Added-value of a Novel Dual Treponemal/Non-Treponemal Rapid Diagnostic Test for Syphilis among Pregnant Women

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Background
- In resource-limited settings, syphilis rapid diagnostic tests (RDTs) aid in the prevention of congenital syphilis. However, most syphilis RDTs detect only treponemal antibodies which persist after treatment. Consequently, treatment may be provided unnecessarily to pregnant women with past infection, their neonate(s) and their partner.
- A new immunochromatographic rapid point-of-care test, Dual Path Platform Syphilis Screen and Confirm assay (DPP test, CHEMBIO Diagnostic System, Inc, USA) combines simultaneous detection of treponemal (T) and non-treponemal (NT) antibodies.

Objectives
- **Main objective**: to estimate the potential reduction of over-treatment of pregnant women using DPP test compared to T-RDT (SD Bioline Syphilis Test).
- **Secondary objectives**:
  - to estimate the proportion of treatment misclassification (over-treatment or under-treatment) comparing different algorithms to the reference tests;
  - to estimate the prevalence of presumptive active syphilis;
  - to estimate inter-user agreement between medical staff and laboratory technician.

Methods
- **Study design**: Prospective study
- **Study area**: Maternity of Deou, Oudalan, Burkina Faso
- **Inclusion criteria**:
  - Pregnant woman
  - Attending antenatal consultations in study site
  - Eligible for routine syphilis screening according to routine practices in the maternity
  - Consent to participate to the study
- **Interventions**:
  - DPP test 1st user
  - Finger prick blood collection
  - Consultation room Midwives
  - DPP test 2nd user
  - Venous blood collection
  - Whole blood
  - DPP test 3rd reading
  - Plasma extraction
  - Plasma storage for shipment to ITM reference lab
  - SD Bioline Syphilis test
  - T-RDT

Results
- **Main objective**
  - 242 pregnant women were included from May to August 2014.
    - Median age = 25y
    - No history of syphilis or current clinical symptoms of syphilis
- **Prevalence of presumptive active syphilis** = 37.6% (half with RPR titre ≥ 1:8)
- **DPP inter-user agreement**
  - T-line = 0.95; NT-line = 0.75
- **4%** of women who were **not to be treated** would have been using T-RDT only against 0.0% using DPP (p=0.02).
- 48.4% of women who **had to be treated** would have not been using DPP against 2.2% using T-RDT (p<0.001) (Figure 2).
- The **sensitivity** of DPP test was almost 52% but increased up to 85% for RPR titre ≥ 1:8 (Table 1).

Discussion
- DPP test showed no added value in reducing the proportion of unnecessarily treated women. Conversely, DPP underestimated women needing treatment.
- We found a high prevalence of presumptive active syphilis. However, this could suggest that non-venereal treponematoses are endemic in the study area as previously shown in the 90’s.
- The overall sensitivity of the DPP test lower compared to other studies performed in behavioral high risk groups or symptomatic patients.

Conclusion
This study was the first evaluation of DPP test in pregnant women. Additional studies are required to evaluate the potential benefits of the DPP tests for preventing congenital syphilis in resource-limited settings.

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