High frequency of invalid CD4 test results using the Alere Pima CD4 POC analyzer in MSF field projects in nine countries

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Introduction

CD4 testing is required to identify HIV-positive people eligible for antiretroviral therapy (ART). Point-of-care (POC) CD4 testing enables persons who test HIV-positive to be assessed for antiretroviral therapy (ART) eligibility the same day, thus minimizing pre-ART loss to follow-up. Since 2011, Médecins Sans Frontières (MSF) has introduced POC CD4 testing using Pima POC CD4 analyzers (Alere) in MSF-supported HIV projects in 9 countries in order to decentralize CD4 testing. Several projects reported a high frequency of invalid results using the Alere Pima POC CD4 analyzer prompting us to assess the extent of the problem and to try to identify causes associated with invalid results.

Methods

MSF projects using the Alere Pima CD4 assay were contacted and asked to submit Pima CD4 testing records, and to complete a questionnaire on the use of Pima CD4 analyzers in the project. Simple descriptive statistics were used to describe the dataset. In addition, adjusted risk ratios (aRR) were calculated using binary regression analyses to identify factors associated with errors. Pima analyzers that had been used to perform <50 tests, tests performed by unidentified users or users who had performed <20 tests were excluded from the analysis. Information on cartridge lot numbers was not available.

Results

35,749 tests done from January 2011 to June 2013 were included in the analysis. These tests were performed by 155 users, on 54 analyzers, across 33 sites. The average invalid rate by country was 13.2% (Fig A). Each user performed a median of 103 tests, with a median user invalid rate of 12.2% (IQR: 7.1 – 19.5%). The error rate did not differ by type of user (Fig B), number of users per instrument (Fig C), or type of setting (Fig D). The error rate was 12% when capillary blood was used and 14% when EDTA whole blood (Fig E). Each analyzer was used for a median of 515 tests, with a median device invalid rate of 13.0% (IQR: 10.5 – 16.6%). The source of errors were attributed to operator/instrument (51.0%), operator (26.0%), sample (10.0%), instrument (4.0%), or other unknown factors (9.0%) (Fig F). The type of error is depicted in Fig G. Errors were significantly less common with finger prick blood than with venous blood (aRR: 0.52; 95% CI: 0.45 – 0.60) and differed significantly by country, but did not differ significantly by user’s experience (aRR: 1.15; 94% CI: 1.05 – 1.25 for <50 versus ≥50 tests), or show a time trend (Table 1).

Conclusion & Recommendations

Causes of Pima CD4 errors appear to be multi-factorial and pinpointing the exact cause remains difficult to elucidate. In view of the unacceptably high error rate across multiple different sites, analyzers and users, regardless of the user’s experience, there is an urgent need for simpler, more reliable POC CD4 tests.