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MEDIA NOTE

Point-of-Care for Early Infant Diagnosis Project Overview

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POINT-OF-CARE FOR EARLY INFANT DIAGNOSIS PROJECT OVERVIEW

Early diagnosis, prompt return of 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 life-saving treatment.

EGPAF is working hand-in-hand 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 250,000 HIV-exposed infants will be tested and more than 13,000 HIV-infected infants will be initiated on life-saving 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 goals, 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 as HIV-positive are immediately linked to care and treatment services.

In 2015, more than 1.2 million babies were born to mothers living with HIV in the 21 UNAIDS priority countries.[1] 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.[2,3] Among those

diagnosed with HIV, only half were placed on treatment.[4] 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,[5,6] and 50% will die by their second birthday.[7]

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 unmotivated to have an infant 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 "spoke" facility, and quickly receive their test results so that HIV-positive infants can rapidly be enrolled 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 machine analyzes blood drawn from a heel-prick, and produces a test result in about 50 to 90 minutes. Infants who test positive can immediately be initiated onto treatment before leaving the clinic.

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

2 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).

3 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).

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

5 Bourne DE, Thompson M, Brody LL, Cotton M, 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

6 Innes S, Lazarus E, Otwombe 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

7 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

PROMISING RESULTS FROM EARLY ROUTINE POINT-OF-CARE TESTING

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

Between December 2016 and July 2017, 2,636 infants were tested using POC EID across 95 sites in six intervention countries: Cameroon, Côte d'Ivoire, Lesotho, 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 73 project sites)	Post-Intervention Results (POC EID testing in 95 project sites)
Number of infants tested	2,210	2,646
% of results returned to caregiver	77.4%	99.6%
Median turnaround time from blood sampling to caregiver receipt of results	53 days (range: 2-438 days)	0 days (range: 0-38 days)
Number of infants tested who were diagnosed as HIV-positive	69	145
Median turnaround time from receipt of results to initiation on treatment	0 days (range: 0-75 days)	0 days (range: 0-28 days)
% HIV-Infected children initiated on treatment	72.4%	86.8%

*Data for Mozambique, Kenya and Zambia are forthcoming.

With POC EID, almost 100% of caregivers received their test results, up from 77.4% under conventional testing. The turnaround time between blood sample collection and return of results to the infant's caregiver decreased from 53 days at baseline to 0 days post-intervention; 67% of tests were returned on the same day and 92.8% were returned within 7 days. With the introduction of POC EID, more caregivers are getting back 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.

REPORTING FUTURE POC EID TESTING RESULTS LIVE AND IN REAL TIME

The United States President's Emergency Plan for AIDS Relief (PEPFAR) urges continuous assessment of the HIV/AIDS epidemic through real-time data to strengthen health systems, prevention efforts, and the quality of care provided to patients living with HIV/AIDS. In response to this appeal, and to demonstrate the real-time impact of the Unitaid/EGPAF initiative, EGPAF has partnered with Microsoft to implement the "Power BI dashboard" in its POC EID project. The dashboard is an online single page tool that uses visualizations to tell a story based on aggregated project data. All of the project data is fed into the dashboard, allowing for real time updates on key metrics and indicators of this project in an innovative and impactful way.

This new approach to reporting Key Performance Indicators (KPIs) will change the way data speaks to implementers, donors, and other stakeholders. Compared to traditional reports, this interactive dashboard automatically visualizes customized data that is updated as it is fed into the system. No longer do separate reports for different stakeholders need to be manually prepared. The dashboard allows users to select data subsets and thus facilitates the reporting process using just a few clicks. To monitor specific progress indicators, the user simply chooses the indicators they wish and the system generates the visualization based on the aggregated updated data. This allows for targeted report communication.

Power BI is a cloud-based business analytics service that provides a single view of the most critical data. It allows the user to monitor progress in real time through the live dashboard, create rich interactive reports with Power BI Desktop, and access data on the go with native Power BI Mobile apps.

Access the tool here: http://www.pedaids.org/pocdashboard

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 26 million women with services to prevent transmission of HIV to their babies. It currently supports nearly 6,000 sites and works in 19 countries 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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