INFORMATION NOTE

HIV DIAGNOSTICS

NOVEL POINT-OF-CARE TOOLS FOR

EARLY INFANT DIAGNOSIS OF HIV

JULY 2017

World Health Organization

While a decade of investment in conventional laboratory networks has expanded access to Early Infant Diagnosis (EID) testing, only 51% of HIV-exposed infants were tested before two months of age in 2015.[1]

The advent of point-of-care (POC) EID technologies[2] is a breakthrough that creates the opportunity to increase coverage of EID testing. It will allow same-day test results and enable the initiation of earlier treatment, as well as address some of the key limitations of conventional EID networks – in particular long turnaround times for tests and high rates of loss to follow up.

Significant progress has been made in ensuring the quality of new POC EID technologies.

POC EID regulatory approvals and technical evaluations*:

- **CE-IVD (Conformité Européene In Vitro Diagnostics)**: Four POC EID technologies have received CE-IVD: Alere™q HIV-1/2 Detect, Cepheid Xpert®HIV-1 Qual, and Diagnostics for the Real World's SAMBA I HIV-1 Qual Test and SAMBA II HIV-1 Qual Whole Blood Test.
- **WHO-PQ (WHO prequalification)**: Two POC EID technologies have met WHO requirements: Alere™q HIV 1/2 Detect[3] and Cepheid Xpert®HIV-1 Qual[4] received WHO prequalification on 13 June 2016.

Independent technical evaluations:

The POC EID Consortium is composed of a group of principal investigators across six countries conducting technical field evaluations of POC EID technologies to expedite the release of independent performance data to accelerate national approval processes and in-country implementation. Results from nine technical field evaluations were consolidated across the six countries. A total of 3,383 specimens were tested using the Alere™q HIV-1/2 Detect and 4,401 specimens were tested using the Cepheid Xpert®HIV-1 Qual.[5]

Assay	Evaluator	Sample Type	Sensitivity (95% CI)	Specificity (95% CI)
Alere™q HIV-1/2 Detect	WHO PQ CDC/NHLS	whole blood	98.67% (95.27-99.84)	100.00% (97.59-100.00)
	EID Consortium	whole blood	99.00% (96.45-99.88)	99.97% (99.83-100.00)
Cepheid Xpert® HIV-1 Qual	WHO PQ CDC/NHLS	whole blood	98.86% (93.83-99.97)	100.00% (97.55-100.00)
	EID Consortium	whole blood	96.79% (92.68-98.95)	99.91%(99.76-99.97)
	WHO PQ CDC/NHLS	dried blood spots	99.34% (96.40-100.00)	100.00%(97.60-100.00)

*These approvals are often considered by countries when procuring diagnostic technologies.

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WHO RECOMMENDATIONS

The *2016 WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* recommend nucleic acid testing (NAT) technologies that are developed and validated for use at or near to the point of care can be used for early infant HIV testing. POC EID provides the opportunity to reduce test turnaround times, limit patient loss along the HIV testing cascade, reduce infant mortality, and allow for task shifting to lower cadres of health workers at decentralized facilities.[6]

CURRENT USE

A number of countries are currently implementing POC EID technologies. Malawi, Mozambique, and South Africa for example, reported results from POC EID pilots in 2016 showing significantly shorter test turnaround times for results and increased patient initiation rates compared to conventional laboratory systems[7,8,9]. Considering the high and early mortality rate of untreated HIV infected infants[10,11], POC EID could also reduce observed infant mortality.

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SUMMARY OF RECOMMENDATIONS

CONCLUSIONS

Sufficient evidence has been generated on the performance of these assays in the intended field settings to support rapid national regulatory approval and initiation of scale-up. Performance was consistent between laboratory and field settings, and across countries. Further technical evaluations of these technologies are unlikely to add value, but may instead delay implementation and timely diagnoses of HIV-infected infants, a critical and vulnerable population.

National regulatory agencies are encouraged to not delay adoption by conducting further evaluations, but instead adopt a rapid and streamlined registration and national approval process for immediate implementation.

Based on the CE-IVD and WHO PQ approvals, robust results from independent technical field evaluations, procurement eligibility, the WHO recommendation for the use of POC EID, and initial patient impact results from implementation pilots, countries should begin planning the implementation of POC EID by incorporating POC EID into National HIV Care and Treatment Guidelines, National Strategic Plans, PEPFAR Country Operational Plans, Global Fund grant applications, and HIV Program budgets.

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