Expanding Viral Load through Partnerships: Performance Evaluation of Cepheid GeneXpert HIV-1 Viral Load Assay in Botswana

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Adults aged 15 to 49 prevalence - 22.2%

The Botswana National ARV guidelines defines virologic failure as a viral load >400 cp/mL

34 GeneXpert platforms currently in use for TB
To evaluate the performance and quality of Cepheid’s Xpert HIV-1 Viral Load plasma assay compared to a current gold standard test used in Botswana (Roche CAP/CTM HIV-1 V2.0) using clinical specimens from 4 clinical sites

- Agreement/concordance with reference standard
- Misclassification rate
- Sensitivity and specificity of the assay compared to the reference standard above and below the WHO cutoff and Botswana National guidelines for virological failure
- Bias and the Standard Deviation of the mean difference between the Xpert VL test result and the reference standard will also be calculated
Xpert Viral Load: Methods

- **Study population:** HIV positive adults initiating ART or returning for 3, 6, or 12 month VL visit or re-initiating ART after a default.

- **During blood draw for baseline labs for ART initiation or follow-up labs on ART > 3 months, draw 1 extra 10ml tube**
  - Centrifugation and processing at Xpert testing site.

- **Conduct VL testing using:**
  - Xpert HIV-1 VL assay
    - Area W Clinic Laboratory (Francistown)
    - National TB Reference Laboratory (Gaborone)
  - Roche (Reference Standard)
    - Botswana-Harvard National HIV Reference Laboratory (Gaborone)
    - Nyangabgwe Hospital HIV Reference Laboratory (Francistown)

*Note: results returned for all Roche tests*
Correlation of the Xpert and Roche Plasma VL
n=746

\[ y = 0.9216x + 0.2888 \]

\[ R^2 = 0.8861 \]
Sensitivity and Specificity at 400 and 1000 cps/mL

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<tr>
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<th>400 cps/mL</th>
<th>1000 cps/mL</th>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>97.80%</td>
<td>98.50%</td>
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<tr>
<td>Specificity</td>
<td>97.00%</td>
<td>98.12%</td>
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<tr>
<td>False Failures (upward)</td>
<td>3.00%</td>
<td>1.88%</td>
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<tr>
<td>False Treatment Successful (downward)</td>
<td>2.20%</td>
<td>1.50%</td>
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Cepheid Xpert VL Errors

- Xpert instrument error rate 1.2% (9/746)
  - 2037 (n=2)-Cartridge integrity test failed
  - 2123, 2124-Loss of connectivity/reconnection error
  - 2097 (n=3)-Incorrect specimen volume
  - 2008-Syringe pressure error
  - 2096-No specimen added
Conclusions

- Data here suggest Xpert is suitable for VL testing but as with any POC instrumentation appropriate placement is important

1. In-country discussions to determine effective use
2. Which settings are most fitting given the population
3. Quality assurance procedures are in place with documentation and corrective action taken when needed

- Ongoing study, as we continue to gather data on the use of Xpert we will update and disseminate our findings
Who Are Our Partners?

- **Study is a true partnership**
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  - University of Botswana
  - CDC Botswana, TB/HIV Research Unit
  - ASLM Laboratory Fellows
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