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IMPACT OF SMS ALERTS ON ENROLMENT IN ENHANCED ADHERENCE COUNSELLING AMONG PATIENTS WITH AN HIV VIRAL LOAD ≥1,000 COPIES/ML IN TWO RURAL DISTRICTS IN ZIMBABWE

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Background:
Among HIV-positive patients on antiretroviral therapy (ART), routine HIV viral load (VL) monitoring helps to detect adherence problems. The World Health Organization (WHO) recommends that patients with a VL ≥1,000 copies/ml have enhanced adherence counselling (EAC) to prevent treatment failure. We assessed the effect of short messaging system (SMS) alerts sent from the central VL laboratory in Harare to patients with a VL ≥1,000 copies/ml in two rural districts in Zimbabwe.

Methods:
In June 2014, the laboratory began sending SMS alerts to patients to inform them that their VL results were available. The SMS advised patients with a VL ≥1,000 copies/ml to return to the clinic as soon as possible, and those with a VL <1,000 copies/ml to collect their result during their next clinic visit. Using data from clinical and laboratory records, we compared EAC uptake among patients with a VL ≥1,000 copies/ml whose results were reported from October to December 2013 (before SMS; n = 867); or from August to October 2015 (after SMS; n = 500).

Results:
The proportion of patients who were documented as having at least one EAC session was 20.4% before SMS, and 14.4% after SMS. Of those who had EAC and had the date of the first EAC session recorded, the median time from the laboratory reporting VL results and patients starting EAC was 41 days (interquartile range [IQR]: 27 to 64 days) before, and 30 days (IQR: 15 to 51 days) after, introducing SMS alerts. After introducing SMS alerts, the median time to starting EAC was 13 days (IQR: 10 to 25 days) among patients who responded to the alert, 32 days (IQR: 23 to 39 days) among those contacted by clinic staff, and 48 days (IQR: 20 to 77 days) among those who returned to the clinic at their next scheduled visit.

Conclusions:
Sending SMS alerts to patients with a VL ≥1,000 copies/ml can substantially reduce the time to starting EAC. The proportion of patients starting EAC is likely to be greater than that reported because staff frequently do not complete the EAC register. Sending SMS alerts to patients with abnormal laboratory results is a simple and efficient way to improve responsiveness to the results, particularly in rural settings remote from the laboratory, and where patients live far from health facilities.

FIELD EVALUATION OF POINT OF CARE CEPHEID GENEXPERT HIV QUAL FOR EARLY INFANT DIAGNOSIS

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Background:
Loss to follow-up and delayed result turn-around times has been indicated to be the main barrier to linkage to care and treatment among HIV infected children. Diagnosis of HIV infection among children is often conducted using advanced polymerase chain reaction (PCR) procedures which are only centralized to specific regions in Kenya. There are point of care (POC) early infant diagnosis (EID) technologies in the pipeline but none has been evaluated in Kenya despite the urgent need of data that can be used in policy making. The POC GeneXpert for EID offers a positive direction towards ensuring that the high morbidity and mortality rates are minimized through decentralization of testing, at the same time ensuring that same-day results are given back to patients thus facilitating prompt linkage of HIV-infected children to treatment.

Objective: We evaluated the GeneXpert HIV Qual EID POC in Homabay County against the standard of care platform using dried blood spots (DBS).

Methods: Performance of the GeneXpert HIV Qual POC was evaluated against the Roche CAP/CTM HIV-1 qualitative PCR for EID using DBS samples collected from HIV-exposed children <18 months of age. The samples were tested by both the field and conventional laboratory technicians on the two platforms.

Results: A total of 1511 mother/baby pairs were included in the study. Out of the 917 GeneXpert HIV Qual tests performed on children, 34 (3.7%) were concordantly positive using both platforms. GeneXpert yielded a sensitivity of 100% and specificity of 100% with an overall error rate of 2.1%.

Conclusion, recommendations and implications : Our findings show that the POC GeneXpert performs well when compared with the conventional CAP/CTM using DBS, therefore indicating promising results of a technology that can be adopted in the laboratory as a near POC and used in the quick diagnosis and linkage to care of children who are found to be HIV-exposed, at the same time supplementing the progress of EID in the region.

DIAGNOSTIC ACCURACY VALIDATION OF ABBOTT M2000 FOR HIV VIRAL LOAD TESTING ON DBS SAMPLES (VERSION1.0); MALAWI PILOT STUDY

Keywords: HIV-1 Viral load, Dried blood spot, low-resource settings

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Background:
The strict requirements for storage and transport of plasma samples from clinics to laboratories for HIV viral load (VL) testing, limits access to HIV VL monitoring among patients on antiretroviral therapy (ART) in resource-limited settings. Dried blood spots (DBS) provide an alternative to plasma because there are no cold chain requirements and DBS can be stored at room temperature for up to three months. The Malawi Ministry of Health has adopted the Abbott m2000 system (Abbott) as the national standard for VL testing. As part of the switch from bioMérieux NucliSENS EasyQ/Easy Mag (NucliSENS) to Abbott, we did a study in Thyolo District Laboratory in Malawi to assess the diagnostic accuracy of the Abbott m2000 system for HIV VL testing on BDS samples.

Methods:
EDTA venous blood was collected from 412 patients on ART in August and September 2015, and processed into DBS and plasma samples. Plasma samples were tested on NucliSENS, and DBS samples were tested on Abbott and NucliSENS. The diagnostic accuracy of DBS VL at a threshold of 1,000 cells/ml was assessed using the plasma VL result as the reference.

Results:
Of the 412 study participants, 257 (62.4%) were females. DBS VL measured on Abbott had a sensitivity of 88.2% (95% CI: 72.5 – 96.7%) and specificity of 91.1% (95% CI: 87.8 – 93.7%) compared to plasma NucliSENS. DBS VL measured on NucliSENS had a sensitivity of 91.4% (95% CI: 76.9-98.2%) and specificity of 92.0% (95% CI: 88.8 – 94.6%) compared to plasma NucliSENS. Assuming a prevalence of VL >=1,000 copies/ml of 10%, DBS had a positive predictive value (PPV) of 52.4% and negative predictive value (NPV) of 98.6% on Abbott, and a PPV of 55.9% and NPV of 99.0% on NucliSENS.

Conclusion:
DBS had satisfactory diagnostic accuracy, making DBS samples suitable for VL testing on Abbott.

DIAGNOSTIC ACCURACY OF BD FACSPRESTO FOR MEASURING CD4 ON WHOLE BLOOD SAMPLES STORED FOR UP TO 14 DAYS IN BD STABILIZATION TUBES AT ROOM TEMPERATURE IN A RURAL LABORATORY IN ZIMBABWE

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Background:
Among HIV-positive people, CD4 testing is used to assess eligibility for antiretroviral therapy, and to identify late-presenters (CD4 ≤100 cells/µl) who have a high risk of opportunistic infections. In rural settings, access to CD4 testing may be limited. Access can be increased by using point-of-care (POC) tests, and sample collection and storage methods that do not require a cold chain. We did a study at a rural hospital in Zimbabwe, to assess the diagnostic accuracy of BD FACSPresto, a POC CD4 test, and the stability of samples stored in BD CD4 Stabilization Tubes (ST).

Methods:
From February to June 2016, 93 HIV-positive patients provided venous blood, collected in ST. On arrival in the on-site hospital laboratory (Day 0), CD4 was measured using FACSPresto and FACSCount. Samples were stored in ST at room temperature (16oC to 34oC), and retested on Days 3, 5, and 7, using FACSPresto.

Results:
On Day 0, the median CD4 (in cells/µl) was 449 using FACSCount, and 504 using FACSPresto. At a cut-point of 100 cells/µl, the sensitivity of FACSPresto relative to FACSCount was 71.4%, and the specificity was 100%. Of the 52 samples retested at all time points, the median CD4 (in cells/µl) was 533 on Day 0, 457 on Day 3, 463 on Day 5, and 436 on Day 7. At a cut-point of 100 cells/µl, the sensitivity of FACSPresto relative to FACSPresto Day 0, was 100% on Days 3, 5, and 7, and the specificity was 98.6% on Day 3, 97.2% on Day 5, and 98.5% on Day 7.

Conclusion:
In rural resource-limited settings, access to CD4 testing can be increased by POC testing using FACSPresto, and by using ST to transport and store samples, if immediate POC testing is not possible. Among late presenters, this can minimize delays in starting potentially life-saving treatment.

DIAGNOSTIC ACCURACY OF EIGHT HIV RDTS AND TWO SIMPLE CONFIRMATORY ASSAYS FROM FIVE SUB-SAHARAN AFRICAN COUNTRIES

Keywords: HIV, RDT, diagnosis.

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Background:
WHO pre-qualified HIV rapid diagnostic tests (RDT) showed very good performance in initial evaluations on an international panel of specimens, however reports from several African countries highlight performance issues that seem to vary geographically. We aimed to evaluate the performance of eight HIV RDTs and two simple confirmatory assays individually using specimens from five sub-Saharan African countries.

Methods:
Specimens collected in six sites in five sub-Saharan African countries were tested at HIV reference laboratory at the Institute of Tropical Medicine, Antwerp, with state of the art reference tests and with eight RDT and two confirmatory assays. Weighted analysis was carried out to adjust for sampling strategies.

Results:
A total of 2785 samples collected from August 2011 to January 2015 in the 6 sites were tested at the ITM. All RDTs showed very high sensitivity, ranging from 98.9% for First Response HIV 1-2.0 to 100% for Determine HIV 1/2, SD Bioline HIV 1/2 3.0 and INSTI HIV antibody test. Specificity varied from 90.4% for First Response HIV 1-2.0 test to 99.7% for HIV 1/2 STAT-PAK. The specificity also varied greatly with the origin of specimens. The level of concordance between the users was high. For confirmatory assays, the total sensitivity and specificity was 100% and 98.2% for ImmunoComb II HIV 1&2 CombFirm (IC) and 99.9% and 97.5% for Geenius HIV 1/2. Indeterminate rates were 8.9 % for IC and 9.4% for Geenius HIV 1/2.

Conclusion:
Overall, the performances of individual RDTs were lower than in the WHO evaluations and only HIV 1/2 Stat-Pak would have passed the suggested thresholds of >99% sensitivity and >98% specificity. However, acceptable RDT-based algorithms could be found when combining them according to WHO-recommended algorithms. These results confirm the geographical differences in HIV RDT performance and highlight the importance of designing locally-adapted algorithms following the latest WHO recommendations, particularly in a context of increasing testing coverage with the test and treat strategy.

PERFORMANCE OF HIV DIAGNOSTIC ALGORITHMS AT SIX SITES IN FIVE SUB-SAHARAN AFRICAN COUNTRIES

Keywords: HIV, algorithm, performance.

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Background:
In resource-constrained settings, HIV testing algorithms are based on the use of rapid diagnostic screening tests, allowing high accuracy HIV diagnosis in decentralized testing sites by non-skilled personnel and same day results. Local design and evaluation of the testing algorithm performance is recommended, but rarely performed.

Methods:
We compared the on-site performance of the HIV testing algorithms at six sites in five sub-Saharan African countries. In each site, at least 220 positive and 220 negative clients by the on-site algorithm had a specimen sent to the HIV reference laboratory at Institute of Tropical Medicine, Belgium, for testing by a state of art testing algorithm for resource rich settings.

Results:
Between August 2011 and January 2015, more than 14 000 clients were tested for HIV at the six HIV counseling and testing sites and 2786 were included in the study. HIV positivity rate at the testing sites ranged from 8.0% in Baraka (DRC) to 63.7% in Conakry (Guinea). When adjusted to account for the under-representation of negative results by the study design, the sensitivity of the testing algorithms ranged from 89.5% in Arua (Uganda) to 100% in Douala (Cameroun) and Conakry (Guinea). The specificity of the algorithm used was lowest in Douala (98.3 %) and highest in Conakry (100 %). Overall, 24 (1 %) clients would have been misclassified, ranging from 0-8 per site (0-1.7%), with 16 false positive and 8 false negative results. Six false negative specimens were re-tested on-site with a back-up sample and were found positive. Thirteen false positive specimens were similarly re-tested and 9 remained positive.

Conclusion:
Several sites showed performance below the expectations, with unacceptably high false positive and negative results. Lot validation, respecting incubation time, correct labelling, testing on plasma versus whole blood can reduce the risk of false results. Beside all the quality issues, careful selection of HIV RDTs and algorithms should be conducted regularly in order to keep misclassification as low as possible. Strategies such as retesting at the start of antiretroviral therapy are needed to identify false positive individuals in existing HIV-positive cohorts.