In the Kenya 2020 Country Operational Plan (COP20), PEPFAR Kenya committed to support only six point-of-care early infant diagnosis (POC EID) machines despite two years of activism by people living with HIV and civil society captured in the People's COP 2019 and the People's COP 2020. The six machines that will be supported by PEPFAR are part of the UNITAID-funded, CHAI- and EGPAF-implemented project that ended in 2019 and had supported procurement of 67 POC EID instruments: 39 Alere Q and 28 GeneXpert machines that would tackle Kenya’s challenges of diagnosis, treatment scale up, retention in care and viral load suppression for children with HIV. This program led to an increase in the initiation of treatment by children with HIV from 43% to 93%.

As PEPFAR supports six machines, the Kenya government is yet to confirm its support for any of the remaining dormant 61 machines, while perinatal HIV transmission continues to rise, with current transmission rates of 11%.

In PEPFAR Kenya’s COP20 analysis of POC EID, contained in Appendix E (p. 107-115), in response to the Kenya 2020 People’s COP, PEPFAR focuses heavily on only the facility-level costs required to implement POC EID without serious consideration of either the needs of the recipients of service, in particular their rights to quality and accessible healthcare services, or the evidence base that clearly demonstrates the superiority of POC EID in timely linkage of HIV positive infants to treatment and in retention of HIV positive children in care.

In response to PEPFAR’s analysis, we call for the following:

1) Removal of barriers to prevention services for women and increased access to PrEP for all pregnant HIV negative mothers and prioritisation of quality programs designed to start, retain, and support pregnant and breastfeeding women with HIV on treatment, such as community level health workers tasked with finding and retaining women in care and support groups for newly diagnosed mothers.
PEPFAR Kenya should strive to provide essential prevention services to pregnant and breastfeeding women. All HIV negative women should be able to access prevention options such as multiple HIV tests during pregnancy and breastfeeding and pre-exposure prophylaxis at the facility — especially when in serodiscordant relationships as part of antenatal care (ANC). In Kenya, the COP20 PrEP target for all populations is 113,727, a far cry from the 1.08 million women visiting the health facilities each year, of whom more than one million are HIV negative. Government directives increasing the age of consent for young people to be able to access PrEP are a gravely concerning barrier for women to accessing prevention options despite an increase in adolescent pregnancy and HIV infection. They should be removed.

While it is true that of women attending first antenatal care (ANC 1) in FY19, 99% knew their HIV status and 98% of those who were identified as HIV positive initiated ART, there are still a large number of pregnant women who do not visit healthcare facilities. This was also highlighted by PEPFAR Kenya during the regional planning meeting. Strategies must be put in place to find these women in the community and offer testing and prevention options to them.

2) Prioritisation of quality testing options for children, ensuring that they do not experience second-class care

In the Appendix E analysis, PEPFAR Kenya’s COP20 argues that expanding POC EID will not directly address retention among women in ANC. Indeed, comprehensive strategies are required in order to ensure access to continuous, quality treatment for HIV positive women in ANC. But evidence indicates that POC EID is a critical piece of solving this treatment retention crisis.

Kenya is facing unacceptably high rates of perinatal transmission. The country also cannot reliably report the length of time it takes for conventional HIV test results of an HIV-exposed child to reach the caregiver and for the caregiver to return to the facility. The massive hardship most patients face navigating the back and forth visits to healthcare facilities must not be overlooked, particularly when women have already left the healthcare system and their children are potentially exposed to HIV and their status is unknown. POC EID provides an invaluable opportunity for those women to be able to quickly and efficiently know the status of their children – either when they give birth or when they get back to the facility should they have had children outside the health system – and have treatment offered to their children immediately. Major delays in turnaround time to test results reaching caregivers undermine retention in care, and evidence indicates POC EID increases early retention on pediatric treatment.

PEPFAR Kenya’s analysis highlights that the majority of infants diagnosed with HIV did not receive infant ARV prophylaxis and were brought to clinics for HIV testing after eight weeks of age (66%) and that many (97%, KDHS 2014) infants do come for their first DPT immunization at six weeks. However, suboptimal HIV screening at this point contributes to missed opportunities for offering HIV testing. What the analysis does not highlight however is that without treatment, 10-15% of those HIV infected infants will have died by 4-6 weeks, 50% will die by age 2 and 80% will die by age 5. This is precisely why children need immediate diagnosis when women go to the facility. Bringing services closer to new mothers is a critical intervention to improve linkage and retention and to prevent infant death.

PEPFAR Kenya’s analysis also acknowledges that the majority of mothers of infants living with HIV that are newly diagnosed HIV-positive during pregnancy or breastfeeding did not attend ANC, and/or started ART during the postnatal period. HIV programs must be designed to cater for the needs of children whose mothers did not attend ANC. POC EID does exactly this, by providing immediate diagnosis and linkage to treatment. Offering POC EID at immunisation will reduce these gaps by providing mothers...
the opportunity to immediately learn of the status of their children. The ability of POC EID to improve timeliness in receiving results and linkage to ART initiation is an integral component of quality PMTCT programming and we call on PEPFAR Kenya to revise its flawed analysis. Six POC EID instruments committed in COP20 are not enough—that is a dismally low number compared to the needs of new mothers.

3) Redefine testing turnaround time to include calculation of the time it takes for a mother and or a caregiver to return to the facility for the child’s test results and the duration it takes for children to receive treatment. This will ensure that the program is truly able to ensure that turnaround, inclusive of sample transport and sample processing.

According to PEPFAR Kenya’s detailed analysis, the average turnaround time (TAT) is eight days for conventional testing, five days for near POC testing, and less than one day for POC testing. But this metric is flawed.

The PEPFAR Kenya definition of turnaround time does not take into consideration the time it takes for test results that arrive at the facility to reach caregivers which significantly increases the turnaround time when using conventional platforms unlike with POC EID whose turn around time remains the same. PEPFAR Kenya should focus beyond the lab and facility to the needs of clients — whose turnaround services are far longer than the eight days it takes to get tested and for the results to be returned to the facility. At the facility clinicians report that they “cannot predict” how long it will take for mothers or caregivers to return, especially where there are challenges of transportation and disclosure.

Finally, PEPFAR Kenya does not consider the implementation reality. While the analysis states “some facilities are already near other conventional platforms and have a short TAT, there is a preference to use their existing functional system over POC,” in reality since the conventional EID requires a larger number of samples to be run to ensure “cost effectiveness,” unlike the POC EID, even a close facility might delay the return of results just as those clinics that are more distant.

4) Fix the perinatal HIV transmission that represents a failure of the program to reach women in time with quality services that also contributes to the failure of the program to reach children in time with diagnosis and treatment services.

As stated in the analysis, a majority of mothers of infants living with HIV are newly diagnosed HIV-positive during pregnancy or breastfeeding, did not attend ANC, and/or started ART in the postnatal period.¹⁰

PEPFAR Kenya considers mother-to-child transmission of HIV as a failure of the program to reach women in time with services. We agree. PEPFAR Kenya’s analysis however elides diagnosis with retention. The program highlights that the difference in the outcomes between the infants who had testing done by conventional EID or POC EID [126 PCR positive infants (POC EID – 56, conventional EID – 70)] in Homabay (2019) have similarly high proportions of patients reported as lost to follow-up (LTFU) (16% for conventional EID compared to 14% with POC EID).

Early HIV diagnosis of HIV exposed infants ensures PEPFAR and caregivers can immediately link HIV positive children with lifesaving treatment, and ensure HIV exposed infants continue with the necessary algorithm of testing at four-six weeks, nine months, after cessation of breastfeeding.
In cases of conventional EID testing, results take eight days to reach facilities before clinicians begin the task of contacting the caregiver, resulting in even more delays. POC EID offers mothers, caregivers, and clinicians same-day diagnosis and an opportunity to offer treatment for the child instead of lengthy waiting times without life threatening delays in treatment initiation.

Also, given that POC EID turnaround time is less than a day, loss to follow up before treatment initiation would only occur if a clinician opts not to give medication to the child and or if there is a stock out of medication at the facility, which points to a larger problem at the facility.

5) Provide children with access to the same quality of services from diagnosis to treatment as adults — or the program has failed. PEPFAR should ensure that children have access to the highest quality of diagnosis. Funding only six machines whilst scores of POC EID machines lay dormant is an injustice to children.

PEPFAR Kenya’s analysis highlights the placement of the POC EID machines by EGPAF in high burden areas, sites mostly funded by PEPFAR. According to the analysis, as of July 2020, only 17 of the 67 instruments had been utilized in 2020, showing that there is a significant gap in maintaining an investment that is key to saving children’s lives. As the PEPFAR Kenya program chooses to only support six machines and spend resources on providing technical assistance (TA) in: testing and quality assurance for POC EID testing in COP19, EQA (provision of proficiency testing [PT] panels), direct and indirect facilitation of networking, and reviewing site-level results at PEPFAR-supported facilities.

Table 3 of PEPFAR Kenya’s analysis shows a significant drop in the number of EID tests performed in 2019 (23,551) and 2020 (3663) due to the drop in testing capacity; a worrying trend as demand seemed to have been rising. The analysis makes it clear that the challenge of 100% utilisation is not based on the lack of demand but “lack of commodities (including shortage of testing cartridges, reagents, and sample collection apparatus), unreliable power as some areas experience routine power outages, limited or lack of qualified human resources for health (HRH), and level of effort required from staff already experiencing heavy workloads at understaffed facilities.”

Scaled up support for machines is needed as demand rises—not technical assistance to support only six machines. We also note that the utilisation of fewer machines is as a result of gaps in funding and not actual demand for the service.

The analysis cites an incredibly high cost of POC EID maintenance as compared to the costs estimated by the EGPAF pilot of $2.1 million per year. The PEPFAR program assumes the cost of supporting POC EID for six machines is $300,000 whereas EGPAF cites that as the cost of 10 machines. PEPFAR claims higher costs are a justification for prioritizing conventional EID, despite inflated costs.
The data are clear: POC EID is highly cost effective, and spending money on conventional EID when it is not closing the pediatric treatment gap results in high rates of death and rapid disease progression is hardly cost effective or humane. When children are not able to receive same-day diagnosis like their adult counterparts they begin dying starting at six-eight weeks of age. Whilst the cost of cartridges and other inputs for POC EID is higher, the number of lives saved by early diagnosis is also higher, demonstrating its clear superiority compared with conventional EID.

<table>
<thead>
<tr>
<th>Input</th>
<th>Estimated Cost</th>
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<tbody>
<tr>
<td><strong>Fixed Costs:</strong></td>
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<tr>
<td>Power back-up/UPS</td>
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<td>Costs associated with ongoing operation and maintenance</td>
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<td>Internet Connectivity and Data Bundles</td>
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<td><strong>Total:</strong></td>
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<tr>
<td><strong>Test cartridges and transport</strong></td>
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<td>Sample transport</td>
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<tr>
<td><strong>Anticipated total costs</strong></td>
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<tr>
<td>Per machine/per annum</td>
<td>$59,000</td>
</tr>
</tbody>
</table>

**Source:** PEPFAR SDS COP 2020

The data are clear: POC EID is highly cost effective, and spending money on conventional EID when it is not closing the pediatric treatment gap results in high rates of death and rapid disease progression is hardly cost effective or humane. When children are not able to receive same-day diagnosis like their adult counterparts they begin dying starting at six-eight weeks of age. Whilst the cost of cartridges and other inputs for POC EID is higher, the number of lives saved by early diagnosis is also higher, demonstrating its clear superiority compared with conventional EID.

6) **Place machines in all areas where diagnosis and linkage of children is low and return of results to mothers and caregivers should be tracked**

PEPFAR Kenya’s analysis states that Nakuru, Machakos, Kiambu, Migori, Kakamega, Nairobi, and Mombasa are the counties with the lowest linkage to pediatric treatment, yet none of these counties are supported to get POC EID (except Mombasa where the POC EID machine will be placed in a military site, only reaching 10,000 civilians including men and women receiving service at the facility living in informal settlements around the military base).

The analysis also notes that most infants diagnosed with HIV yet not reported to be linked to treatment are those admitted at referral hospitals who are discharged prior to the availability of EID results. This would be easily fixed by POC EID machines and highlights why the placement of machines at referral hospitals by EGPAF was so important.

The analysis also ignores support that could be provided in the sites previously supported by EGPAF in Kakamega, including Butere District Hospital, Matungu Sub-County Hospital, Lumakanda District Hospital, and Malava District Hospital, and in Migori, which has machines in Isebania Sub-District Hospital, Macalder Sub-District Hospital, Karungu Sub-District Hospital, Uriri Health Centre, and Awendo Sub-District Hospital — all of which could have been supported and would serve large portions of the counties as they are also referral sites.

The program can and should also revive negotiations with counties whose linkage is less challenging to move machines to counties with greater need. MOUs can be revisited and renegotiated. PEPFAR’s statement that “due to current POC EID MOUs with the counties, it’s unlikely to institute intercounty negotiations” only leaves children without services. This should not be used as an excuse to deny access to quality services.
Conclusion

Soon to be released guidance from WHO on POC EID recommends “point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age.” For the PEPFAR program to succeed in diagnosing and immediately treating children living with HIV, the program has to consider provision of services to women and children in ways that make seeking service delivery simpler and more client centered. A heavily facility-reliant approach that does not consider the challenges faced by mothers at a community level and a program that is heavily reliant on cost of service provision as a determinant to care provision rather than the quality of care provided is likely to fail. The Kenya PEPFAR program needs to urgently reevaluate the considerations for provision and support for POC EID to ensure that children have access to quality care and success for the PEPFAR program. PEPFAR at minimum should support an additional 30 POC EID machines, alongside the six it has already committed to supporting.

End Notes

1. PEPFAR Country Operational Plan 2020
2. Kenya People's COP 2019
3. Kenya People's COP 2020
4. Point-of-care Early infant Diagnosis Data Dashboard
5. Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries
7. Kenya People's COP 2020
8. Effect of point-of-care early infant diagnosis on antiretroviral therapy initiation and retention of patients
9. UNITAID-EGPAF-presentation-for-MOH-and-partners_UPDATED_5Jan2016.pptx
10. Analysis of Placement and Use of Point-of-Care Machines for Early Infant Diagnosis to Optimize EID Testing and Return of Results Page 109
11. PEPFAR SDS20 Table 3: Comparing EID POC Capacity in 2018 to 2019
12. PEPFAR SDS 2020