ABSTRACT

Background: Point of care (POC) CD4 cell count can reduce time to eligibility assessment for antiretroviral therapy and improve linkage to care. In a village household setting in Botswana, we evaluated the performance of POC CD4 using EDTA capillary sampling into microtube versus conventional laboratory-based flow cytometry.

Methods: Capillary blood was collected by finger-prick into EDTA microtubes. Venous blood was collected by venipuncture. Both blood collection procedures were performed in households during annual surveys in the village of Mochudi, Botswana. The Alere Pima® system was used for POC CD4 testing while laboratory testing was performed using BD FacsCalibur. The Bland-Altman method was used to estimate the mean bias and 95% confidence limits of agreement (LOA). Sensitivity and specificity were calculated for a threshold of 500 cells/μl CD4 cell count.

Results: A total of 155 adults were enrolled with CD4 results for both field POC and lab-based testing. The median age was 32 years old and 63% were females. The median CD4 was 827 (IQR 668, 1058) cells/μl. Using a threshold of 500 cells/μl, POCD4 was tested in the household using capillary blood collected into BD EDTA microtubes (500 microlitres). Flow Cytometry CD4 testing was performed using BD FACScalibur. The Bland-Altman method was used to estimate the mean bias and 95% confidence limits of agreement (LOA). Sensitivity and specificity were calculated for a threshold of 500 cells/μl CD4 cell count.

Conclusion: The Alere Pima® POC CD4 testing with EDTA capillary sampling into microtube had one of the lowest non-significant mean bias relative to FACScalibur CD4 testing, compared previous findings using finger prick sampling alone. There were low measurements below CD4 threshold of 350 cells/μl, and sensitivity was low at threshold of 500 cells/μl, but with good specificity. Coupling HIV testing with POC CD4 in a household setting has potential to close gaps in linkage to HIV care in communities.

METHODS

• We evaluated the performance of POC CD4 using EDTA capillary sampling into microtube versus conventional laboratory-based flow cytometry, while coupling with HIV testing in household settings in Mochudi, Botswana.

• We evaluated in a subset a comparison of Finger Prick POC CD4 and Flow cytometry.

RESULTS

• The median age was 32 years and 63% were females. The median CD4 was 827 (IQR 668, 1058) cells/μl. We observed a mean bias between CD4 measurements by Alere PIMA POC and BD FacsCalibur of -14.1 cells/μl ([95% CI -39.5 to -11.3], paired t-test p = 0.2740) (Figure 1).

• Using a threshold of 500 CD4 cells/μl, POC CD4 testing using EDTA capillary sampling into microtube had a sensitivity of 73.3 (95% CI 44.9 – 92.3) cells/μl and specificity of 93.6 (88.1 – 97.0) cells/μl.

• In a subset (n=71), we observed inconsistent performance of Finger Prick sampling versus flow cytometry (Figure 2) with a mean bias of -141 cells/μl (95% CI -228.2 to -53.8).

• The use capillary blood sampling into EDTA microtube shows consistent performance across and is less likely to misclassify especially with higher 500 cells/μl CD4 enrollment threshold.

CONCLUSIONS

• Point of care (POC) CD4 cell count can reduce time to eligibility assessment for antiretroviral therapy and improve linkage to care in a village household setting in Botswana, we evaluated the performance of POC CD4 using EDTA capillary sampling into microtube versus conventional laboratory-based flow cytometry.

• The Alere Pima® POC CD4 testing with EDTA capillary sampling into microtube had one of the lowest non-significant mean bias relative to FACScalibur CD4 testing, compared to previous findings using finger prick sampling alone. There were few measurements below CD4 threshold of 350 cells/μl, and sensitivity was low at threshold of 500 cells/μl, but with good specificity. Coupling HIV testing with POC CD4 in a household setting has potential to close gaps in linkage to HIV care in communities. Careful considerations including training are essential for improving the filed applications of the Finger prick based POC CD4 testing.

REFERENCES