HEALTH GAP
GLOBAL ACCESS PROJECT

Deadly gaps in timely pediatric HIV diagnosis and treatment

Opportunities for action • February 2019

Defining the crisis: despite global gains in cutting rates of perinatal HIV infection, only 52% of children with HIV have access to treatment. Every year, approximately 110,000 HIV positive children die and more than 180,000 become HIV positive. In 2016, only about 43% of HIV-exposed infants received a test in the first 2 months of life. Those children who are on HIV treatment have unacceptably low rates of viral load suppression and are at high risk of loss to follow up, drug resistance, disease progression and death. W**hat are the obstacles leading to unacceptably high rates of death and rapid disease progression among children?**

Inadequate access to timely, accurate HIV diagnosis: Infants infected with HIV during pregnancy or childbirth have rapid disease progression and must be diagnosed within the first few months of life. WHO recommends that all HIV-exposed infants have a virological test at 4-6 weeks, that the results are returned to the caregiver within four weeks, and that positive results are fast tracked to enable prompt initiation of ART. Current diagnosis of children relies on sending samples to central labs that may be hundreds of kilometers away. This results in results only being returned about 70% of the time, with a time-delay of 1-3 months. Point-of-care early infant diagnosis (POC EID) brings the test to the health clinic, resulting in nearly 100% of caregivers receiving results on the same day. Use of POC EID has also increased the percentage of HIV-infected infants starting on ART from 68% to 94%. The cost per test for POC EID is higher than conventional testing, but when compared with the actual cost per test result received, POC EID is *less* expensive.

SOLUTION*:* People with HIV must have access to POC EID nationally. Current programs (in Cameroon, Cote d'Ivoire, DRC, Ethiopia, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Senegal, Tanzania, Uganda, Zambia, and Zimbabwe) must be scaled up, while other countries should rapidly introduce POC EID through COP 2019.

Inaccessibility and excessive prices: more than 50% of children on treatment are being prescribed inferior, nevirapine-containing regimens. This is particularly alarming because a large proportion of perinatally infected children have acquired HIV that is already resistant to nevirapine or efavirenz. Many countries have been slow to implement WHO's recommendations of preferred or alternative first line pediatric treatment regimens. Options for pediatric first line treatment that are simpler and less expensive than these will not become available until early-mid 2020, such as pediatric dolutegravir in dispersible tablets for children <20kgs or pediatric formulations of abacavir/3TC/lopinavir/ritonavir in fixed dose combination. Pediatric treatment prices are excessive. LPV/r pellets, granules and syrup are vital for children <10kg and children >10kg but <20kg who cannot swallow LPV/r tables whole. **But granules and pellets are approximately 4 times more expensive than generic LPV/r tablets, which can only be taken by children >10kg who can swallow whole tablets.** Producing granules and pellets will require new equipment and other outlays by pharmaceutical companies and will be replaced in 2020 by better formulations such as dispersible DTG tablets. Nevertheless Cipla and Mylan must reduce their prices for pediatric formulations of LPV/r.

ACCESS CAMPAIGN

LPV/r pediatric formulation prices

Product	Pack size	Price per unit	Price per year, 6 kg	Price per year, 19.9 kg
Cipla Pellets (40/10 mg per cap)	120 capsules per box	$19.20 per box	$230 (2 caps BID)	$584 (5 caps BID)
Mylan Granules (40/10 mg per sachet)	120 sachets per box	$18.25 per box	$219 (2 sachets BID)	$555 (5 sachets BID)
Abbvie Syrup (80/20mg /mL) *	60 ml x 5 bottles	$30.82 per 5x60ml	$ 74 (1 ml BID)	$ 187 (2.5 mL BID)
Generic LPV/r 100/25 mg tablets	60 tabs per bottle	$5.94 per bottle	Not applicable	$142.56 (2 tabs BID)

*Global Fund listed price

SOLUTION: Cipla and Mylan must urgently increase their production capacity to ease current shortages and bring down their prices to meet global requirements in order to ensure access while the world is waiting for improved products for kids. Multiple factors including limited supplies of LPV/r granules and pellets, complex forecasting requirements across at least 8 WHO-recommended products (with dosage variations for weight and age bands) mean countries face challenges in

defining which products they need and when they need it. Countries must urgently develop and implement revised national pediatric treatment procurement plans in collaboration with the ARV Procurement Working Group (APWG) to ensure supply availability.

Inferior models of care: All national pediatric HIV programs should also be using community-based, family-centered models of treatment that result higher rates of viral load suppression, higher rates of retention in care, and better clinical outcomes for children with HIV—but those service delivery models are not being implemented universally.

SOLUTION: Pediatric treatment programs must adhere to minimum standards of service delivery that include community based lost to follow up prevention—along with the funds required to ensure success.

Inadequate funding: Reaching more HIV positive children with a timely HIV diagnosis through POC EID, effective treatment, and community-based counseling and support using professional and community health workers comes with higher upfront costs than approaches that are currently failing children with HIV. For example, switching to WHO-recommended antiretroviral treatment regimens for all children currently using nevirapine as well as all children newly initiated on treatment will require increased funding from PEPFAR, the Global Fund, national governments, and others. Likewise, funding is needed to ensure adequate numbers of well trained and well paid professional and community health workers are retained to roll out improved pediatric treatment interventions, including providing training and counseling for parents and other caregivers.

SOLUTION: PEPFAR, the Global Fund, and national governments must increase funding in 2019 to support accelerated access to POC EID, WHO-recommended treatment, and models of care that delivery the service children and caregivers require—cost must not be a barrier to saving lives.

What more must be done to save lives? An urgent opportunity to advocate for increased funding, expanded access to POC EID, WHO-recommended treatment regimens, and improved models of care comes in the form of the PEPFAR Country Operational Plan (COP) 2019 process. This process establishes plans for funding in each PEPFAR recipient country for FY2020.[1] It also creates crucial opportunities for national and global activists to intervene and ensure that PEPFAR's priorities, budgets and targets reflect community demands to close gaps in pediatric treatment and diagnosis. PEPFAR's Global 2019 COP Guidance to countries highlights inferior pediatric treatment and barriers to timely diagnosis as priority issues, for example, instructing countries as a 'minimum program requirement' to stop nevirapine use. But this is not enough—pressure by advocates is needed to ensure country COPs reflect community demands. Key priorities include:

1. ACCESS TO POC EID

a) COPs should include sufficient funding to roll out POC EID nationwide in all high prevalence countries. Budgets should include funding for cartridges and operational support;
b) In countries with existing POC EID platforms (Cameroon, Cote d'Ivoire, DRC, Ethiopia, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Senegal, Tanzania, Uganda, Zambia, and Zimbabwe) funding is needed to maintain *and* scale up POC EID.

2. TRANSITION TO WHO-RECOMMENDED PEDIATRIC TREATMENT

a) COPs should fully fund national procurement of all WHO-recommended first line treatment as well as options for treatment experienced children, including all products on the WHO/IATT optimal formulary such as dolutegravir 50 mg (children >20kg); LPV/r 100/25 mg tablets (children >10kg who can swallow whole tablets); and LPV/r granules/tablets/syrup for children <20 kg;
b) Ask for the draft "ART Supply Plan" countries prepare during COP 2019 development in order to determine whether proposed timelines for transition from nevirapine-based regimens are ambitious.

3. MODELS OF CARE THAT PRIORITIZE COMMUNITY BASED SUPPORT AND RETENTION

a) PEPFAR must fund models of care that include sufficient numbers of trained and supported front line professional and community health workers and other efforts that improve retention, such as counselling, education and ongoing support to caregivers and children.

[1]See Health GAP's Activist Guide to the PEPFAR COP 2019 process for a general overview of the PEPFAR COP cycle and how to engage.