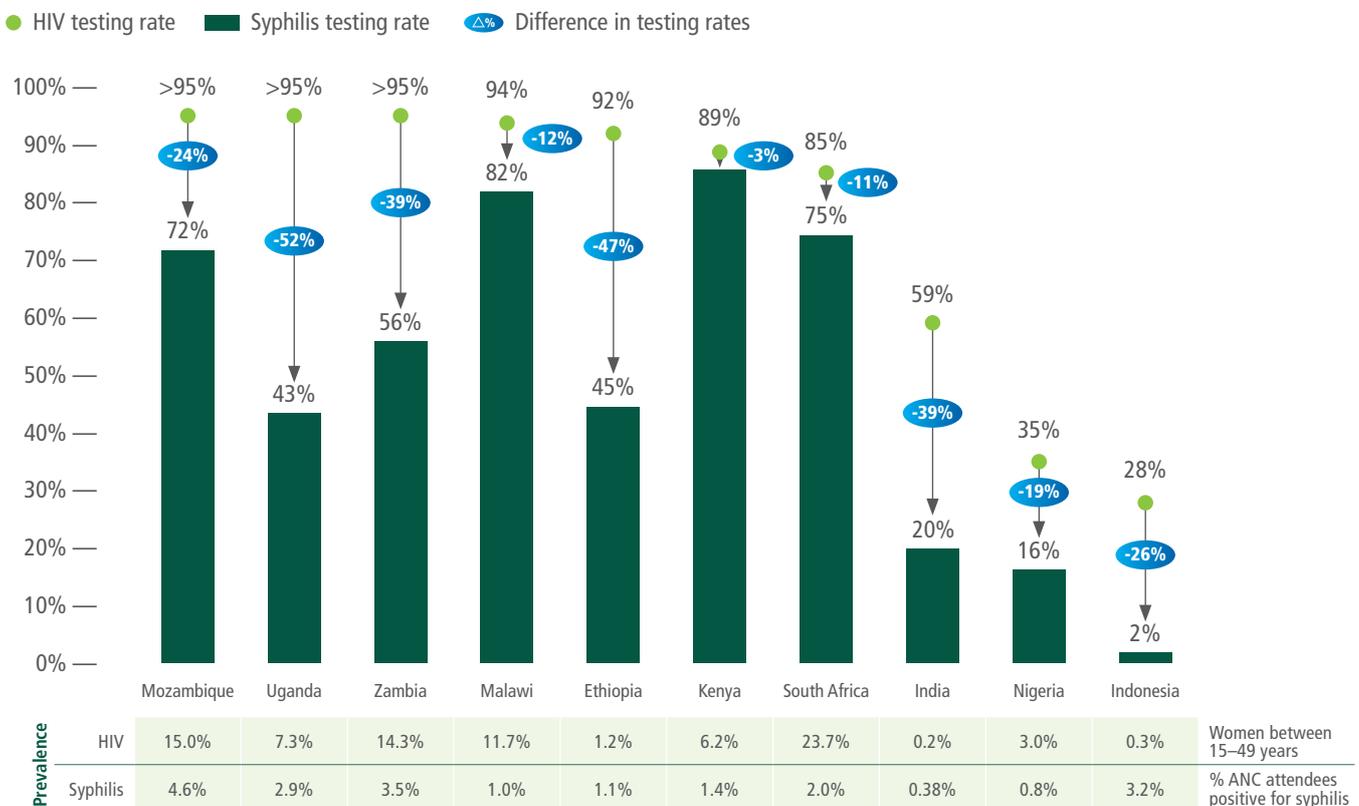
Globally, there has been marked progress toward EMTCT of HIV, with a 41% reduction in new paediatric HIV cases between 2010 and 2018. However, syphilis remains the second most common cause of stillbirth globally. As of 2016, over 660 000 cases of congenital syphilis (that is, due to mother-to-child transmission) are estimated to have occurred globally, with over 350 000 of these resulting in adverse birth outcomes (>200 000 as stillbirths and neonatal deaths).

Box 1. WHO Recommendation and **NEW** implementation guidance

All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible, ideally at the first antenatal care visit (*syphilis: strong recommendation, moderate-quality evidence; HBsAg*: strong recommendation, low-quality evidence*).

Dual HIV/syphilis rapid diagnostic tests (RDTs) can be considered as the first test in HIV testing strategies and algorithms in ANC settings.

*Particularly in settings with a $\geq 2\%$ HBsAg seroprevalence in the general population.



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.

Fig. 1. Differences in coverage of testing for HIV and syphilis in pregnant women visiting ANC in 10 countries, 2016–2018

Syphilis testing and treatment coverage among pregnant women are low in many countries, lower than that of antenatal HIV testing and treatment (Fig. 1). While WHO recommends testing at the point of care using RDTs, the majority of countries still rely on laboratory testing for syphilis. Use of dual HIV/syphilis RDTs offers the opportunity to immediately close the gap between HIV and syphilis testing among pregnant women, with the goal of eliminating adverse birth outcomes due to syphilis.

Dual/HIV syphilis RDTs detect antibodies to both *Treponema pallidum* (TP) (the cause of syphilis infection) and HIV. Like other RDTs used for HIV alone, they do not require refrigeration. Available products currently do not discriminate between active or past syphilis infection. This means that, if a person has had syphilis that is treated/resolved, and treponemal antibodies persist, the dual/HIV syphilis RDT may produce a reactive result for syphilis.

Advantages of rapid dual HIV/syphilis tests in ANC

Use of a dual HIV/syphilis RDT as the first test in ANC offers the opportunity to test for both infections with a single finger prick. Results are available quickly, enabling many to start either or both HIV treatment and syphilis treatment with benzathine penicillin.

In addition to increasing syphilis testing and treatment coverage, use of the dual-purpose RDT can simplify training by using one test instead of separate tests, reduce storage and transportation costs and reduce waste disposal. In both high and low HIV burden settings, use of the rapid dual test has been found to save costs, in both high and low HIV burden settings, in prevention of congenital syphilis and has not negatively affected HIV testing coverage.

Countries should review and consider the dual HIV/syphilis RDTs prequalified by WHO and listed at https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv_syphilis/en/.

Dual HIV/syphilis rapid testing strategy and algorithm for ANC

The testing strategy needed for dual detection of HIV and syphilis (Fig. 2) differs from the recommended strategies for separately testing for HIV or syphilis. Countries introducing the dual HIV/syphilis RDT as the first test in ANC will need to revise their HIV testing strategy for pregnant women. It is important not to use the rapid dual HIV/syphilis test for:

1. women with HIV taking antiretroviral therapy (ART);
2. women already diagnosed with and treated for syphilis during their current pregnancy; and
3. retesting for HIV.

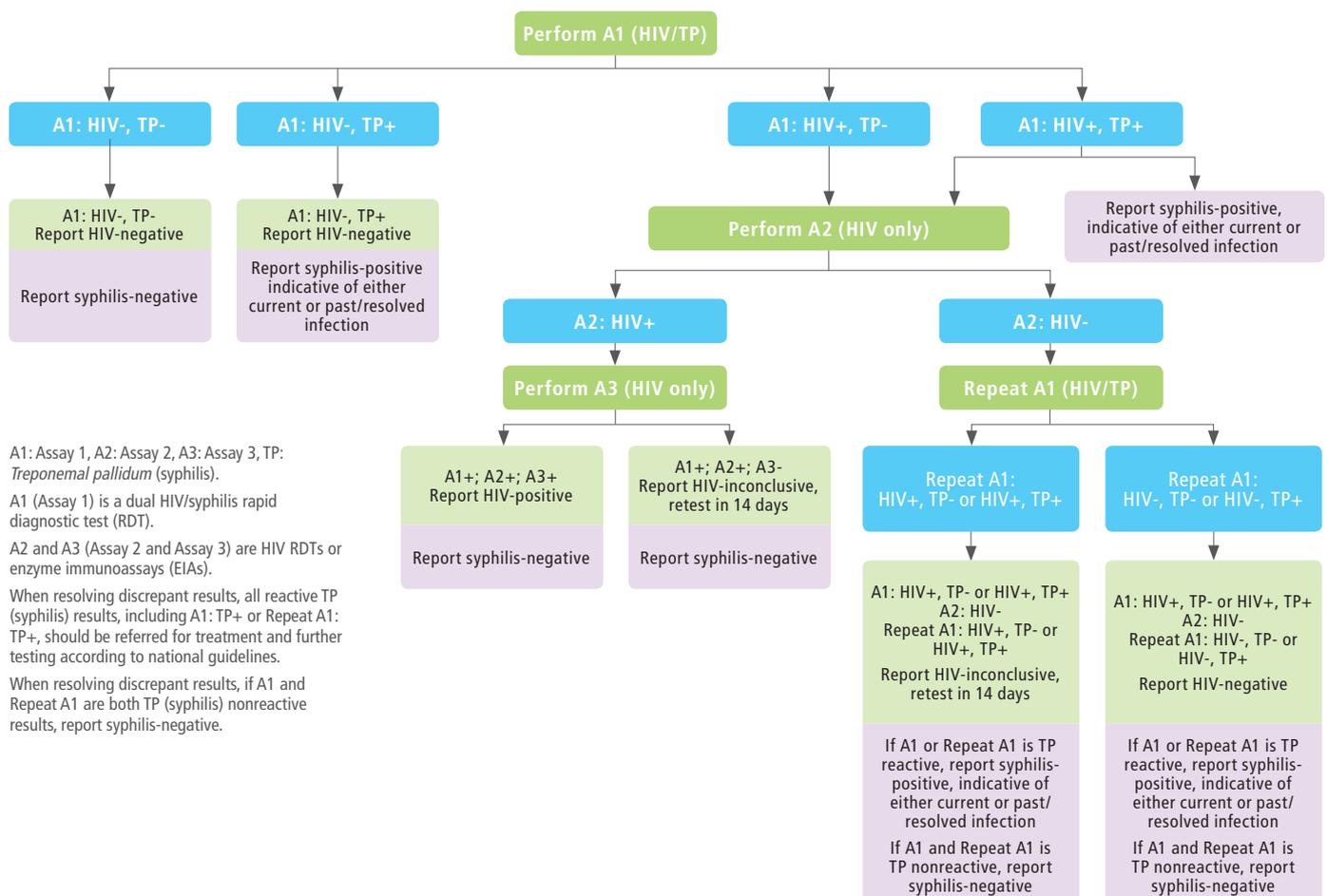


Fig. 2. WHO-recommended testing strategy for dual detection of HIV and syphilis infection for ANC settings

All women whose dual HIV/syphilis test results include a reactive TP (syphilis) result should be treated using benzathine penicillin and referred for further testing to provide final diagnosis of active syphilis.

To verify HIV-positive diagnoses and prevent misdiagnosis of HIV, WHO recommends retesting all people with HIV prior to starting lifelong treatment. This form of retesting is only for HIV and not for syphilis. Therefore, for verification of an HIV-positive result, countries should only use the national HIV testing strategy and algorithm, which would not include dual HIV/syphilis RDTs.

Considerations to maximize the impact of dual HIV/syphilis RDTs

- Countries introducing dual HIV/syphilis RDTs as the first test in ANC will need to verify that the new test works well in combination with the other two HIV tests in the algorithm. Countries should review and consider WHO-prequalified products listed at https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/.
- Use of the dual HIV/syphilis RDT as the first test in ANC allows for integration and improved service delivery coverage. Programmes should consider how they can integrate service delivery in ANC and other settings, such as outreach to key populations at risk for both HIV and syphilis, to maximize public health impact. Opportunities to offer HBsAg testing alongside the use of dual HIV/syphilis RDTs in pregnancy should also be considered.
- As use of the dual-purpose RDTs leads to diagnosis of more syphilis cases, national programmes should prepare for additional procurement of benzathine penicillin to ensure adequate treatment supply and to prevent stock-outs. The increase in demand for benzathine penicillin can be estimated using the WHO congenital syphilis estimation tool. This tool and instructions for its use are located at <https://www.who.int/reproductivehealth/congenital-syphilis/surveillance/en/>.
- When introducing dual HIV/syphilis RDTs, staff, including testers, implementers, procurement specialists and other related staff, will need training and support. Programmes should plan to update training manuals, information and counselling messages, standard operating procedures, quality assurance, operational guidance and tools and procurement planning to include HIV/syphilis RDTs.

ADDITIONAL RESOURCES

WHO (2019). Consolidated guidelines on HIV testing services. <https://www.who.int/hiv/mediacentre/news/hts-info-app/en/>

WHO (2017). WHO guidelines for syphilis screening and treatment for pregnant women. <https://www.who.int/reproductivehealth/publications/rtis/syphilis-ANC-screenandtreat-guidelines/en/>

WHO (2017). WHO guidelines on hepatitis B and C testing. <https://www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/>

WHO (2016). WHO recommendations on antenatal care for a positive pregnancy experience. https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/

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POLICY BRIEF

HIV TESTING SERVICES