# Performance Evaluation of the Xpert Hepatitis B Molecular Test Among Pregnant Women in Uganda

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## BACKGROUND

- Hepatitis B virus (HBV) infection is a major public health burden worldwide, with over 254 million people estimated to be living with chronic HBV infection globally
- In sub-Saharan Africa, HBV is highly endemic, and Uganda has a high burden of chronic HBV infection, with a prevalence of 4.3%.
- The World Health Organization (WHO) recommends a comprehensive approach to prevent vertical transmission of HBV from mother to child, including screening (for HBV surface antigen (HBsAg) and testing (for HBV and providing prophylaxis antiviral treatment to those who are eligible.

## METHODS

- A pilot implementation study was designed in two phases:

### PICO question:

- Is the Xpert® HBV PoC test as accurate and equally easy to use for diagnosing Hepatitis B in pregnant women in Uganda?

### Intervention Characteristics

- **Phase I:** Lab-based-compared Xpert® and COBAS TaqMan using known archived HBV DNA samples not older than 6 weeks
- **Phase 2:** Field-based- assessed operational feasibility, care linkage

### Participant characteristics

- **Phase 2** Involved Pregnant women at ≥24 gestational age
- Only those who provided informed consent
- Conducted in **10 high-volume hospitals** in Uganda
- Data collection was undertaken by trained midwives and laboratory personnel
- Pregnant women screened for HBV at ANC alongside HIV and syphilis screening as part of routine care.
- HBsAg+ Pregnant women's blood samples were sent for Point of Care gene Xpert® testing.
- Pregnant women with VL>200,000 IU/ML were linked to TDF prophylaxis & follow up

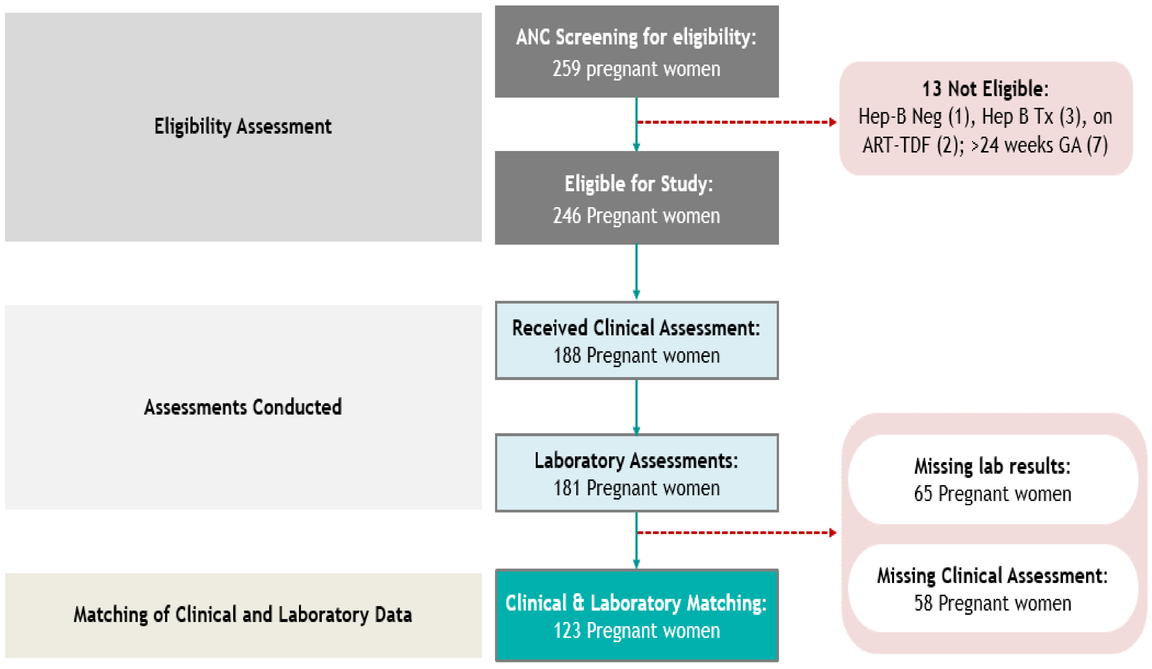
## Results

**Phase I: Lab-based-compared Xpert® and COBAS TaqMan**

**Accuracy: Perfect agreement with COBAS TaqMan reference test**
**Sensitivity:** 100% (95% CI: 90%-100%)
**Specificity:** 100% (95% CI: 78.2%-100%)
**Correlation:** Strong correlation (R=0.99) Xpert® vs Cobas Taqman

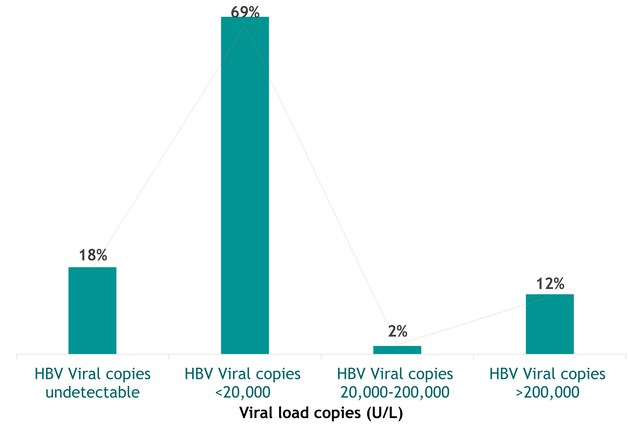
**Phase 2: Field-based- assessed operational feasibility, care linkage**

**Improved Lab Turnaround Time (TAT):** 96.7% of samples were dispatched to the lab, and 99% of results were processed on the same day.
**Improved TAT for results receipt by the care provider:** 77% of care providers received results immediately after dispatch from the lab.
**Improved TAT for results receipt by the mothers:** 61% of mothers received results the same day while 27% waited 1–2 days
The pilot proved that HBV DNA same-day results are achievable and have the potential to break the barriers faced with the centralized testing approach.




## ADDITIONAL KEY INFORMATION

- 87% of patients had low or undetectable HBV viral loads, 18% had undetectable viral copies, 69% had viral copies <20,000 U/L, considered low risk, 2% had viral copies between 20,000-200,000 U/L, 12% had viral copies >200,000 U/L, indicating a high risk of mother-to-child transmission




## CONCLUSIONS

Xpert® HBV PoC enhances linkage to care and is highly recommended for a national scale-up;

- Positive attitudes among ANC teams enabled the successful integration of services, linking HBV-positive women to care
- Integration of hepatitis clinics within maternal care points facilitated comprehensive care for Pw
- Targeted retesting of pregnant women at 24 weeks, beyond initial ANC1 screening, identified previously missed cases.
- Community outreach initiatives successfully integrated HBV and syphilis testing, ensuring all mothers were reached and linked to care.

***ACKNOWLEDGEMENTS***: *Funding for this presentation was through CROI and Global Fund. The study was funded by Cepheid*
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