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MEDIA NOTE

Promising Results from the Routine Use of Point-of-Care Technologies for Early Infant Diagnosis of HIV

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POINT-OF-CARE TECHNOLOGIES FOR EARLY DIAGNOSIS OF HIV IN INFANTS

Early HIV testing, prompt return of test results, and rapid initiation of treatment are critical for reducing morbidity and mortality among HIV-infected infants. Through a four-year (2015-2019), \$63 USD million grant from Unitaid, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is implementing a project that aims to optimize and expand access to early infant diagnosis of HIV (EID) through the integration of innovative point-of-care testing (POC) into national diagnostic networks and thereby significantly increase the number of HIV-positive infants receiving lifesaving treatment.

EGPAF is working with ministries of health and key stakeholders to identify the most appropriate health facilities for placement of POC EID platforms in nine countries: Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, Zambia, and Zimbabwe. Through this project, over 150,000 HIV-exposed infants will be tested and more than 7,000 HIV-infected infants will be initiated on lifesaving antiretroviral therapy.

For more information visit: <http://www.pedaids.org/pages/unitaid-egpaf-project-optimizing-early-infant-diagnosis-and-treatment-for-h>

THE CHALLENGE

In order to achieve the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 goals¹, significant efforts are needed to ensure that all HIV-exposed infants are tested for HIV within their first two months of life, that they rapidly receive their test results, and that those diagnosed with HIV are linked to care and treatment services immediately.

In 2015, more than 1.2 million babies were born to mothers living with HIV in the 21 UNAIDS priority countries.² While the World Health Organization (WHO) recommends that all HIV-exposed infants receive a virological test within two months of birth, only half had access to EID testing in 2015. Further, only 50% of infants who were tested for HIV received their test results, with most waiting 30 to 90 days to receive them.^{3,4} Among those

diagnosed with HIV, only half were placed on treatment.⁵ 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} and 50% will die by their second birthday.⁸

To improve health and save lives, HIV-infected infants must be diagnosed early, rapidly, and efficiently. Yet current EID systems are hindered by long turnaround times for results to reach the caregiver or patient, low rates of return of results to caregivers, and poor initiation of HIV-infected infants on treatment. In turn, families may be less likely to have infants tested if they believe that they will not receive results in a timely manner. Currently, many infected infants are not started on treatment early enough and many patients are lost to follow up, leading to higher morbidity and mortality rates.

THE SOLUTION

New-to-market, POC EID technology ensures that infants are tested at a health facility, or at a nearby facility, and quickly receive their test results so that HIV-positive infants can be enrolled rapidly on treatment. POC testing platforms are easy to use in a variety of service delivery settings, and do not require trained laboratory technicians to perform the test. As the POC EID test can be performed in the health facility where the caregiver brings their baby, the sample no longer needs to be transported to a central laboratory far away from where the test is performed. The POC EID machine analyzes blood drawn from a heel-prick, and produces a test result in about 50 to 90 minutes. Infants who test positive can be initiated immediately onto treatment before leaving the clinic.

¹ 90-90-90 An ambitious treatment target to help end the AIDS epidemic, UNAIDS, 2014

² On the Fast-Track to an AIDS-Free Generation, UNAIDS, 2016

³ Manumba, S., Smart, L.R., Mwale, A., Mate, K.S. and J.A. Downs. (2015) "Shortening turnaround times for newborn HIV testing in rural Tanzania: A report from the field. PLoS Med. Nov. 12(11).

⁴ Sutcliffe, C.G., van Dijk, J.H., Hamangaba, F., Mayani, F. and W.J. Moss. (2014). Turnaround time for early infant diagnosis in rural Zambia: A chart review. PLoS ONE. 9(1).

⁵ UNICEF. https://data.unicef.org/wp-content/uploads/2015/12/2015-Children-Adolescents-and-AIDS-Statistical-Update-Executive-Summary_244.pdf

⁶ Bourne DE, Thompson M, Brody LL, Cotton N, Draper B, Laubscher R, et al. (2009) "Emergence of a peak in early infant mortality due to HIV/AIDS in South Africa". AIDS.23(1):101-6

⁷ Innes S, Lazarus E, Otway K, Liberty A, Germanus R, Van Rensburg AJ, et al. (2014) "Early severe HIV disease precedes early antiretroviral therapy in infants: are we too late?" J Int AIDS Soc.,17

⁸ Newell ML, Coovadia H, Cortina-Borja M, Rollins N, Gaillard P, Dabis F. (2004) "Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis". Lancet. 364(9441):1236-43 references

⁹ The Global Fund. HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool, Version 2, April 2017. Available at https://www.theglobalfund.org/media/5765/psm_viralloadearlyinfantdiagnosis_content_en.pdf Accessed on 26 June 2017

EARLY ROUTINE USE OF POC EID TECHNOLOGIES DEMONSTRATES THAT POC TESTING IS EFFECTIVE AND AFFORDABLE

Comparing the results of conventional lab-based EID to POC EID

Is POC EID effective?

Between December 2016 and October 2017, 9,428 infants were tested using POC EID across 191 sites in eight intervention countries: Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, and Zimbabwe. EGPAF is measuring the effect of POC EID introduction through a pre- and post-intervention evaluation study. The evaluation compares pre-intervention baseline data on conventional laboratory-based EID at a sub-set of project sites with post-intervention data on POC EID testing at all project sites. The table below summarizes the early results of this evaluation.

TABLE 1: PRE- AND POST-INTERVENTION DATA: KEY FINDINGS*

	Baseline Results (conventional, lab-based testing prior to the introduction of POC EID in a sub-set of 92 project sites)	Post-Intervention Results (POC EID testing in 191 project sites)
Number of infants tested	2,701	9,428
Percent of results returned to caregiver within 30 days	18.6%	99.8%
Median turnaround time from receipt of results to initiation on treatment	55 days (range: 3-451 days)	0 days (range: 0-168 days)
Percent of newly identified HIV-Infected infants initiated on treatment	70.0%	91.8%
Median turnaround time from blood sample collection to ART initiation for infants identified as HIV-infected	49 days (range: 0- 213 days)	0 days (range: 0-168 days)

*Data for Zambia is forthcoming.

With POC EID, almost 100% of caregivers received their test results within 30 days, up from 18.6 % under conventional testing. The turnaround time between blood sample collection and return of results to the infant's caregiver decreased from 55 days at baseline to 0 days post-intervention. With the introduction of POC EID, more caregivers are getting test results for their infants sooner. In addition, a larger proportion of infants who tested HIV-positive on POC EID were initiated on treatment. Furthermore, because the turnaround time from sample collection to return of results was greatly reduced with POC EID, HIV-infected infants were initiated on lifesaving treatment at a younger age, greatly increasing their prospects of survival.

Is POC EID affordable?

The price of diagnostic technologies is a key consideration for national programs, implementers, and funders. Currently, the individual test price for POC EID is higher than conventional, laboratory-based EID. However, it is important to consider not only the price of the test itself, but also other costs, such as

service and maintenance costs, and to factor in the proportion of test results returned to the caregiver. The cost per test result received is a closer measure of the true value of a diagnostic. Any result not received by a caregiver cannot impact clinical decision-making, which can be considered a waste of scarce human, financial, and material resources that are used to collect and analyze a blood sample, but not deliver a test result. Using The Global Fund's total cost of ownership (TCO) calculations⁹, and EGPAF's pre- and post-intervention data for the proportion of results returned to caregivers, the estimated cost per test result returned is approximately \$20-\$41 for conventional, and \$21-\$33 USD for POC. These findings suggest that POC and conventional EID are nearly equivalent for cost per result returned to caregiver. As demand for POC EID increases, lower prices may be negotiated and the cost per result returned may become even more attractive for POC EID.

CONCLUSIONS

If left undiagnosed, at least 50% of HIV-positive infants will die by their second birthday, with a peak mortality at 2 to 3 months of age. However, when HIV-exposed infants are tested early, and caregivers and clinicians get test results sooner, they can make patient care decisions faster and save infants' lives. Early results from the routine use of POC EID technologies are very encouraging, suggesting that POC EID is affordable, and that there are significant benefits to incorporating POC into the existing EID network. National programs, funders, and other implementers should consider introducing or expanding the use of POC EID testing.

Access the live data here: <http://www.pedaids.org/pocdash-board>

ABOUT THE ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION (EGPAF):

EGPAF is the global leader in the fight against pediatric HIV/AIDS and has reached more than 27 million pregnant women with services to prevent transmission of HIV to their babies. With a global footprint spanning 19 countries, it currently supports over 5,000 sites to implement prevention, care, and treatment services; to further advance innovative research; and to execute global advocacy activities that bring dramatic change to the lives of millions of women, children, and families worldwide.

For more information, visit <http://pedaids.org/>.

ABOUT UNITAID:

Unitaid is an international organization that invests in new ways to prevent, diagnose and treat HIV/AIDS, hepatitis C, tuberculosis and malaria more quickly, more affordably and more effectively. It accelerates access to innovation so that critical health products can reach the people who most need them. Unitaid's work facilitates large-scale introduction of health products through funding by the Global Fund, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and by governments.

For more information, visit <https://www.unitaid.org/>.



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