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Elizabeth Glaser
Pediatric AIDS
Foundation



Catalyzing Pediatric Tuberculosis Innovations (CaP TB): Implementation and Integration of New TB Care and Treatment Models

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is pioneering a project that will save children's lives by introducing and using innovative diagnostics, drugs, and models of care for pediatric TB. The Unitaid-funded CaP TB project will run from October 2017 to September 2021 in nine sub-Saharan African countries (Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe) and India.*

The Problem

The World Health Organization (WHO) estimates that, in 2016, about one million children (under 15 years) were affected by TB worldwide, and more than 250,000 children died due to this disease, including 52,000 HIV/TB co-infected children. TB is one of the top 10 causes of death in children. Yet, globally, national TB programs are notified of only 42% of pediatric TB cases, leaving a large proportion undiagnosed or unreported.¹ Many more children are infected with TB without developing symptoms. This is known as latent TB infection (LTBI). People with LTBI may develop active TB disease in the future. Children with LTBI are at higher risk than adults of developing active TB.²

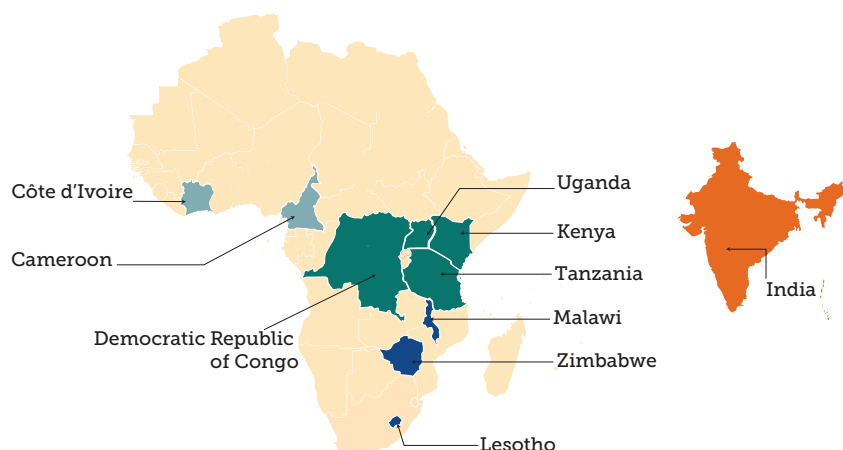
This is especially true for children whose immune systems are compromised due to young age, malnutrition, or HIV infection.^{3,4,5}

Until recently, TB medicines did not exist in formulations that were appropriate or well-tolerated by children. Diagnosing and treating pediatric TB remains a key challenge and is hampering progress in childhood TB care. Although effective preventative treatment is available to help ensure children exposed to TB do not develop TB disease, these treatments are not being widely used.

Sub-Saharan Africa accounts for about one-third of all pediatric TB cases;¹ TB incidence in these countries combined is double that of the global average.⁶ In HIV-endemic African countries, 40%–60% of pediatric TB patients are also infected with HIV.^{7,8} Due to the heavy burden and large population, India accounts for the largest number of pediatric TB cases globally, with an estimated 227,000 pediatric TB cases in 2016.¹

CaP TB Project Map

West Africa (Cameroon and Côte d'Ivoire) <ul style="list-style-type: none"> • Francophone countries • Highly centralized pediatric TB services • Comparatively lower TB/HIV co-infection rates • Low private sector expenditure on health 	East Africa (DRC, Kenya, Tanzania, Uganda) <ul style="list-style-type: none"> • Potential to demonstrate models of care in diverse settings (e.g. urban slums, refugee camps, decentralized areas, post-conflict settings) • Mid-level private sector expenditure on health • Mid-high TB/HIV co-infection rates
Southern Africa (Lesotho, Malawi, Zimbabwe) <ul style="list-style-type: none"> • Comparatively high TB/HIV co-infection • High private sector expenditure on health • Strong prioritization of pediatric TB by national governments 	India <ul style="list-style-type: none"> • Build model to integrate public and private response to pediatric TB • Producer of pediatric TB FL FDC



* EGPAF will also work with a local well-known partner, Solidarity and Action against The HIV Infection in India (SAATHII), to implement the project in India.

The Opportunity

Recently, critical progress has been achieved. The first child-friendly drug formulations, aligned with the 2010 WHO guidelines, were announced in 2015, as a direct result of Unitaids' investment and partnership with TB Alliance. New diagnostic technology, such as the Xpert Ultra cartridge, and use of alternative sample types can improve identification of children suffering from TB. Lessons learned from other global health programs, in particular HIV, will support implementing innovative models that focus on integration and decentralization of pediatric TB care to broaden access to diagnosis, care and treatment among children in need.

The project will put these critical pieces of evidence and experience into practice to save children's lives. Expanding access to effective diagnostics, drugs and models of care will also help to reveal the true burden of pediatric TB. Expanding demand for testing and treatment will ensure that more quality products are available and developed for pediatric TB.

The CaP TB package of care will be designed in a way that is scalable, while providing crucial evidence for rapid adoption by national health authorities. Evidence generated through CaP TB will include the impact of innovative models of care, uptake of new diagnostic and treatment tools, costs of interventions and effect of the CaP TB approaches on the pediatric TB cascade of care.

By the end of the project (2021), EGPAF aims to achieve the following goals in two main areas:

Diagnosis and treatment of children with active TB disease



More than double the number of children diagnosed with active TB.



Double the number of children initiated on first-line TB treatment, and treat more than 16,000 children with active TB.



Ensure that 90% of children diagnosed with active TB are initiated on treatment and that 90% achieve treatment success.

Access to preventive therapy among eligible children



Increase the proportion of children who are initiated on LTBI treatment from 13% (global estimates) to 80% of those eligible.[†]



Treat more than 52,000 children with LTBI.



Increase the share of children completing LTBI treatment from 50% (current estimates) to 80%.

[†] In 2016, only 13% of eligible children (1.3 million children under 5 years of age who were in household contact with an active TB case) received preventive TB treatment.¹



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Key Interventions

Innovation	Description
Models of care	
Integration of TB care in key health care entry points and the private sector	Through the CaP TB project, EGPAF will strengthen case-finding approaches for childhood TB through the integration of TB screening, diagnosis, and treatment initiation into maternal, newborn, and child health; pediatric inpatient and outpatient; nutrition; and HIV care and treatment entry points. In India, efforts will be focused on integrating pediatric TB care in the private sector.
Community-based household contact tracing, screening, and initiation of preventive therapy	Community health workers or other community cadres will be trained and empowered to conduct household contact tracing, screening of identified pediatric contacts of TB index cases, counseling, initiation of preventive therapy (if feasible, depending on the country context), and monitoring of treatment adherence.
New drugs and treatment options for childhood TB	
Dispersible fixed-dose combinations for drug-sensitive TB (rifampicin + isoniazid + pyrazinamide [RHZ] and rifampicin + isoniazid [RH])	New fixed-dose formulations are appropriately dosed for children, dispersible in water to ease administration to younger patients, and come in palatable fruit flavors to improve adherence. Availability of these new formulations represents a critical opportunity to provide children with adequate and effective treatment.
New drug regimens for LTBI (three months of rifampicin + isoniazid [3RH] or three months of isoniazid + rifapentine [3HP])	In countries that are interested in introducing the 3RH regimen for treatment of LTBI, EGPAF can support the introduction and use of this new regimen. EGPAF will support in-country partners to increase access to 3HP for pediatrics.
New diagnostic cartridge and instrument	
Xpert Ultra cartridge (for Cepheid's GeneXpert diagnostic instrument) and use of alternative sample types	The new Xpert Ultra cartridge is expected to improve detection yield in children due to improved sensitivity. The CaP TB project will support product switching and the roll-out of this new cartridge, in combination with the use of sample types that are higher yield or more feasible to obtain in children.
Omni (Cepheid's new diagnostic instrument)	Omni is expected to be released on the market at the end of 2018. Once the product becomes available, and if it proves fit for this purpose, the project will collaborate with national TB programs and national laboratories to support roll-out of the new technology, with the aim of improving access to Xpert testing.

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