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Issue Brief

Point-of-Care Early Infant HIV Diagnosis

Quality Products to Deliver Quality Care: Monitoring the Performance of Point-of-Care Nucleic Acid Testing Manufacturers

In 2015, more than 1.2 million babies were born to mothers living with HIV in 21 high-prevalence countries. While the World Health Organization (WHO) recommends that all HIV-exposed infants receive a virologic test for HIV within two months of birth, only half had access to early infant HIV diagnostic (EID) screening in 2015. Almost 50% of infants who were tested never received the results.¹ For those who do receive the results, the turnaround time between sample collection and the return of results to the caregiver can take as long as 30 to 90 days in sub-Saharan African countries.^{2,3,4,5} Among those diagnosed as HIV-infected, only half were placed on treatment. Without treatment, up to 30% of HIV-infected children will die by their first birthday, with a peak mortality at 2 to 3 months of age.^{6,7,8}

While coverage of conventional, laboratory-based EID has increased in recent years throughout resource-limited countries, testing could be greatly expanded through the integration of new point-of-care (POC) testing technologies into national EID networks. POC technology ensures that infants are screened on-site, that their caregivers quickly receive their test results and that those who test HIV-positive are rapidly enrolled on lifesaving antiretroviral treatment (ART).

POC EID and Viral Load Procurement Consortium: Partners, Goals and Approach

Unitaid is investing over US\$200 million in projects that aim to increase access to affordable POC HIV diagnostics in resource-constrained settings. Implementers of Unitaid-funded projects include the Clinton Health Access Initiative (CHAI), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), United Nations Children's Fund (UNICEF), and Médecins Sans Frontières (MSF).

These partners have joined together with Unitaid, The Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. Agency for International Development (USAID), the U.S. Centers for Disease Control and Prevention (CDC), and others to form a global procurement consortium, the goal of which is to ensure uninterrupted provision of timely, high-quality EID and viral load test results in countries most in need. The consortium aims to catalyze demand for and uptake of POC technologies, and ensure sustainability of the market, by applying strategies such as: pooling test volumes across purchasers; sharing market intelligence; providing advanced procurement forecasts to manufacturers; agreeing on procurement principles and negotiation targets; jointly negotiating prices as well as service and maintenance terms; and coordinating the placement of orders. At least 15 early adopter countries provide the base for operational forecasts and early implementation. These include: Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Tanzania, Senegal, Swaziland, Uganda, Zambia, and Zimbabwe.

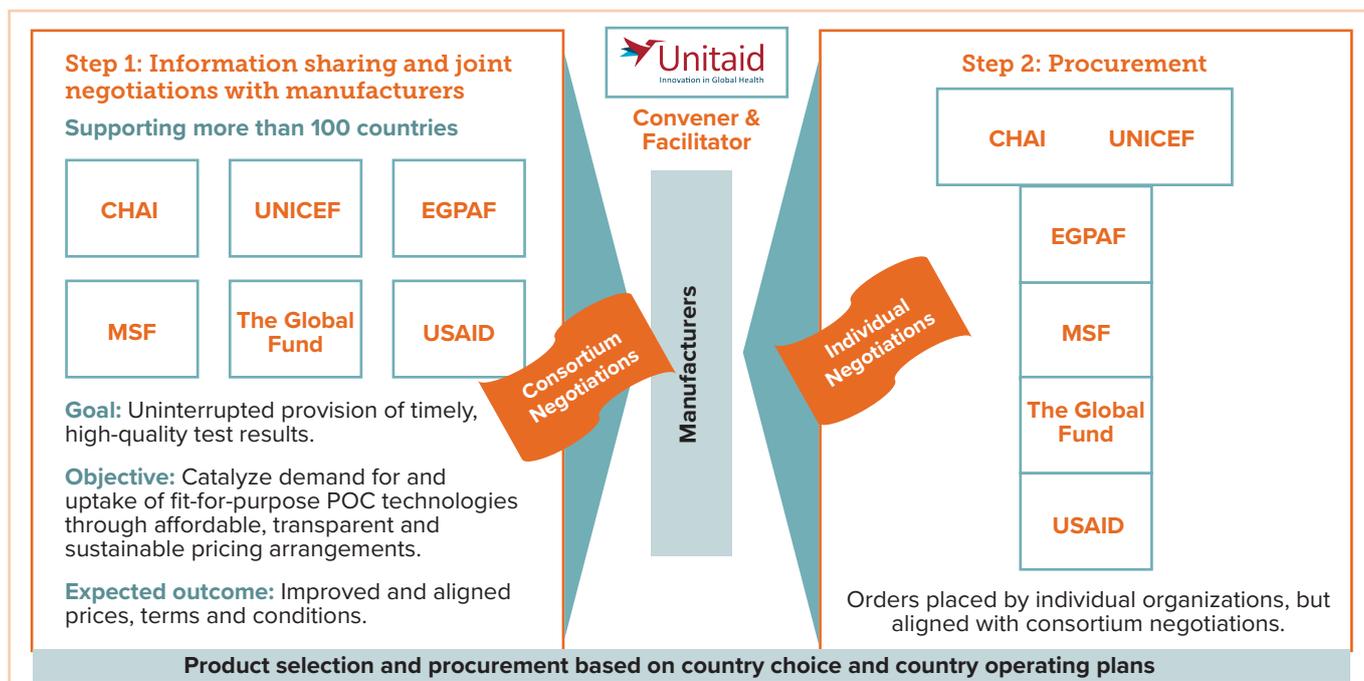


Figure 1. Consortium approach to catalyzing the adoption and uptake of POC EID technologies and ensuring sustainability of the market

Defining and Measuring Key Performance Indicators (KPIs)

Monitoring manufacturer performance is an integral component of any procurement cycle, and sheds light on how manufacturers are doing in terms of cost, quality, delivery, service, and other key areas. Routine monitoring of KPIs can ensure immediate problem solving in the field and be used to determine if agreed practices are being achieved or if corrective actions are needed. EGPAF and CHAI developed the following set of KPIs and proposed these for use by the global procurement consortium (Table 1).

Table 1. Proposed KPIs

Procurement indicators	In-country, device performance indicators
Number of orders and time taken until manufacturer acknowledges orders	Rate of errors, invalid and undetermined tests
Number of orders and rate of correct shipping documents	Number and rate of platform and module breakdowns reported per year
Number of orders and rate of on-time delivery against agreed delivery dates	Median, range, and interquartile range (IQR) time from receipt of complaint to response by manufacturer
Number and rate of full and complete deliveries against quantities ordered	Median, range, and IQR time taken by manufacturer to provide replacement platform
Number and rate of agreed shelf life orders delivered	Median, range and IQR time taken by manufacturer to repair defective platform
Number and rate of defective/non-functional platforms delivered and/or missing accessories	Number and proportion of breakdowns covered by service warranty
Are repair services available through the manufacturer or a designated distributor and are replacement parts and/or devices available in-country?	Median, range, and IQR additional cost outside of service warranty per breakdown
Costs of annual service contract and/or incremental price-per-test for service and maintenance	Number and rate of intervention reports provided by manufacturer after repair of platform

Data on these indicators should be routinely collected, both at global and country level, and measured against the terms and conditions in agreements with manufacturers, including purchase orders and service and maintenance terms and conditions. Data should be collected continuously for each consignment and across the period of the procurement contract in accordance with the principles of on-time, in-full. If possible, data should also be collected for each device in order to gauge in-country device performance. EGPAF currently uses several tools to collect information on overall manufacturer performance, such as excel sheets, device error logs, the Verian procurement system, and a recently-developed data dashboard.

Preliminary Results of KPI Monitoring

From October 2016 to July 2017, EGPAF monitored the following procurement indicators for POC EID devices and tests kits ordered for eight project countries: Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, and Zimbabwe.

Table 2. Early results of procurement indicator monitoring, as of June 2017

Procurement indicators	Result
Number of orders and time taken until manufacturer acknowledges orders	27 orders; Mean: 7 days; Median: 4 days (range: 0 – 50 days)
Number of orders and rate of correct shipping documents	23 orders; Rate: 35%
Number of orders and rate of on-time delivery against agreed delivery dates	23 orders; Rate: 17%
Number and rate of agreed shelf life orders delivered	23 orders; Rate: 13%
Number and rate of defective/non-functional platforms delivered and/or missing accessories	6 incidences reported; Rate: 13%
Are repair services available through the manufacturer or a designated distributor and are replacement parts and/or devices available in-country?	Out of eight project countries currently implementing POC EID, four do not have designated distributors in-country
Costs of annual service contract and/or incremental price-per-test for service and maintenance	US\$2,250 - US\$2,280 per device, per year if purchased with device in single transaction or US\$2,500 - US\$2,898 per device, per year if purchased separately

Manufacturers are experiencing challenges in providing accurate and error-free shipping documents. Out of the 23 orders delivered, only 35% provided correct shipping documentation. Out of the 23 orders completed, only 17% met the agreed delivery date. They also face challenges in meeting the guaranteed shelf life of cartridges on delivery. Only 13% of the delivered orders met the shelf life stipulated in the purchase orders. Upon receipt and inspection of the 46 platforms and accompanying accessories, a total of six defective platforms and/or missing accessories (equivalent to 13%) were reported. Preliminary results indicate that service and maintenance per device is costly and difficult to manage since each device warranty has to be tracked separately.

From December 2016 to June 2017, EGPAF monitored device performance indicators for POC EID instruments in six project countries: Cameroon, Cote d'Ivoire, Lesotho, Rwanda, Swaziland, and Zimbabwe.

Table 3. Early results of device performance indicator monitoring (as of May 2017).

In-country device performance indicators	Results
Rate of errors, invalid and undetermined tests	8% (231 out of 2,922 tests performed)
Number and rate of platform and module breakdowns reported per year	N =7 breakdowns; Rate: 15%
Median, range, and IQR time from receipt of complaint to response by manufacturer	5 days; Range: 0-9 days, IQR: 2 days
Median, range, and IQR time taken by manufacturer to provide replacement platform	Median: 7 days; Range: 0-17 days; IQR: 13 days
Median, range and IQR time taken by manufacturer to repair defective platform	Median: 17 days; Range: 7-22 days; IQR: 10.5 days
Number and proportion of breakdowns covered by warranty	7 breakdowns (proportion covered: 100%)
Number and rate of intervention reports provided by manufacturer after repair of platform	1; Rate: 14%

From December 2016 to June 2017, a total of 2,922 tests were performed in six project countries, out of which 231 errors, invalids and undetermined tests were reported. In addition, seven breakdowns were reported, but only one intervention report was provided detailing the works performed and parts replaced. The manufacturers were responsive to complaints raised and the preliminary results indicate a median response time of 0.5 days with a range of 0 to 9 days. In the course of repairing defective devices, manufacturers provided replacement devices within a median of 7 days and IQR of 13 days. The time taken to repair defective devices ranged from 7 to 22 days, with a median of 17 days. All of the reported breakdowns were covered by the manufacturer warranty.

Conclusions and Recommendations

What do the preliminary results tell us?

Preliminary results show that it is critical to ensure manufacturer performance in order to provide uninterrupted, timely, and high-quality EID and viral load test results.

What can procurement partners do to ensure standardized and routine tracking and reporting on KPIs?

The procurement partners should work together to standardize expectations from manufacturers. Inclusion of the standardized KPIs in the contracts with manufacturers will go a long way toward ensuring uniform evaluation of manufacturers. For manufacturer performance information to be useful and effective, the identified areas of non-compliance should be shared with the manufacturer routinely with a request for a corrective action plan. Positive feedback should also be provided to acknowledge good or improving performance and encourage continued manufacturer commitment.

What can manufacturers do?

Manufacturers should consider investing in an online maintenance tool to track the status of module replacement, warranty contracts, and module calibration due date.

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