Poster # 993

Accuracy of HIV and CD4 Field Testing in the Botswana Combination Prevention Project

Bile, Ebi[1], Bachanas, PJ[2], Maurice F[1], Modise, S[3], Chebani L[3], Makovore V[1], Fonjungo P[2], Alwano M G[1], Bapati W[4], Jarvis JN[1]

[1]Centers for Disease Control and Prevention, Gaborone, Botswana; [2]Centers for Disease Control and Prevention, Division of Global HIV/AIDS and TB; [3]Ministry of Health, Gaborone, Botswana; [4]Tebelopele Counseling and Testing Center, Gaborone, Botswana

BACKGROUND

- HIV point-of-care (PoC) testing and diagnostics are now widely available and increase access to testing in resource limited settings.
- Quality assurance activities are an integral part of PoC testing to ensure clients receive accurate results.
- During the Botswana Combination Prevention Project (BCPP), robust quality assurance (QA) measures have been implemented to ensure lay counselors deliver accurate test results in the field.
- This study reports the results of the quality assurance measures and concurrence of reference lab testing of samples from the field.

METHODS

- BCPP is a randomized controlled trial designed to evaluate the impact of a combination prevention package on population level HIV incidence in 15 intervention and 15 control communities.
- The trial is ongoing; we describe preliminary data from the first round of testing campaigns in the 15 intervention communities.
- Interviews and HIV testing were offered to residents ≥16 years through home-based and mobile testing from October 2013 through February 2016.
- Lay counselors (130) were trained to conduct PoC HIV testing using Determine and First Response assays and conducted PoC CD4 tests on HIV-positive individuals not on ART using PIMAs.
- Robust QA measures were implemented including, annual refresher training, weekly internal Quality Control (QC) panel testing, and proficiency testing (PT) 3 times/year.
- In the first community, 100% of field HIV test samples were retested in the reference laboratory using EIA HIV testing. In subsequent communities, a random sample of 5-10% of all samples were retested.
- Laboratory based PIMA CD4 counts were repeated on samples from 155 field PIMA CD4 counts.
- Monthly supervision and monitoring visits were conducted.

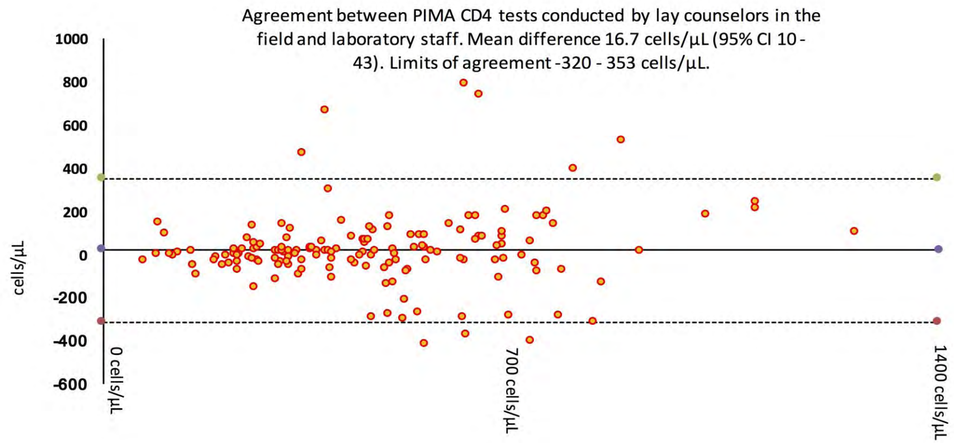
RESULTS

HIV Tests

- At baseline, lay counselors averaged 78% on proficiency testing results; however, they scored an average of 96% and 97% in the final two rounds. These results indicate that the counselors improved significantly over time with experience.
- Weekly Quality Control panels conducted on 1000 positive and 975 negative HIV tests in the field using Determine and First Response assays produced 100% accurate results.
- Repeat EIA testing of 3,002 Dried Blood Spot samples demonstrated a **99.6% agreement** between field and laboratory HIV-test results, with a kappa score of 0.99, $p < 0.0001$.
- Of the 12 discordant results, 4 were false negative and 8 were false positive in field-testing.

PIMA Tests

- The overall pass rate for PIMA CD4 Proficiency Testing was 89% (81%, 93%, 95%, and 88% rounds 1-4).
- Levels of agreement between field and lab PIMA CD4 results are shown in the figure, with a mean difference of 16.7 cells/μL (95% CI -10 – 43). At the CD4 threshold of 350 there was 86% agreement (21 of 155 misclassified).



CONCLUSIONS

- These results demonstrate that with proper training, refresher training and monitoring, lay counselors can perform extremely well conducting point-of care HIV tests.
- Lay counselors' strong performance in difficult and challenging settings in the field such as home-based and mobile testing suggests that they can contribute significantly to increasing access to testing in community settings and reaching the first 90 target of UNAIDS 90-90-90 targets.
- The extremely high concordance rate between the field and lab samples gives confidence in the results of the BCPP HIV tests and that clients received correct test results.
- Concordance between PIMA CD4 field results and lab results were within expected ranges.
- Although point-of-care CD4s at testing are no longer needed for eligibility in settings that are implementing "Treat All", these findings suggest that lay counselors can be trained to assist with additional diagnostics to relieve burdens in clinics.
- Overall, these results reinforce the need for a strong QA program to ensure well-trained staff who can conduct HIV tests correctly and deliver correct results to clients.

ACKNOWLEDGEMENTS

Centers for Disease Control – Atlanta
Botswana Ministry of Health
Tebelopele Counseling and Testing Center
Harvard Chan School of Public Health
Botswana-Harvard Partnership
Botswana Participants

www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Center for Global Health
Division of Global HIV/AIDS and TB