



HHS Public Access

Author manuscript

Sex Transm Infect. Author manuscript; available in PMC 2019 September 17.

Published in final edited form as:

Sex Transm Infect. 2017 November ; 93(7): 458–459. doi:10.1136/sextrans-2017-053301.

Role of dual HIV/syphilis test kits in expanding syphilis screening

Melanie M Taylor^{1,2}, Rosanna W Peeling³, Igor Toskin¹, Massimo Ghinidelli⁴

¹Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland ²Department of STD Prevention, US Centers for Disease Control and Prevention, Atlanta, Georgia, USA ³International Diagnostics Centre, London School of Tropical Medicine and Hygiene, London, UK ⁴International Diagnostics Centre, Pan American Health Organization, Washington, District of Columbia, USA

Screening pregnant women for HIV and syphilis is a critical component of national programming to achieve elimination of mother to child transmission (EMTCT) for the two diseases. Many countries have well-resourced programmes for HIV screening in pregnant women and key populations (men who have sex with men and sex workers), but screening for syphilis in these same risk groups is seldom centralised and often falls within the responsibilities but outside the priorities of reproductive health, antenatal care and sexually transmitted infection (STI) control programmes. The tragedy of babies avoiding HIV and dying of syphilis and the lack of progress in Africa in congenital syphilis elimination despite tremendous successes in EMTCT for HIV has once again reminded us of the need to re-examine this situation.^{1,2}

In this issue, Obure *et al* describes a comparative analysis of costs of single versus dual rapid diagnostic tests for HIV and syphilis in the cities of Bogota and Cali in Columbia.³ The authors report higher costs associated with the use of rapid dual HIV/syphilis tests compared to single rapid HIV and syphilis tests. At baseline, the Columbia purchase price of the rapid dual test kits was more expensive than the single test kits; US\$3.62 for the dual test versus US\$2.26 for the two single tests (US\$1.03 for single HIV and US\$1.23 for syphilis). A comprehensive diagnostic brief of rapid dual tests has recently cited the average cost of US \$1.50 per test kit.⁴ Pan American Health Organisation's (PAHO) Strategic Fund is offering the same rapid dual test kits for US\$1.50 per test.

In the selection of diagnostic tests, country programmes face trade-offs between accuracy, affordability and accessibility. Rapid dual HIV/syphilis tests are accessible to the lowest levels of the healthcare system. In this case, however, only one dual HIV/syphilis rapid test kit has been prequalified by WHO,⁵ although others are in various stages of this process.⁶

Contributors All the authors equally contributed to the development, review and editing of the manuscript.

Publisher's Disclaimer: Disclaimer The views expressed in this commentary are those of the authors and do not reflect the position of the WHO or the US Centers for Disease Control and Prevention.

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.

As this is the only rapid dual HIV-syphilis test prequalified by WHO, countries are not in a position to ask for competitive pricing. So what other factors should be considered by Ministries of Health?

Cost-effectiveness in terms of cost per woman screened and per adverse pregnancy outcome averted would be an important consideration. In addition, efficiencies for the healthcare systems gained by combining two tests in a single cartridge for a single visit in terms of staff time and patient convenience. Practical considerations of using a rapid dual HIV/syphilis test over two single tests include: streamlined purchasing, storage, transport, waste management and savings incurred from halving the cost of supplies.⁷

Obure and colleagues recognised that costs per woman tested were higher in Bogota as compared with Cali and noted that in Bogota where HIV and syphilis incidence were lower, dedicated staff were not allocated to solely providing HIV and syphilis testing services. This comment implies that staff in Bogota may be less familiar with delivering HIV and syphilis testing possibly increasing time in delivery and interpretation of the newly introduced rapid dual test. We also highlight inclusion of staff costs and the finding of higher average time for delivery and interpretation of the rapid dual HIV/syphilis test (29 min) versus the two single tests (25 min). We note that delivery of two separate tests increases complexity in specimen collection and results interpretation and would intuitively require more time.

We recognise the higher costs associated with the use of the rapid dual test in this study but noted the authors' acknowledgement that cost-effectiveness was not evaluated. Prenatal syphilis screening is one of the most cost-effective health interventions, and integrating syphilis screening alongside HIV screening improves this more.⁸

Recent analyses have demonstrated the cost-effectiveness of HIV and syphilis screening using dual rapid diagnostics over single HIV and syphilis tests or HIV testing alone. Of the antenatal testing algorithms in the analysis by Bristow *et al*, a dual rapid diagnostic test was estimated to result in the lowest number of adverse pregnancy outcomes and had the lowest overall costs.⁹

A systematic review has shown that the field performance of rapid dual HIV/syphilis tests are comparative to reference testing performed in the lab.¹⁰ The added utility and feasibility of a single platform for testing of multiple infections makes these tests attractive for use among populations recommended for routine screening for both infections, particularly pregnant women. The WHO recognises dual HIV/syphilis (multiplex) point of care diagnostics as an option for HIV testing¹¹ and has released interim guidance on use and interpretation of these tests pending a WHO-approved algorithm.⁷

In 2007, WHO released the strategy for elimination of congenital syphilis,¹² which stated as a primary pillar the need for advocacy to improve coverage of syphilis testing in pregnancy. This was followed in 2014 by the WHO global guidance on the processes for country validation of EMTCT of both HIV and syphilis. This guidance sets as process criteria for country validation of EMTCT; 95% coverage of antenatal care, 95% testing coverage of pregnant women for HIV and syphilis and 95% treatment coverage for those pregnant women testing positive for HIV or syphilis.¹³ In 2016, WHO released the Global STI

Strategy which calls for a reduction of congenital syphilis rate to <50 cases per 100 000 live births in all countries by 2030.¹⁴ The delivery of HIV and syphilis testing using a single testing platform offers countries an option to improve both syphilis and HIV testing coverage in antenatal care in pursuit of EMTCT of both infections. The combined platform offers the potential to leverage HIV testing resources to purchase rapid dual test kits.

Obure *et al*, recently published a comparative effectiveness evaluation¹⁵ of rapid dual tests versus single tests among the same sample of women and antenatal care service centres in Columbia. They found no differences in patient acceptability, testing and timely treatment.

A lower negotiated test kit cost in this study by Obure *et al* would have reduced overall costs and may have led to different conclusions. Test kit cost is a key factor in the uptake of rapid diagnostic tests. Volume purchasing and leveraging HIV funds are options that should be considered by countries to cover this upfront cost of rapid dual HIV/syphilis tests and maintain capacity to continue integrated testing in antenatal care settings.

The anticipated improvements in syphilis screening coverage when aligned with HIV through this novel test technology offer the opportunity to expand syphilis screening in pregnancy, as well as key populations, and avert adverse birth outcomes such as stillbirth and neonatal death which occur commonly to pregnant women with untreated syphilis. This effect would be greatest in regions where maternal syphilis morbidity is high and syphilis screening in pregnancy and in key populations is low such as sub-Saharan Africa and some countries in South America and the Western Pacific. Though cost-effectiveness studies evaluating the rapid dual HIV/syphilis test alongside other testing strategies are limited, those that are available show benefit in use of rapid dual test kits.⁸ Additional cost-effectiveness studies may provide more detail regarding the effect of improving syphilis screening among pregnant women and key populations to reduce adverse birth outcomes due to congenital syphilis.

To date, five countries in the PAHO region have been validated by WHO for EMTCT of HIV and syphilis. Columbia and other PAHO countries continue to advance knowledge of effective EMTCT strategies through evaluation of testing technologies such as rapid dual HIV/syphilis testing in antenatal settings and achievement of validation targets.³¹⁵ We encourage other countries to support the use of rapid dual HIV/syphilis test kits and to evaluate cost effectiveness in antenatal care settings and among key populations.

REFERENCES

1. Peeling RW, Mabey D. Celebrating the decline in syphilis in pregnancy: a sobering reminder of what's left to do. *Lancet Glob Health* 2016;4:e503–4. [PubMed: 27443768]
2. Peeling RW, Mabey D, Fitzgerald DW, et al. Avoiding HIV and dying of syphilis. *Lancet* 2004;364:1561–3. [PubMed: 15519615]
3. Obure CD, Gaitan-Duarte H, Saenz RL, et al. A comparative analysis of costs of single and dual rapid HIV and syphilis diagnostics: results from a randomized controlled trial in Columbia. *Sex Transm Infect* 2017;10:1136.
4. Dual HIV/Syphilis Rapid Diagnostic Tests. Diagnostic brief series. The International Diagnostics Centre (IDC). London School of Hygiene and Tropical Medicine, 2014:10.

5. World Health Organization. WHO prequalification of in vitro diagnostics programmes public report. Product: SD Bioline HIV/Syphilis Duo. Number PQDx 2015;00:0179–012.
6. World Health Organization. HIV/syphilis rapid tests: progress of the active applications in the prequalification of IVDs assessment pipeline. http://www.who.int/diagnostics_laboratory/140714_syphilis.pdf (accessed 16 Jun 2017).
7. World Health Organization. Information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT). <http://www.who.int/reproductivehealth/publications/rtis/dual-hiv-syphilis-diagnostic-tests/en/>
8. Owusu-Eduesei K, Tao G, Gift TL, et al. Cost-effectiveness of integrated routine offering of prenatal HIV and syphilis screening in China. *Sex Transm Dis* 2014;41:103–10. [PubMed: 24413489]
9. Bristow CC, Larson E, Anderson LJ, et al. Cost-effectiveness of HIV and syphilis antenatal screening: a modeling study. *Sex Transm Infect* 2016;0:1–7.
10. Taylor MM, Gliddon H, Peeling RW, et al. A systematic review and meta-analysis of studies evaluating the performance and operational characteristics of dual point-of-care tests for HIV and syphilis. *Sex Transm Infect*. In Press 2017.
11. World Health Organization. Consolidated guidelines on HIV testing services. 2015 <http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/>
12. World Health Organization. The global elimination of congenital syphilis: rationale and strategy for action, 2007.
13. World Health Organization. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis. Geneva: WHO, 2014.
14. World Health Organization. The global health sector strategy on sexually transmitted infections, 2021, 2016 <http://apps.who.int/iris/bitstream/10665/246296/1/WHO-RHR-16.09-eng.pdf>
15. Pan American Health Organization. Update: elimination of mother to child transmission of HIV and congenital syphilis in the Americas. Washington, DC: PAHO 2016.