



Executive Summary

Paediatric Tuberculosis Portfolio Joint End-of-Grant Evaluation Report

Catalyzing Pediatric Tuberculosis Innovations (**CaP TB**) &
Strengthening Paediatric TB Services for Enhanced Early
Detection (**TB Speed**)

By **BroadImpact**
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BroadImpact was contracted by Unitaid to conduct the Joint End-of-Grant Evaluation of the Strengthening Paediatric TB Services for Enhanced Early Detection (TB Speed) & Catalyzing Pediatric Tuberculosis Innovations (CaP TB) projects. The evaluation was conducted between December 2021 and June 2022.

Unitaid invested 58.4 million USD towards global goals to reduce child mortality from TB, reflected in the United Nations Sustainable Development Goals (2016-2030), the WHO End TB Strategy (2015-2035) milestones and the Political Declaration of the 2018 United Nations General Assembly high-level meeting on TB (2018-2022). The Area for Intervention (Afi): Scale-up of better TB treatment in children aimed to address child-friendly TB diagnoses through the development of innovative models of care, to reach more children, and the scale-up of new child-friendly Fixed Dose Combination (FDC) formulations that had been developed under the Speeding Treatments to End Paediatric Tuberculosis (STEP-TB) project. This was implemented through two grants awarded in 2017: TB Speed and CaP TB. The two projects covered 14 countries (12 in Sub-Saharan Africa, one in South-East Asia Region and one in the South Asia Region). These were also complemented with an enabler grant to the WHO Global TB (GTB) programme to support the revision of the paediatric TB guidelines and accelerate the adoption and uptake of new diagnostics and drug regimens. TB Speed was implemented by the University of Bordeaux (lead grantee) and seven consortium members.¹ The focus countries were Cambodia, Cameroon, Côte d'Ivoire, Uganda, Sierra Leone, Mozambique, and Zambia. CaP TB was implemented by Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) as lead grantee and Solidarity and Action Against the HIV Infection in India (SAATHII) as consortium partner implementing in India. The focus countries were Cameroon, Côte d'Ivoire, Democratic Republic of the Congo (DRC), Kenya, India, Lesotho, Malawi, Tanzania, Uganda and Zimbabwe.

The evaluation assessed the performance of the Unitaid Paediatric TB portfolio across the following Organisation for Economic Co-operation and Development (OECD), Development Assistance Criteria (DAC)²: relevance, coherence, effectiveness, efficiency, impact and sustainability. The evaluation also synthesised good practices and lessons learnt. The evaluation employed a mixed-methods approach comprising document review, qualitative interviews, site visits, impact modelling and case studies.

The assessment found that the design of the projects, their objectives and expected results were very relevant and responsive to the needs of targeted project countries, other TB endemic countries and the global TB response as a whole. With the high burden of TB, high mortality rates, under-reporting of TB cases (due to weak diagnosis, sample collection challenges and limited health worker capacity in paediatric TB services) as well as limited resources allocated to interventions/research globally that focus on childhood TB, the projects were much needed. Also, with the new diagnostic tools and child-friendly medicines available in the market, there were a number of innovations that were ready to be tested operationally or deployed. The projects implemented a set of interventions and conducted research that addressed the major priorities in the childhood TB space at global and national levels. The projects adapted to important changes in the childhood TB context during the life of the projects; these included pivoting to an increased focus on diagnosis at design stage, alignment with other complementary implementers/funders activities, site removals/new selections due to extenuating socio-political factors, changes in availability of expected products (i.e., unavailability of Cepheid's Omni platform) and global policy changes (e.g., 2018 LTBI guidelines). In addition, both projects adapted to implementation delays and disruptions imposed by the COVID-19 pandemic, including providing COVID-19 prevention services and health facility support.

The projects were internally and externally coherent. External coherence was achieved through strong alignment with global policies such as the WHO End TB strategy, SDGs, and the Roadmap towards ending TB in children and adolescents. The projects also had productive and synergistic partnerships with global actors, especially through convening the Paediatric TB Operational and Sustainability Expertise Exchange (POSEE) group as well as strong engagement with the two critical sustainability partners (The Global Fund and United States Government – USG). At the country level, Both projects worked very closely with National TB programmes and Ministries of Health (MoH) at the country level. CaP TB, however, engaged more broadly with other implementers (INGOs) and leveraged EGPAF's US government funded-projects (PEPFAR, USAID) extensively. It also worked closely with MoH at sub-national level and Civil Society Organizations (CSOs), while TB Speed also actively engaged WHO and the global scientific community, notably the collaboration with FIND and KNCV on testing stool processing methods. By design, **the projects were also internally coherent with each other and the WHO enabler grant, and worked collaboratively towards contributing**

¹ TB Speed consortium partners were: Institut de Recherche pour le Développement (IRD); Makerere University - Johns Hopkins University Research Collaboration, Uganda (MUJHU); Therapeutic Solidarity and Initiatives for Health (Solthis); PAC-Cl, Côte d'Ivoire; Instituto Nacional de Saude, Mozambique (INS); Institut Pasteur, Cambodia; and University of Zambia (UNZA).

² <https://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm>.

to WHO's paediatric TB research agenda and updated guidelines. They also built on the successes of past interventions such as STEP-TB, increasing the adoption of new and existing tools/commodities. There was some overlap in support for TB prevention therapy across Unitaid's paediatric TB project portfolio for prevention therapy, but with minimal overlap in project locations reducing the potential for duplicated efforts. CaP TB's global and national advocacy efforts also created momentum around new formulations and regimens that other Unitaid paediatric TB projects (IMPAACT 4 TB and BENEFIT KIDS) leveraged.

The projects were largely effective and achieved their intended outcomes: generating evidence across their target childhood TB diagnosis and treatment interventions to inform the 2022 revision of the WHO guidance; the catalytic introduction of innovative diagnostic tools and models of care; and creating an enabling policy and regulatory environment for adoption and potential scale-up of these interventions. The Afl had defined critical access barriers at inception, including; the need for more sensitive child-friendly diagnostic tools to bridge the gap in paediatric case detection (Innovation & Availability); the large unmet need in paediatric TB treatment, with only about 36% of cases diagnosed of an estimated 1 million children that require TB treatment per year (Demand & Adoption); and the availability of new child-friendly TB treatments that need to be scaled-up in countries (Supply & Delivery). The projects addressed these key access barriers and others to increase access to paediatric TB diagnosis and treatment services in project locations.

- **TB Speed successfully generated evidence across several target childhood TB diagnosis interventions to inform WHO guidance on improved childhood TB diagnosis approaches.** The need for more sensitive child-friendly diagnostic tools was addressed primarily by TB Speed through three studies (exploring decentralisation of childhood TB diagnosis to district health system level and below; assessing the impact of early TB detection in children with severe pneumonia on mortality & case detection; and optimising specimen processing and collection methods), with final results still pending from two (Diagnostic tools and algorithms in HIV-infected and severely malnourished children; and cost-effectiveness analysis of the proposed approaches and modelling of their market impact).³ Even though results from these studies did not show some targeted outcomes such as decreased mortality in the pneumonia study or mixed results (increased detection yield at district hospitals but not primary health care facilities) in the decentralisation study, the studies all demonstrated the feasibility of deploying these improved diagnostic approaches, especially at lower-level facilities, and their ability to improve coverage of services for children, with especially high levels of acceptability among HCWs and beneficiaries. This will contribute to bridging the gap in paediatric case detection (**Innovation & Availability**).
- **CaP TB strengthened national policies, guidelines, strategies and training curricula, aligning them with WHO recommendations and working effectively with local actors to implement improved models of care and diagnostic tools.** The large unmet need in paediatric TB treatment was addressed by supporting countries to adopt and utilise improved diagnostic tools to increase case detection, child-friendly formulations, treatment regimens and models of care. CaP TB demonstrated consistent engagements with key policymakers at global and country-level, resulting in increased interest by global actors and ownership and buy-in of the project's interventions at country-level. Achievements include the alignment of national policies to WHO recommendations as well as the inclusion of these new paediatric formulations FDCs (RH 75/50 and RHZ 75/50/150); single dispersible formulations (INH and EMB); new regimens-3RH,3HP; diagnostic tools (MTB/RIF Ultra cartridges); and models of care (screening integration and household contact tracing) into national paediatric TB policies, strategies, practice guidelines/algorithms, training materials, national registration and national essential medicines lists. There were varying levels of inclusion in countries, with eight or more countries including at least eight of these initiatives in their guidelines. The exceptions include the single dispersible INH formulation prequalified in the final year of the project before NCE (four countries) and stool sample collection (three countries). A critical element of the project's success was investments in designing and rolling out trainings to strengthen the capacity of health workers and community health structures to deliver paediatric TB interventions. The CaP TB project achieved the majority of its objectives, with the project increasing TB case detection and treatment rates in children. The project achieved most output and outcome targets: over 4.7 million children were screened; 89% of paediatric TB cases were successfully treated, and 42% of children were initiated on preventive therapy among eligible contacts at the national level, exceeding the 30% target. However, despite demonstrating improvement over very low levels estimated at baseline, the project struggled to achieve high coverage of testing presumptive TB cases with Xpert (59% of eligible children overall, with substantial variation by country as the use of Xpert was very dependent on national regulations) and conducting successful contact tracing for index cases (33% of TB index cases overall, with

³ These are based on preliminary results; as final research findings were unavailable at the point of the evaluation.

substantial variation by country due to varying national recommendations regarding contact tracing as well as COVID-19 movement restrictions). Further, preliminary results from the CaP TB INPUT study on the integration of systematic paediatric TB screening into MNCH, HIV and Nutrition Services showed a statistically non-significant increase of 20% in TB case detection between the control and intervention arms. However, the results varied by country, with Cameroon showing a statistically significant 10-fold increase in case detection and Kenya showing no difference between control and intervention arms. **(Demand & Adoption).**

- **The CaP TB project also strengthened the market for new paediatric TB formulations through advocacy to phase out old formulations and the introduction of the new products in project countries.** All project countries have now successfully transitioned to the new child-friendly first-line FDCs, compared to only four countries at baseline procuring 100% of the new formulations. In addition, four countries procure EMB dispersible formulation exclusively, and five have transitioned to the dispersible INH formulation. Further, CaP TB supported NTPs to switch to the 3RH regimen as the regimen of choice for delivering treatment of LTBI to paediatric contacts. Seven countries have also updated their LTBI guidelines accordingly. CaP TB utilised its partnership with GDF effectively, supporting national quantification processes, as well as commodity distribution, monitoring and management at site level. The project, however, experienced pockets of stock-outs of paediatric FDCs at national and site levels in a few countries through the life of the project, including the NCE year due to transition to domestic funding or GF funding and delays in release of the funds from these new procurement sources **(Supply & Delivery).**
- **The high level of coherence between the projects and the WHO enabler contributed to the effectiveness, scalability and sustainability of the project's interventions.** The WHO GTB team, under the umbrella of the WHO enabler, participated actively in both projects. They participated in the design of the studies (enabling almost seamless alignment with WHO's research agenda), they served as a member of the POSEE, and provided strategic guidance for the implementation of the project's innovations. The enabler team also supported the review of preliminary evidence towards the inclusion of results of Unitaid-funded innovation into the development of WHO normative guidance; and dissemination of results within and beyond project countries.

Factors that positively influenced achieving the project's objectives included their high external validity with a scope of 14 countries spread across East Africa, West Africa, Southern Africa and Asia; and testing/delivery of new tools and innovative delivery processes for existing tools (FDCs, models of care – decentralised and integrated services – household contact tracing and community-based TPT, use of Xpert Ultra, standardised/simplified chest X-ray interpretation and stool and NPA samples). Other factors were: evidence-based programming; supportive supervision and monitoring, skilled staff with local/global context knowledge, expertise and relationships; consistent engagement with WHO GTB; extensive engagement with the sustainability partners (the Global Fund and USG) at both global and country level; and very close working relationships with a spectrum of country actors from MoH and NTPs to CSOs and community champions. Factors that negatively impacted the effectiveness of the projects include delays in commencing research activities, with TB Speed experiencing protracted protocol development timelines of up to 8 months on one study; delayed ethical approval processes at both global and in-country review boards, especially with approving amendments; delays due to cancellation of the commercial availability of Cepheid's portable Omni platform that had promised point-of-care molecular diagnosis; and slow recruitment into studies. In addition, there were commodity/equipment and other resource constraints due to working at lower levels of the health system and several human resource challenges from strikes to attritions. The projects also had a few iterations on sample size and targets due to inaccurate assumptions and estimations made at baseline, which were further derailed by COVID-19 disruptions. CaP TB had to terminate some expansion activities in some project locations due to challenging socio-political conditions, weak health systems and experienced some financial transition gaps in the national and scale-up partner's budget in its final year. Despite these challenges, both projects demonstrated that these resource-intensive interventions could be delivered at lower health facility levels while improving TB case detection and treatment. The projects also developed training materials, standard operating procedures and budgeting tools that are available for utilisation globally.

The potential impact of the projects was estimated as diagnosing and treating additional children for TB, as well as corresponding years of life lost due to premature mortality (YLLs) averted. Mobilized through projects' advocacy efforts and update of WHO normative guidelines, in a scenario where countries scale up screening by 50% in the next five years compared to project years, there is potential that an additional 102,500 [37,100 - 267,500] children with TB will be diagnosed, and an additional 106,100 [30,400 - 274,100] more children will complete TB treatment in the 14 project countries and other countries in the WHO Africa region with high TB burdens, from 2019-2027. This increase in screening and diagnosis of paediatric TB could avert 4.3m [1.6m - 10.2m]YLLs. The impact model

utilised inputs mainly from CaP TB's project results, as the project was more implementation-focused and less from TB Speed, being a research-focused project operating in very few health facilities. The results from the cost-effectiveness studies being conducted by both projects were unavailable at the time of this evaluation.

The projects were moderately efficient, with both projects experiencing internal and external challenges that slowed the implementation speed in the early and later stages of the project. These include early delays such as late receipt of funds in the first year and delays in obtaining ethical approvals to start the research as described earlier. The onset of COVID-19 in March 2020 exacerbated existing delays in the third and fourth years of the projects. Subsequently, both projects applied for no-cost extensions to utilise consistent underspends and complete research and dissemination activities. The projects were largely cost-efficient, with negligible expenditure rates in the first year due to receipt of funds in the last months of the year. However, the projects expended 83% and 87% for CaP TB and TB Speed, respectively, by 2021. The projects delivered most of their planned activities across all outputs, with over 85% spent on every output for TB Speed and 97% for CaP TB. Project implementers collaborated strongly with national authorities facilitating the integration of project interventions into the health system and creating significant efficiencies. CaP TB's consortium arrangement was fit for purpose and efficient. However, TB Speed's consortium was more complicated, with too many members and partners implementing the project. This created coordination/administrative bottlenecks.

Overall, the projects have contributed significantly to creating conditions for scale-up and sustainability, especially through evidence generation and dissemination, but also through demonstration of the feasibility of the project's interventions and effective global and local partnerships, resulting in an immediate response towards supporting country adoption and partial scale-up by partners (GF and USG). However, the pathway to scale-up and sustainability is not very strong, as a countrywide scale will be a mammoth task compared to the project's implementation in limited geographical areas. Both projects successfully generated and disseminated knowledge and evidence on their intervention sets, which informed the new recommendations on models of care in the 2022 WHO consolidated guidelines on tuberculosis (Module 5: Management of tuberculosis in children and adolescents) and an accompanying Operational handbook. Both projects introduced new innovative delivery models, and CaP TB also strengthened the supply base for new paediatric formulations, with two suppliers secured for each of the new dispersible paediatric formulations (except RHZ FDC). The projects aligned very well with local and global stakeholders, leveraging extensive existing relationships with NTPs, funders and other programme implementers. The project successfully updated policies and guidelines, developed and deployed training packages and secured some scale-up funding for most countries. The scalability conditions were not fully met in a few of the defined areas, most notably, the inadequacy of transition and scale-up funding. There are also concerns about the ability of countries to go to scale without technical support due to the technical nature of these services and the level of planning, supervision and staffing implementers utilised to support implementation in the smaller geographical focus of the projects.

Lessons learnt through the life of the project have been categorised into three areas: lessons on health systems strengthening (HSS), paediatric TB diagnosis and community engagement.

Lessons on HSS

- The early dissemination of preliminary findings simplified the advocacy process towards national policy and guideline updates and funding opportunities.
- The strong capacity-building efforts, including trainings and supportive supervision of the programme, were critical for the implementation and roll-out of paediatric TB services, especially on-site training, as it enabled full coverage of all HCWs at facility level.
- Systematic screening in child health services requires task shifting or additional workforce.

Lessons on Diagnosis

- Access to Xpert testing alone does contribute to improved diagnosis of TB in children, and microbiological TB diagnosis can simplify the diagnostic pathway as a first step in diagnosis.
- Clinical diagnosis remains the main method of diagnosis, and its deployment in a decentralised/integrated manner was the projects' most valued innovation.
- Prioritisation of X-ray machines and alternative sample collection consumables in procurement is necessary, as these were simply unavailable in many countries.

Lessons on Community Engagement

- CSO grants can contribute to improving project outcomes beyond awareness creation, especially policy change and sustainability.
- A collaborative relationship between implementing partners, CSOs, and communities amplifies advocacy results.

- Community-led monitoring improved advocacy efforts, allowing for ownership of observations/results and evidence-based asks.
- Early engagement of CSOs is essential to increase local ownership and optimise their contribution to sustainability.

In conclusion, the projects were responsive to the needs and priorities of stakeholders at country and global levels, as they addressed priority evidence gaps in TB detection and treatment in children. They were also internally and externally coherent with effective country and global partnerships established, and synergies with other Unitaid projects. The projects were moderately efficient with a myriad of early delays, mostly research-related, impeding project implementation and subsequently exacerbated by the COVID-19 pandemic. Effectiveness was largely achieved, with project activities translating into expected outcomes: introducing and deploying innovative diagnostic tools, models of care and new treatments; demonstrating the feasibility of the project's interventions; and generating evidence to inform WHO guidance; with early adoption and integration of some interventions into country systems. The projects have also contributed significantly to scalability conditions through evidence dissemination, demonstrating the feasibility of the project's interventions, and effective global and local partnerships. Despite these efforts, the pathway to scale-up and sustainability will be challenging, as countrywide scale will be an enormous task with respect to technical service requirements, in comparison to the projects' implementation in limited geographical areas with a sizeable complement of additional project staff. Also, secured funding does not cover the full range of interventions in each country.

Recommendations from this evaluation for different stakeholder groups include:

To National TB Programmes/Ministries of Health:

- **Identify opportunities to integrate these interventions into future requests for donor funding and country budget lines**, as most countries have only secured partial scale-up funding.
- **Implement complementary health systems strengthening efforts to increase the effectiveness of TB diagnosis services:**
 - **In integrating TB screening for children at non-TB entry points, assess HRH requirements**, with considerations for task shifting this role to CHWs.
 - **In decentralising diagnosis services, capitalise on adapting existing sample transportation networks for TB samples** as an alternative to making significant investments in equipment.
 - **Strengthen diagnosis capacity holistically**, with focus on improving provider skills; developing infection control plans; creating functional sample transportation networks; developing procurement plans for equipment and consumables; and infrastructure upgrades where needed.
- **Implement community-based services and advocacy efforts through organised community structures such as CSOs.** These ensure increased acceptance among several stakeholder groups, including policy-makers, as well as effective and sustained linkages between communities and health facilities.

To Donors & Policy Makers:

- **Continue funding support to scale up these paediatric TB innovations per recent WHO guidelines, as childhood TB is still severely underfunded.** Investments should include the deployment of rapid molecular diagnostic tests that are suitable for point-of-care in LMIC settings and continue to support the development of diagnostic innovations that will overcome some of the performance and affordability issues with current diagnostic tests.
- **Fund technical support to complement existing financial support for scale-up in project countries**, as countrywide scale of these technical approaches will be challenging without additional support for planning, supervision, and monitoring.

To Unitaid:

- **Prioritise streamlined consortium structures, with a goal to select organisations/consortiums with a relatively wide set of competencies and/or operational scope.**
- **Directly engage with scale-up partners at the Afl development stage, ensuring alignment from inception and through project life and beyond.** The heavy reliance of Unitaid's catalytic approach on other funders who support implementation at scale, required this level of alignment.
- **Safeguard resources allocated to research dissemination**, especially dedicated time for evidence dissemination and provide resources for advocacy towards the adoption of the study findings. With research results only finalised at the end of the project, there is a need to ensure the evidence is well disseminated.
- **Consider intervention-focused evaluations that may cut across multiple projects in a specific portfolio rather than evaluating a portfolio of complex projects/interventions.** The former will produce succinct findings and more actionable recommendations. It will also increase the accuracy of impact estimates with strong assumptions.



Paediatric TB Portfolio Joint End-of-Grant Evaluation Final Report

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Strengthening Paediatric TB Services for Enhanced Early Detection (**TB Speed**)

11 Aug 2022

by **BroadImpact**
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Conclusions
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Afi	Area for Intervention
BENEFIT Kids	Better Evidence and Formulations for Improved MDR-TB Treatment for Children
CAD	Club des Amis Damien
CaP TB	Catalyzing Pediatric Tuberculosis Innovations
CHWs	Community Health Workers
COVID-19	Coronavirus Disease
CSO	Civil Society Organization
CXR	Chest X-Ray
DAC	Development Assistance Criteria
ERP	Expert Review Panel
FDC	Fixed Dose Combination
GDF	Global Drug Facility
GF	Global Fund
GTB	WHO Global TB Programme
HBC	High Burden Country
HCWs	Health Care Workers
IMPAACT4TB	Increasing Markets and Public Health Outcomes through Scaling Up Affordable Access Models of Short-Course Preventive Therapy for TB
INS	Instituto Nacional de Saude, Mozambique
IRD	Institut de Recherche pour le Developpement, France
LTBI	Latent Tuberculosis Infection
MoH	Ministry of Health
MOU	Memorandum Of Understanding
MDR	Multi-Drug Resistant
MUJHU	Makerere University – Johns Hopkins University Research Collaboration, Uganda
NCE	No Cost Extension
NTP	National TB Programme
OECD	Organisation for Economic Co-operation and Development
PEPFAR	Presidents Emergency Response For AIDS Relief
POSEE	Paediatric TB Operational and Sustainability Expertise Exchange group
PHC	Primary Health Centre
SAATHII	Solidarity and Action Against The HIV Infection in India
Solthis	Therapeutic Solidarity and Initiatives for Health
STEP-TB	Speeding Treatments to End Paediatric Tuberculosis
TB SPEED	Strengthening Paediatric TB Services for Enhanced Early Detection
TPT	TB Preventive Treatment
UNZA	University of Zambia
USG	United States Government
3HP	Three months of isoniazid and rifapentine
3RH	Three months of rifampicin and isoniazid





1. Introduction

- Background
- Programme Description
- Theory of Change
- Evaluation Design
- Strength of Evidence Framework



Background

TB Prevalence and Mortality

Tuberculosis (TB) has been the leading cause of death from a single infectious agent globally until the recent coronavirus (COVID-19) pandemic. In the past two years, COVID-19 has not only become the leading cause of death, it has also reversed progress in essential TB services, as well as the already slow progress towards global TB targets. There has also been an increase in TB deaths due to reduced access to services, with an estimated 1.3 million TB deaths in 2020 as compared to 1.2 million in 2019 among HIV-negative people, similar to 2017 levels. There were also an estimated 10 million cases of TB reported in 2019 and 9.9 million in 2020. The forecasts for 2021 and 2022 are expected to be worse. Paediatric cases rose slightly from one million in 2015 to 1.2 million in 2019; in 2020, there were still one million cases.^{1,2}

Recent Innovations

Innovations in Paediatric TB treatment in the last decade include the launch of the first child-friendly fixed-dose combination (FDC) formulations that combine rifampicin, isoniazid, and pyrazinamide. These are easier to administer as they are flavoured and dissolvable; as a result, they will improve treatment initiation, which is likely to improve adherence.⁴ They were developed in 2015 by the Unitaid-funded “Speeding Treatments to End Paediatric Tuberculosis” (STEP-TB) project. There are also improved diagnostic technology for TB identification, such as the Xpert Ultra cartridge and alternative sample types that are underutilised.⁵ Further, in 2018, WHO also recommended shorter regimens for TB preventive treatment, including three months of daily isoniazid and rifampicin (3 RH) for children < 15 years and three months of weekly isoniazid and rifapentine (3HP) for children above two years.⁶

TB Diagnosis in Children

Paediatric TB continues to be challenging, with nearly two-thirds of cases undiagnosed or unreported. This results in fewer children receiving timely treatment and higher mortality among children. There are also high rates of latent TB infection (LTBI) among children with the potential to develop active TB in the future.

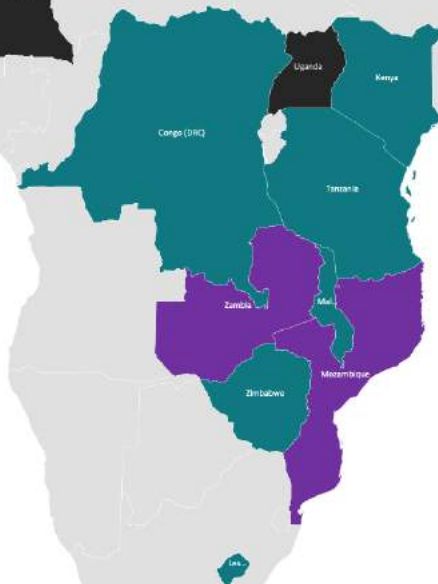
Furthermore, confirming TB diagnoses in children is somewhat challenging as collecting sputum samples from young children is difficult. Even when sputum can be collected, it may have very few TB bacteria in it, which are not easily detected by microscopy and Xpert testing (paucibacillary smear-negative disease).³



1. *Global TB Report 2021 (2020 data):* <https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2021>
2. *Global TB Report 2020 (2019 data):* <https://www.who.int/publications/i/item/9789240013131>
3. *Making the best out of available tools and approaches. Summary guidance for Microbiological and Clinical Diagnosis of pulmonary tuberculosis among children. POSEE Taskforce. 2021:* https://www.pedaids.org/wp-content/uploads/2021/06/POSEE-Info-Note_Pediatric-TB-diagnosis_Final_17.6.2021.pdf
4. <https://unitaid.org/news-blog/unitaid-tb-alliance-announce-worlds-first-appropriate-tb-medicines-children-correct-doses/>
5. *Roadmap towards ending TB in children and young adolescents:* <https://www.who.int/tb/publications/2018/tb-childhoodroadmap/en/>
6. *Global TB report 2017 (2016 data):* https://www.who.int/tb/publications/global-report/gtbr2017_main_text.pdf

Programme Description

- CaP TB Countries
- TB Speed Countries
- Both Projects



Unitaid's Response

Unitaid invested 58.4 million USD⁷ towards global goals to reduce child mortality from TB, such as the United Nations Sustainable Development Goals (2016-2030), the WHO End TB Strategy (2015-2035) and the Political Declaration of the 2018 United Nations General Assembly high-level meeting on TB (2018-2022).

The area for Intervention (Afi): Scale-up of better TB treatment in children's Theory of Change (ToC) aimed to address child-friendly TB diagnoses through the development of innovative models of care to reach more children with TB and scale-up new child-friendly FDC formulations developed under STEP-TB.

This has been implemented through two grants awarded in 2017: Strengthening Paediatric TB Services for Enhanced Early Detection (TB Speed) and Catalyzing Pediatric Tuberculosis Innovations (CaP TB).

The two projects covered 14 countries (12 in Sub-Saharan Africa, 1 in South- East Asia Region and 1 in the South Asia Region).

7. This includes funding for CaP TB, TB Speed and the WHO Enabler-TB



Programme Description

TB Speed

Budget: US\$14.7 million, co-funded with \$1.6million from Initiative 5%.⁸

Timeline: 4-year project (October 2017–September 2021), extended to September 2022 via a No Cost Extension (NCE).

Implementers: University of Bordeaux (lead grantee) and seven consortium members: Institut de Recherche pour le Développement (IRD); Makerere University - Johns Hopkins University Research Collaboration, Uganda (MUJHU); Therapeutic Solidarity and Initiatives for Health (Solthis); PAC-CI, Côte d'Ivoire; Instituto Nacional de Saude, Mozambique (INS); Institut Pasteur, Cambodia; and University of Zambia (UNZA).

Countries: Cambodia, Cameroon, Côte d'Ivoire, Uganda, Sierra Leone, Mozambique, and Zambia.

Objective: The overall objective of the project is to contribute to a reduction in childhood mortality from TB by generating evidence on an available, feasible, cost-effective and decentralised childhood TB diagnostic approach to enhance case-finding and access to treatment, including the improvement of TB diagnosis among high-risk children (HIV-infected, malnourished and children with pneumonia).⁹

8. <https://www.initiative5pour100.fr/en/5-initiative>

9. <https://www.tb-speed.com/>

10 [Unitaid_CaP TB-FactSheet_06.20.pdf \(pedaids.org\)](#)

11 [WHO TB Enabler Project Plan](#)

CaP TB

Budget: US\$36.3 million

Timeline: 4-year project (October 2017–September 2021), extended to September 2022 via an NCE.

Implementers: Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) as lead grantee and Solidarity and Action Against The HIV Infection in India (SAATHII) as consortium partner implementing in India.

Countries: Cameroon, Côte d'Ivoire, Democratic Republic of Congo (DRC), Kenya, India, Lesotho, Malawi, Tanzania, Uganda and Zimbabwe.

Objectives: The project was designed to strengthen the market for child-friendly anti-TB medicines and develop and test innovative models of care that focus on integration and decentralisation of paediatric TB care to broaden access to diagnosis, care and treatment among children in need. The implementation of these innovative models of care is anticipated to increase demand and uptake of the paediatric FDCs by increasing the number of children identified with active TB disease and therefore in need of treatment and increasing the uptake and scale-up of TB Preventive Treatment (TPT) services and therefore the number of children enrolled on TPT regimens.¹⁰

WHO Enabler

Budget: US\$1.9 million

Timeline: 4-year project (2017–2021), also extended to 2022 to align with support provided to TB Speed and CaP TB.

Implementer: WHO Global TB (GTB) programme.

Objectives: The enabler grant was designed to accelerate the adoption and uptake of new TB diagnostics, drugs and new regimens in high-burden countries by “supporting and facilitating implementation of projects funded by Unitaid within its mandate to leverage innovation for global health in the field of tuberculosis and contribute to country efforts towards achievement of targets under all the three pillars of the End TB Strategy. The project comprised three work streams supporting other Unitaid TB programmes. Workstream 1 covered MDR-TB, Workstream 2 covered LTBI, and Workstream 3 covered Childhood TB working closely with TB Speed and CaP TB.”¹¹

Programme Description

The projects introduced and deployed a spectrum of paediatric TB innovations. CaP TB spanned prevention, diagnosis and treatment, while TB Speed was focused on diagnosis (with linkage to treatment).



Triage Unit, Madhvani Children's Hospital, Jinja, Uganda



GeneXpert Machine, Saint Sacrement Health Centre, Kinshasa, DRC



Pharmacy at Madhvani Children's Hospital Jinja, Uganda

Models of Care:

- ✓ The **integration of paediatric TB Care** into MNCH, HIV and Nutrition Services. (CaP TB)
- ✓ **Community-based household contact tracing**, screening, and initiation of preventive therapy. (CaP TB)
- ✓ **Decentralised childhood tuberculosis diagnostic approaches** at district health system level. (TB Speed & CaP TB)

Tools & Processes:

- ✓ Introduction of **New Diagnostics Tools** and Processes –Xpert Ultra, NPA & Stool samples/ optimisation processes. (TB Speed)
- ✓ **Systematic early detection of TB** by Xpert Ultra among children with severe pneumonia. (TB Speed)
- ✓ **New Algorithms for HIV-infected and severely malnourished children** with Presumptive TB. (TB Speed)

Medicines and Treatment Options:

- ✓ **INH single dispersible formulation** for IPT. (CaP TB)
- ✓ **EMB single dispersible formulation** for the treatment of drugs sensitive TB in HIV co-infected children. (CaP TB)
- ✓ **New dispersible FDCs** (RH 75/50 and RHZ 75/50/150) (CaP TB)
- ✓ **3 RH regimen** for treatment of latent TB. (CaP TB)



KEY ● TB-SPEED ● CAP TB ● WHO Enabler

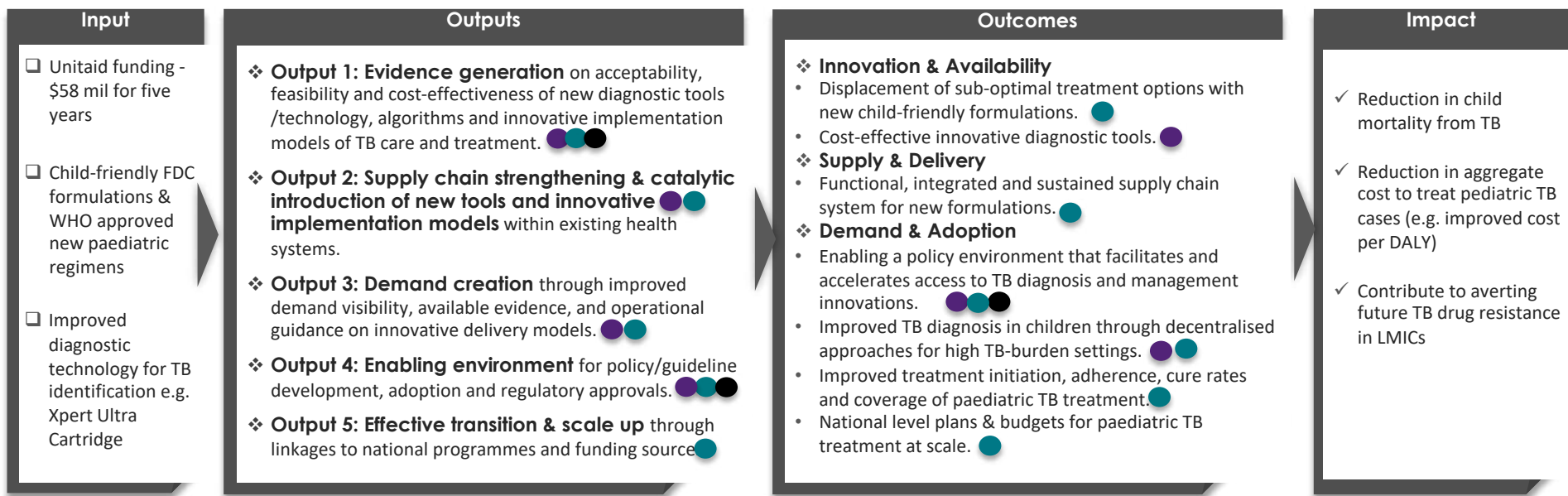
Problem

Public Health Need

Access Barriers

- TB is a top 10 cause of death in children; 140,000 children died in 2015 from TB. The South-East Asia and Western Pacific Regions accounted for 58% of the world's TB cases, the African Region for 28%, with the most severe burden relative to population (281 incident cases per 100,000 population).¹² Drivers in these regions include poor living conditions, underlying diseases, poverty, and weak health systems.
- 1. **Innovation & Availability:** The need for more sensitive child-friendly diagnostic tools to bridge the gap in paediatric case detection.
- 2. **Supply & Delivery:** New child-friendly TB treatments are now available, but a number of barriers remain to ensure their scale-up.
- 3. **Demand & Adoption:** An estimated one million children require TB treatment per year; however only 36% of all paediatric TB cases are diagnosed/reported.

Conceptual Pathway



Risks

Strategic risks

- Untimely delivery of evidence to contribute to WHO normative guidance.
- Country health systems unsupportive of integration and decentralisation efforts.

Implementation risks

- New paediatric TB FDCs, GeneXpert Omni and Xpert Ultra are not available in project countries.
- Countries' MoH are unprepared to adopt and use new fixed dose combinations.

Sustainability risks:

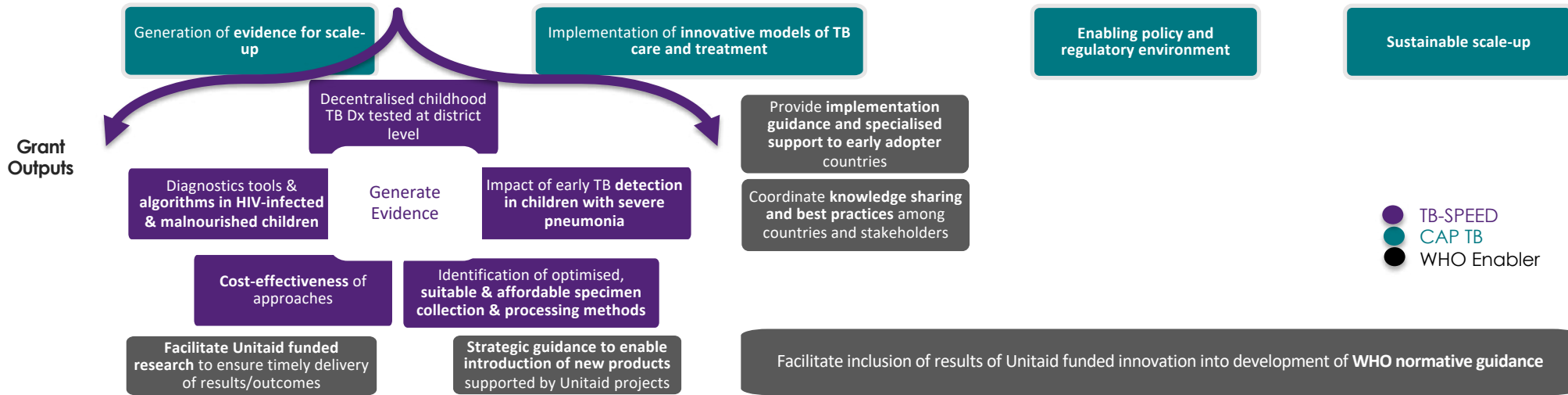
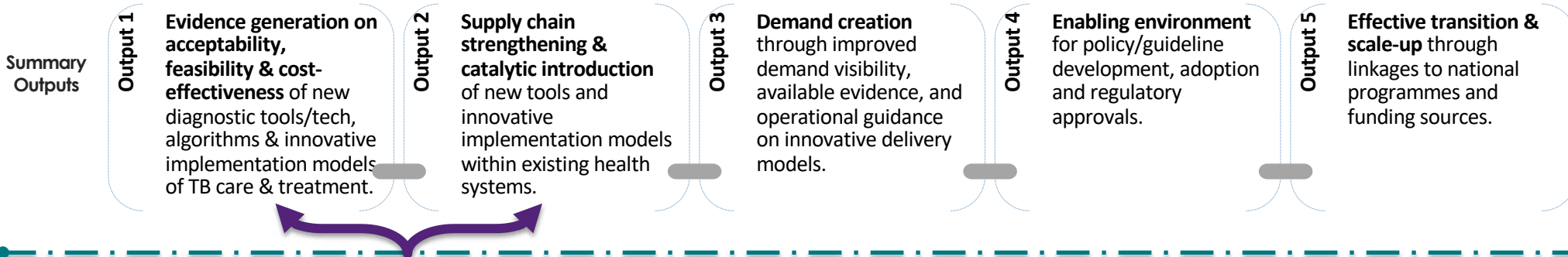
- Limited political commitment for scale-up in implementation countries.
- Inadequate funding from scale up-donors and country governments.

12. World Health Organization, 'Global Tuberculosis Report 2015', WHO, Geneva, 2015



- Impact**
- ✓ Reduction in child mortality from TB
 - ✓ Reduction in aggregate cost to treat paediatric TB cases (e.g. improved cost per DALY)
 - ✓ Contribute to averting future TB drug resistance in LMICs

- Outcomes**
- ❖ **Innovation & Availability**
 - Displacement of sub-optimal treatment options with new child-friendly formulations.
 - Cost-effective innovative diagnostic tools.
 - ❖ **Supply & Delivery**
 - Functional, integrated and sustained supply chain system for new formulations.
 - ❖ **Demand & Adoption**
 - Enabling policy environment that facilitates and accelerates access to TB diagnosis and management innovations.
 - Improved TB diagnosis in children through decentralised approaches for high TB-burden settings.
 - Improved treatment initiation, adherence, cure rates and coverage of paediatric TB treatment.
 - National level plans & budgets for paediatric TB treatment at scale.





Evaluation Design

Purpose

To assess the overall impact of Unitaid’s ‘Scale-up of better TB diagnosis and treatment in children’ investment between 2017 and 2022 across the following evaluation domains: relevance, coherence, effectiveness, efficiency, impact and sustainability.

Objectives

1. To assess the relevance of Unitaid’s direct and indirect investments towards scaling up TB treatment in children. Examining how each grant implemented the right things, the right way, including engaging stakeholders and adapting the course as needed. (Relevance & Coherence)
2. To assess the contribution of Unitaid’s investments towards achieving the milestones outlined in the WHO roadmap to end TB in children and adolescents. (Effectiveness)
3. To determine the extent to which Unitaid’s direct and indirect investments accelerated access to childhood TB diagnostics and treatments in LMICs and the potential scalability of these interventions. (Effectiveness, Scalability & Sustainability)
4. To assess the efficiency of the projects (Efficiency)
5. To determine the impact of the Unitaid childhood TB investments portfolio. (Impact)

Methods

Desk review of existing project documents, reports and publications to harness qualitative and quantitative data on project outcomes.

Qualitative interviews: virtual or in-person key informant interviews.

Site visits to two project locations each in four countries: Cameroon, Uganda, DRC and Zambia.

Modelling the expected public health and economic impact of the portfolio of projects.

Case Studies of six countries (Cameroon, Uganda, DRC, Zambia, India and Cambodia) assessing the projects’ performance at country-level, based on site visits, qualitative interviews and document reviews.

Triangulation of data from different sources/stakeholders to establish the strength of evidence and level of contribution of achieved results.

Theory of Change (ToC) Review: The ToC was reviewed and revised to update changes in assumptions, the projects’ focus and context since the Afl design, as well as to identify the project contributions to different elements of the ToC. Further, the ToC informed evaluation questions, analysis and the reporting structure.

Geographical Scope

The evaluation covered all project countries via global key informant interviews and document review. It also conducted country-level interviews in six countries and an in-person site visit in four countries, as detailed above.

Participants

85 participants were interviewed, either one on one or in groups.

- Lead grantees (EGPAF & University of Bordeaux)
- Consortium partners (SAATHII, IRD, MUJHU, Solthis, PAC-CI, INS, Institute Pasteur and UNZA)
- Global Fund
- USAID
- World Health Organization GTB/POSEE
- Stop TB Partnership
- Aurum Institute
- University of Stellenbosch/PADOTB
- Global TB Caucus
- Ministry of Health (MoH)/ National TB Programme (NTP)- National & Sub-National levels
- Community Group Representatives
- Civil Society Organizations
- Clinicians from implementing countries
- Community Health Workers
- Unitaid

Limitations

- The evaluation took place when many research activities were still in progress and some important data/study results, including on cost-effectiveness, were not available.
- The number of interventions within the projects created challenges with estimating impact, especially decision-making around assumptions.
- The large scope of the portfolio evaluation, with each individual project having its own large portfolio of interventions, was not ideal for a single evaluation report.

Strength of Evidence Framework

Quantitative Data

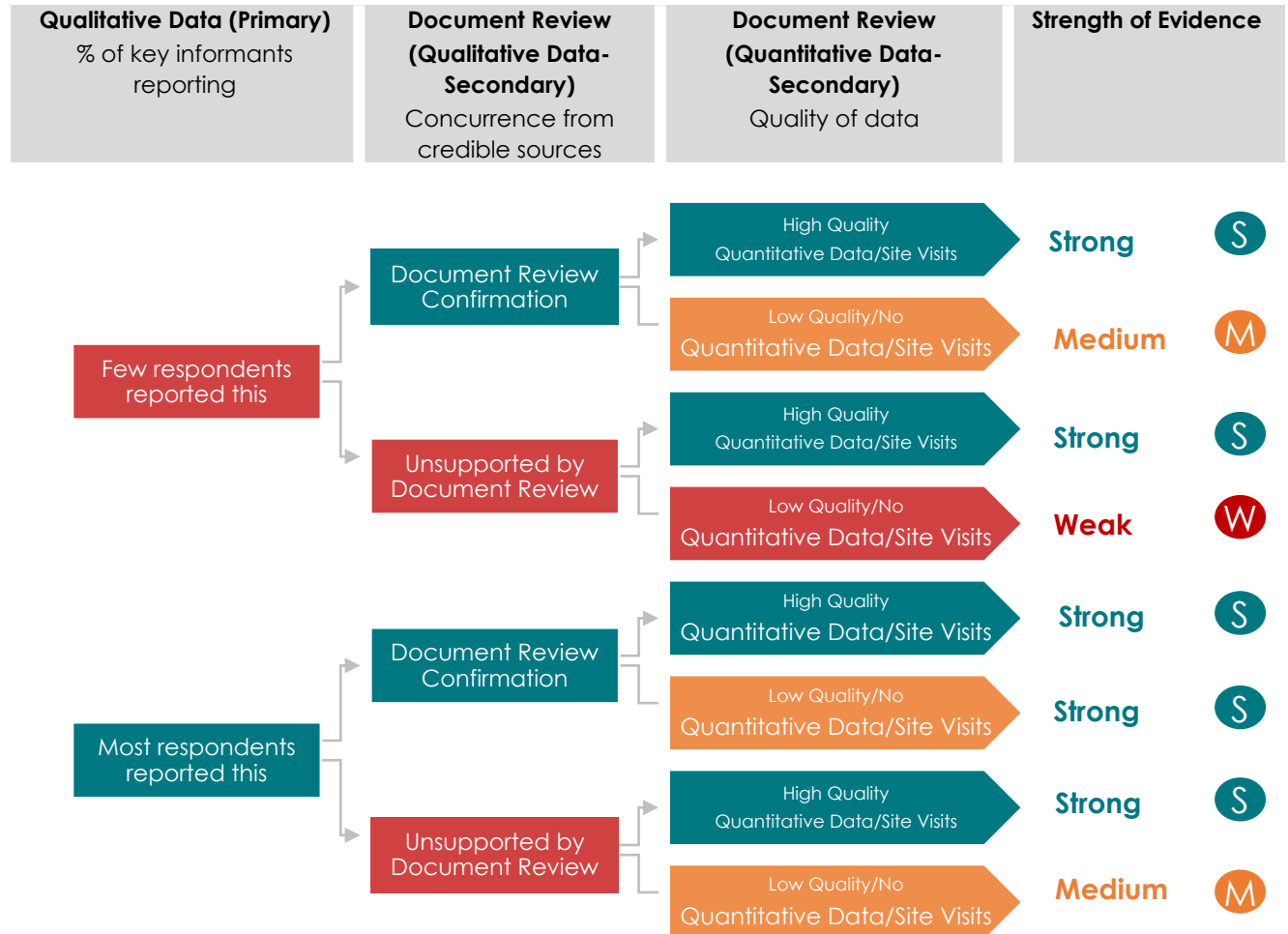
We consider high-quality quantitative data sources to be objective; hence, any result backed with verifiable quantitative data is considered strong irrespective of the presence of qualitative interview feedback or qualitative inputs from document review.

Qualitative Data

Qualitative data is often more subjective and prone to a number of biases from both the interviewer and responder, thereby affecting the validity and reliability of findings. The strength of qualitative interview data increases where a large volume of respondents provide the same feedback, and where this is complemented by qualitative inputs from document review and/or quantitative data findings or observations during site visits. Our framework emphasises this.

This framework guided the final compilation of evaluation findings and recommendations. **Evidence is categorised as Strong, Medium or Weak.** Results based on weak evidence are not included in the report.

Fig 3. Strength of Evidence Pathway





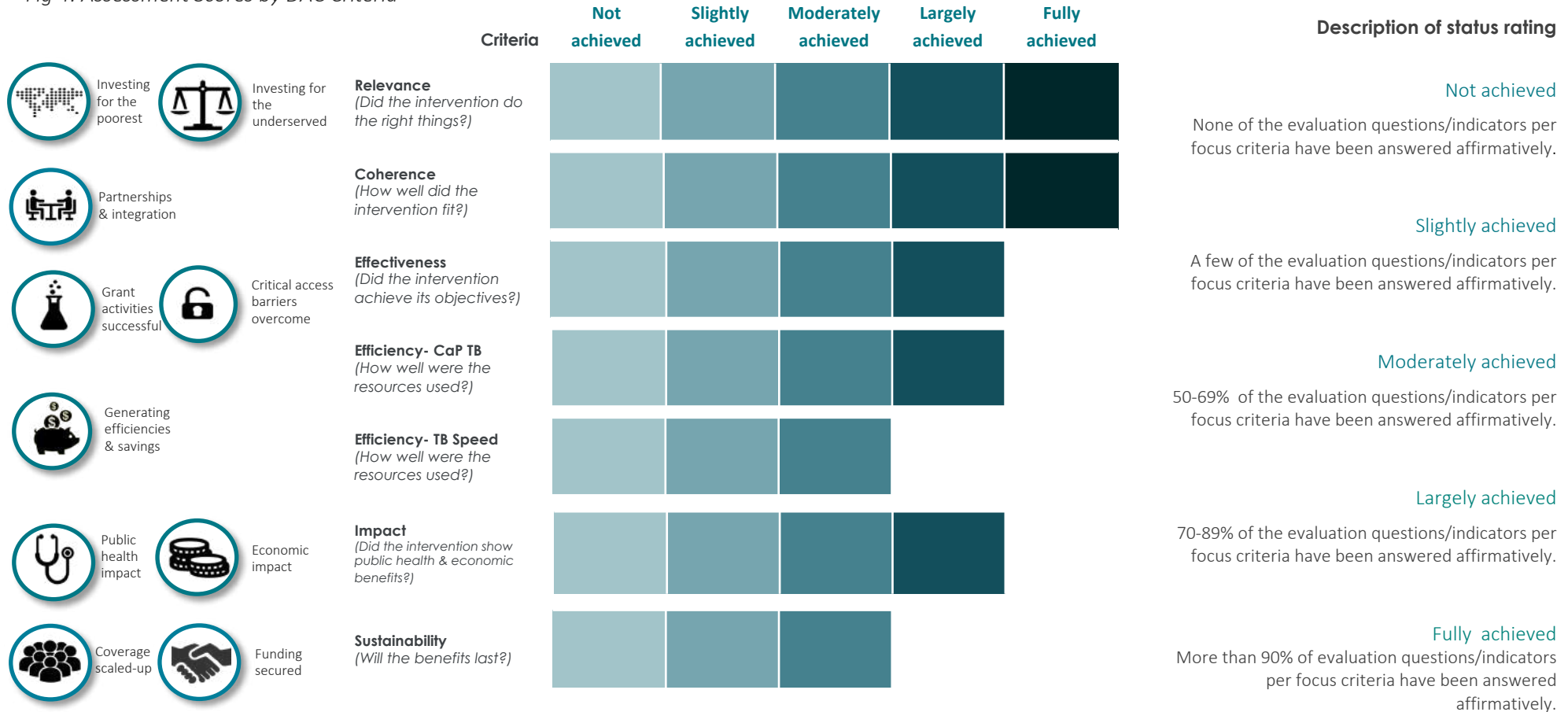
Findings

- Assessment Scores
- Relevance
- Coherence
- Effectiveness
- Impact
- Efficiency
- Sustainability
- Learning
- Risk Mitigation



Assessment Scores

Fig 4: Assessment Scores by DAC Criteria



Relevance

To what extent did the projects respond to the needs of targeted beneficiaries, including adaptation of design and implementation approaches to contextual changes and addressing issues related to inclusion and equity?

Overall, the projects were responsive to the needs of the beneficiary countries as well as the global TB response as a whole.

With the high burden of TB, high mortality rates, underestimated prevalence due to weak diagnosis, sample collection challenges and limited health worker capacity in paediatric TB services, the projects were much needed. In addition, there has been limited funding for interventions/research focused on childhood TB. Also, with new diagnostic tools and child-friendly medicines on the market, several innovations were ready to be tested operationally or deployed. The projects were composed of a selection of interventions and research questions that included these new innovations and addressed the major priorities in the childhood TB space at global and national levels. Respondents at all levels agreed that projects with a paediatric TB focus are not just important but critical because of the dire need and limited actors focusing on this area.



Beneficiaries at Jinja Regional Referral Hospital, Uganda

S Finding 1. The projects targeted the most vulnerable populations. They were implemented in almost half of the 30 HBCs, and prioritised highly vulnerable groups of children (HIV+, SAM and Severe Pneumonia) within LMICs, contributing to equity and inclusion.

The projects targeted about half of the countries listed in the 30 TB High Burden Countries (HBC) list¹³, with at least two countries from each region covered (East Africa, West Africa, Southern Africa, South Asia and South-East Asia). This focused geographical scope meant that the impact achieved would not only be significant to the individual countries, but impactful to the global disease burden. The large number of countries would potentially allow for significant external validity of research findings. As a result, evidence generated is expected to be more representative of many diverse contexts with a high potential to be transferable to other countries in the regions. Many respondents differentiated these projects because of their geographical scope, indicating that these multi-country projects will hasten the generation of evidence that would be contextually appropriate for many different countries. A few respondents argued that the projects could still have achieved their results with half the number of implementation countries. However, due to the limited research on new innovations in the paediatric TB space, it was important to have a sizeable number of countries testing these innovations.

13. <http://www.tbfacts.org/tb-children/#sthash.F7e8OM9G.dpuf>



Relevance

The projects demonstrated equity and inclusion by prioritising children (including highly vulnerable groups of children) in LMICs, attempting to improve TB diagnostics and treatment access for this underserved population. The focus on diagnosing TB in children is a demonstration of equity because of the disproportionately higher mortality among children compared to adults. The projects also targeted paediatric high-risk groups such as children with clinical presentation of severe acute pneumonia, as well as HIV-infected and malnourished children through targeted studies and integrated services. The countries selected for implementation by these projects include low-income and lower-middle-income countries according to the World Bank classification. In addition, project locations selected within the country included lower income strata and areas with very weak health systems, ensuring that the projects really invested for the poorest and underserved, with poverty being a well-established facilitator for the transmission of Mycobacterium tuberculosis. Many respondents reported that funding available for childhood TB services in these countries is very limited, with some countries not having an earmarked line for paediatric TB. They also described the importance of the decentralisation approach to district hospitals and Primary Health Care Centres (PHC), as necessary to enable the most socio-economically disadvantaged populations access these services.

Finding 2. The projects refocused the Afl to the most important health service delivery needs: the huge diagnosis gap, limited paediatric TB services at lower-level facilities and limited health worker capacity in paediatric TB services.

Among the estimated one million cases of paediatric TB (<15 years) reported by WHO in 2015, only 36% of these cases were diagnosed or reported.¹⁴ WHO estimates reveal that there were over 210,000 child deaths from TB globally in 2015 and most of these were never diagnosed, and so could not have been treated.¹⁴ This diagnosis gap is attributed to weak case finding, inadequate or underutilised diagnostic tools, difficulties diagnosing children through sputum production, and health workers at lower levels of the health system in LMICs untrained in TB diagnostics and management. Childhood TB detection is also more complex than detection in adults, thus requiring different approaches and tools. Further, there was also a lack of appropriate paediatric formulations, and poor linkage to care, but these were secondary to diagnosis. Both projects were designed to address these gaps, with a heavy focus on implementing innovations to increase screening, identification, and diagnosis. These innovations include; better clinical diagnostic algorithms, leveraging available diagnostic technologies, integration models, improved index case tracing and improved health worker capacity at lower levels of the health system.^{15,16} Implementers and other global respondents reinforced the fact that diagnosis was the real gap

and continues to be an important intervention area to improve access to TB care for children.

In addition, TB diagnosis and treatment services have largely been centralised in most LMICs, with trained clinicians and well-equipped laboratory facilities available at secondary and tertiary facilities. These facilities are hardly accessible to the populations who need TB services the most, who are often in remote and poorer communities. Children are screened at district hospital and lower level health facilities but rarely make the referral to higher level facilities, where confirmatory tests and treatment are available. Both projects implemented decentralisation initiatives that strengthened the capacity of health workers at these lower levels to deliver more advanced diagnosis and treatment services for children. The decentralisation models of these projects were seen by many stakeholders at global and national levels as a game changer of sorts, and described by many as the most relevant intervention the projects deployed. There was, however, a different perspective in Uganda, where decentralisation was not viewed as the “magic pill.” Respondents reported that communities had already developed a belief system that rated lower-level health facilities inferior and that these facilities were inadequate to deliver all the services they needed. Respondents described the need for targeted campaigns to address this mindset shift, not just awareness about childhood TB and available services.

14. WHO Global Tuberculosis Report 2015. Available at http://www.who.int/tb/publications/global_report/gtbr2015_executive_summary.pdf

15. CaP TB Project Plan

16. TB Speed Project Plan



Relevance

S Finding 3. The projects adapted well to several challenging contextual changes, including the COVID-19 pandemic, political unrest, economic instability and industrial actions (strikes) across many implementation countries.

The COVID-19 pandemic was the most critical contextual change through the life of the projects. Implementers described reduced patient attendance, resulting in low enrolment rates; health care workers fearing exposure and going on strike due to lack of Personal Protective Equipment (PPE) or compensation for their risk; procurement delays and movement restrictions affecting supervision and site support activities.

The implication of this was that most studies on both projects had to be halted temporarily and subsequently required an extension period for completion, thus the NCE. The projects also terminated activities in some project locations earlier than planned and experienced an underspend due to implementation delays. TB Speed was impacted more by the pandemic-related disruptions as some studies were still in early stages or requiring modifications to their ethical approvals; the pandemic exacerbated existing delays, prolonging study timelines by up to an additional 12 months.

The projects were responsive and made efforts

to mitigate the impact of the pandemic. The CaP TB team monitored the situation closely, regularly collecting data on the situation and its impact. They also provided PPE for health services in project locations. TB Speed developed remote monitoring processes to manage research teams, and the University of Bordeaux also obtained an ANRS-approved funding for a COVID-19 sub-study to assess the impact of SARS-CoV-2 in children with severe acute malnutrition. The projects adapted well to this challenge; however, it caused significant time inefficiencies and slowed down progress towards project targets. All respondents alluded to COVID-19 disrupting access to health services.

There were also other contextual changes in specific countries that impacted health workers, health care services and project implementation. In Zimbabwe, the high inflation rates and cost of living, industrial actions by service providers and a bloodless coup which resulted in the removal of the long-time President, Robert Mugabe. Kenya also experienced industrial actions by service providers, and in Sierra Leone, there were significant health systems gaps due to the past Ebola epidemic. These resulted in a decrease in the available workforce at sites and decreased numbers of patients served, resulting in a decrease in number of children diagnosed. CaP TB project had to close activities in two implementation districts, and TB Speed SAM study (Output 2) had to be transferred from Sierra Leone to Zambia, where there was a more enabling environment for

implementation. All respondents described the challenges faced due to disruptions by COVID-19 and other emergencies, stating that the projects responded well.





Coherence

To what degree do the projects' interventions fit with other interventions and align with priorities/needs identified by partners/the global disease response? How are the projects adding value?

Overall, the projects were externally coherent and made significant efforts to ensure alignment of global and country priorities and partners. They were also internally coherent with each other as well as WHO through its enabler grant, and also complementary to other Unitaid projects, with negligible overlaps. The projects were coherent by design and implementation approaches, ensuring alignment with global and country priorities and partners through close working relationships with key global actors especially convening the Paediatric TB Operational and Sustainability Expertise Exchange (POSEE) group. The CaP TB project also consistently engaged the two critical sustainability partners (The Global Fund and USG through PEPFAR, USAID and CDC). At the country level, both projects worked closely with National TB programmes and Ministries of Health. CaP TB engaged more with other implementing partners and advocacy actors, while TB Speed actively engaged the scientific community. The projects were complementary to other Unitaid projects with CaP TB's global and national advocacy efforts creating momentum around new formulations and regimens that other Unitaid TB projects leveraged (IMPAACT 4 TB and BENEFIT Kids).

Finding 1. The projects were externally coherent. They aligned very well with global policies (WHO End TB strategy, SDGs and Roadmap to end TB) with productive and synergistic partnerships with key actors in the global TB response, as they generated urgently needed evidence on feasibility and cost-effectiveness.

Global Policies & Strategies

The goal of both projects was to contribute to the reduction in childhood mortality from tuberculosis, aligning with the WHO End-TB strategy (2015-2035) with its vision of zero deaths, disease and suffering due to tuberculosis in children; the United Nation's Sustainable Development Goals (2016-2030), and the Roadmap towards ending TB in children and adolescents (2013, revised 2018). The projects were almost perfectly aligned to the aims and specific gaps identified in the 2018 roadmap, with over half of the priority gaps being addressed by these projects.

These gaps include:

- Further capacity building is required to ensure health workers' knowledge and confidence in prevention, diagnosis and management of children and adolescents exposed to/with TB;
- Functionality of regional Task Forces and national Working Groups variable and not always optimal due to a lack of a secretariat and other support;
- Limited reach or integration of TB services beyond TB programmes;
- Further scale-up of GeneXpert Ultra and child-friendly sample collection;
- Clear mandate required in most settings for TB to be addressed through maternal, newborn and child health (MNCH) programmes;
- National registration of child-friendly formulations and use of domestic resources for procurement is

slow/limited; and

- Need to develop and roll out child-friendly and sensitive point-of-care tests to diagnose TB in children earlier and at all levels of the health care system.¹⁷

The Projects' results also align with the road map milestones. The contribution to milestones is presented on page 31.

The projects were also set up to generate evidence to inform normative guidelines; evidence from these projects has already informed the new WHO guidance for the management of tuberculosis in children and adolescents.¹⁸ Further results to be released on conclusion of outstanding studies are also expected to be incorporated in future guideline revisions. Respondents also described the projects' objectives as very well aligned with the End-TB strategy and WHO's current paediatric TB research agenda.

The CaP TB project also aligned with the 2018 WHO LTBI guidelines.¹⁹ The new guidelines include a recommendation on the use of 3 Rifampicin and Isoniazid (3RH) regimen daily for three months for the treatment of LTBI in contacts of TB patients. Other global stakeholders such as PEPFAR also increased their focus on improving LTBI provision for HIV-infected populations during this period, creating further alignment points for the project. These shifts increased funding availability and political will to further LTBI programmes and became scalability and sustainability enablers for CaP TB's Output 3 (Rapid uptake of and access to improved paediatric TB treatments for both active and latent TB).

17. Roadmap towards ending TB in children and adolescents (2018). Available at <https://www.who.int/publications/i/item/9789241514668>.

18. WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

19. Latent tuberculosis infection: updated and consolidated guidelines for programmatic management. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

Coherence



Global Partnerships

The projects established key working relationships with critical global bodies, including the WHO Global TB Programme (GTB), especially the enabler grant team. This enabled seamless guidance and communication for design of research studies, programme implementation and utilisation of findings for global guidance development.

The CaP TB team also created a strong partnership with the Global Drug Facility (GDF) to identify and address any gaps in the paediatric TB market and data to inform demand in project implementation areas. The team worked closely with the Stop TB Partnership, Global TB Caucus and TAG to harness key political and advocacy opportunities to highlight the needs of paediatric TB. CaP TB also convened the POSEE group, which includes representatives from WHO, Global Fund, CDC, USAID, UNICEF, IMPAACT4TB, BENEFIT KIDS, as well as TB Speed, to identify and address key evidence, programmatic and funding gaps. The WHO enabler team were critical actors on the POSEE group and provided strategic advisory on the projects' interventions. Lastly, the project worked closely with the two potential sustainability partners (The Global Fund and USG) at both global and country levels. Keeping them abreast of its implementation models, costs and outcomes towards potential resourcing of Paediatric TB in their upcoming grants.

TB Speed also aligned well with other research projects, with the study design of the in vivo study (TB Speed Output 4) adapted to compare the TB Speed method to two other stool processing methods by FIND and KNCV; thus, the evaluation compared all

three methods. Global respondents applauded the high level of collaboration between the project implementers and other global actors (other project implementers and funders). They also showed keen interest in the projects' objectives as they are also implementing similar interventions, stating that the learnings from these projects are relevant to their work.

S Finding 2. The projects created strong relationships with country stakeholders and adapted well to country priorities and existing programmes. There were, however, some gaps in sub-national level engagement by TB Speed.

Country Partnerships

At the country level, both projects worked very closely with NTPs, Ministries of Health, civil society actors, other project implementers and funders. Country-level respondents reported being engaged by both projects to varying degrees.

EGPAF already had very close relationships with the MoH in most of the implementation countries, so they continued to leverage this relationship on the CaP TB project, engaging them from design through implementation with a goal to ensure technical capacity exists with NTPs, also to ensure that the implementation models are sustainable: feasible, cost-effective and scalable. This included establishment, revitalisation or active participation in paediatric TB Technical Working Groups. Ministries of Health reported the ability to better coordinate activities with other partners towards creating synergies and preventing duplications due to CaP TB's continued interaction and progress updates at these TWGs. The CaP TB project also worked closely with civil society organizations (CSO), utilising these local actors to create community awareness, demand creation and conduct advocacy. The project provided

trainings and small grants for CSOs to conduct these activities. Ministries of Health and CSO respondents reported being involved in project activities, and many reported they were consistently kept abreast of the CaP TB project activities and results.

CaP TB also made efforts to leverage existing projects in-country to create synergies and prevent duplications. EGPAF's USG-funded project had been co-located with CaP TB in nine project countries. This allowed the project to leverage resources already provided to these sites for service provision and focus more on guiding the introduction of the models of care while saving on some equipment, commodities and supply needs. At the end of some of these projects, CaP TB proactively reallocated its budget to begin providing these resources for continued implementation of CaP TB's initiatives.

TB Speed engaged NTPs and other National Scientific leaders in project countries, consulting with them during protocol development to ensure adaptation to local contexts. MoH facility staff were the implementers of project research interventions in the different study sites. They established country project committees for continuous interaction with key stakeholders; however, TB Speed's engagement with communities and sub-national authorities was limited. The project's primary engagement with communities was through community consultations in the design of its research studies. District TB officials in three countries where site visits were conducted reported not knowing about the project or not being well engaged by the project. For a research project, the level of community engagement seemed appropriate; however, District level engagement could have been stronger. These actors could have participated in introductory meetings and conducted periodic joint supportive supervision with implementers.

Coherence

These sub-national actors often play a key role in planning and resource allocation for implementation of activities at their level and would have been better poised to advocate for inclusion of some of the project interventions when these are adopted at national level. They also have a critical role in quality assurance of lower-level health facilities where decentralisation initiatives took place.

TB Speed also leveraged national initiatives to decentralise paediatric TB services in Mozambique, Sierra Leone, and Uganda in 2019. This required a revision of the TB Speed approach to align with the national plans. The project integrated the national decentralisation plan into its approach.

formulations towards creating a sustainable market for these products, further reinforcing the successes of STEP-TB. TB Speed was also designed to generate new evidence that reinforces previous work in the field of childhood TB diagnosis, that showed the high feasibility and the good diagnostic performance of the combination of one Nasopharyngeal Aspirate (NPA) and one stool sample in HIV-infected children with suspected TB.²²

The projects were also expected to be synergistic, with evidence from TB Speed feeding into CaP TB's implementation. This was not fully achieved as TB Speed's research was delayed and too late to fit into CaP TB's implementation timeline. There was also some overlap across Unitaids' TB project portfolio for TB Preventive Therapy, as all four projects (CaP TB, TB Speed, IMPAACT4TB and BENEFIT Kids) were implementing programmes to increase access to TPT. Also, some of the project countries overlapped; however, there was no overlap within countries, reducing the potential for duplicated efforts. Further, CaP TB's global and national advocacy efforts created momentum around new formulations and regimens that these other projects leveraged.

created new algorithms. Its decentralisation of childhood tuberculosis diagnosis to district health system level and below was viewed by most respondents (at global and country levels) as the most valued innovation, with most respondents identifying this as the most unique intervention deployed by the project. Many respondents also mentioned the use of stool samples, evaluating the detection of TB in children with severe pneumonia and algorithms for childhood TB detection in HIV-infected and severely malnourished children as unique because these had not been tested within the paediatric TB diagnostic research landscape. CaP TB's screening in non-TB entry points, household contact tracing, and provision of preventive treatment in households were also deemed unique by respondents, with TB screening only done at TB and HIV service delivery points prior, and contact tracing mostly facility-based. CaP TB's integrated model also included deploying the child-friendly FDCs earlier mentioned, which were partially introduced in many project countries at baseline. These countries benefited from additional support (guideline reviews, sourcing, funding and procurement planning) for full adoption. The projects were considered a valuable addition to NTPs partnerships with the multiple complimentary interventions being tested and deployed, and many respondents expected the project to provide the evidence needed for normative guidance and national policies' updates. Global respondents reported that the projects helped progress adoption of newer medicines and diagnostic tools, increasing visibility of these interventions globally.

Finding 3. The projects were internally coherent with each other as well as the WHO enabler grant. They were also complementary to other current Unitaids projects and built on past investments/initiatives consolidating on the successes and improving on the evidence base for recent innovations.

The weak case finding of paediatric TB cases around the world resulted in an artificially small and fragmented market for paediatric TB medicines, as well as poor research and development and manufacturing investments for child-friendly TB diagnostics and treatment.²⁰ Through a previous investment in 2015, Unitaids' STEP-TB project, implemented by TB Alliance and WHO, launched the first child-friendly (dissolvable and flavoured) first-line fixed-dose combinations (FDC) (RHZ 75/57/150) and (RH 75/50).²¹ The CaP TB project was designed to increase the demand for and uptake of these new

Finding 4. The projects were also unique because they deployed recently developed tools and new service delivery models that were not yet in use in most countries whilst strengthening available health systems resources in project countries, and implementing in underserved locations with limited support for paediatric TB services.

TB Speed deployed and tested new diagnostic tools and approaches, optimised existing technology and

20. Unitaids, 2014 Tuberculosis Medicines Technology and Market Landscape, available at http://Unitaids.org/images/marketdynamics/publications/Unitaids-TB_Medicines_Landscape-2nd_edition.pdf

21. Addressing neglected childhood tuberculosis, available at <https://unitaids.org/project/addressing-neglected-childhood-tuberculosis-step-tb/#en>

22. ANRS 12229 PAANTHER 01 study





Effectiveness

Did the projects achieve their intended results?

Overall, the projects were largely effective and achieved their intended outcomes: generating evidence across several target childhood TB diagnoses and treatment interventions to inform WHO guidance; introducing and deploying innovative diagnostic tools, models of care and new treatments; and creating an enabling policy and regulatory environment for adoption and scale-up of these interventions.

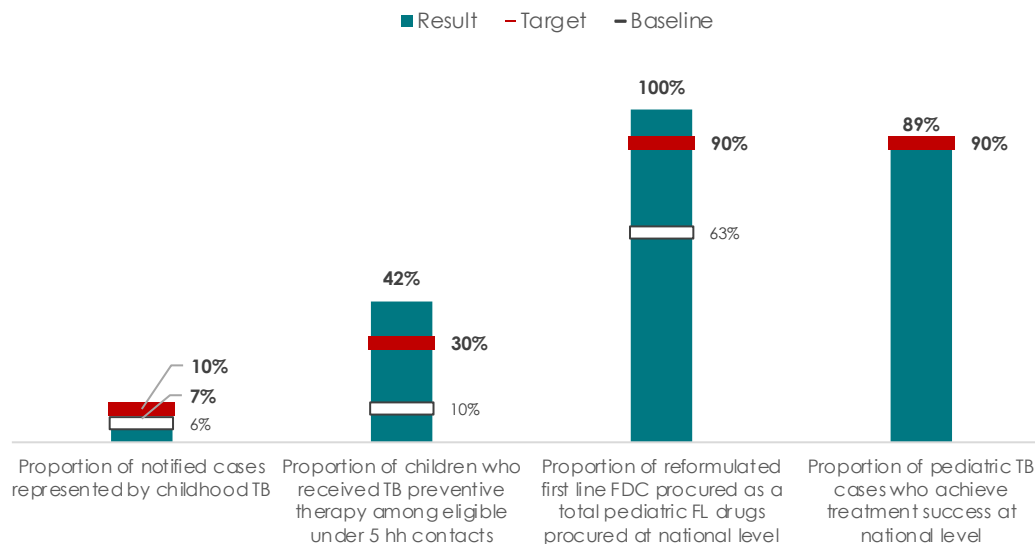
The projects addressed key access barriers, successfully introducing and generating evidence on child-friendly interventions (Innovation & Availability). They strengthened the capacity of health systems (including health workers and community actors) to deliver these interventions through extensive trainings and supportive supervision and created an enabling policy and regulatory environment for adoption and scale-up, including the development of training materials and budgeting tools available globally (Demand & Adoption). Lastly, they collaborated with NTPs and GDF to strengthen supply chains, including supporting product switches to the new paediatric formulations (Supply & Delivery).

S Finding 1. The CaP TB successfully implemented all planned activities across its stated objectives, achieving most of its expected service delivery and policy change outcome targets.

Service Delivery Outcomes

The project largely achieved service delivery outcomes, which were measured at national level: TB preventive therapy was provided to 42% of eligible under five household contacts, 12 percentage points above the 30% target; 100% of paediatric FL drugs procured at national level was the reformulated first line FDCs. An estimated 89% of paediatric TB cases achieved treatment success, just under the 90% target. An estimated 7.1% of notified cases were represented by childhood TB, below the target of 10%.

Fig 5. CaP TB Service Delivery Outcome Indicators





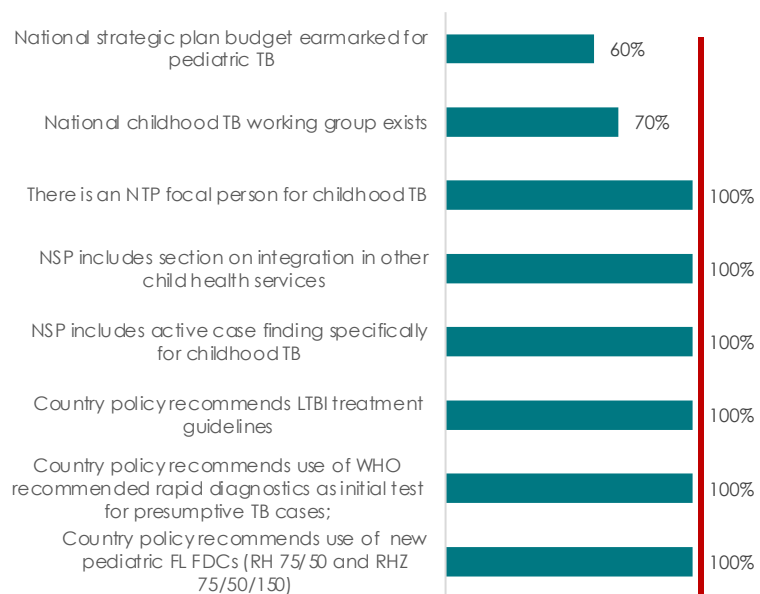
Effectiveness

Did the projects achieve their intended results?

Policy and Guideline Outcomes

The projects also achieved most policy-related outcomes: 100% of project countries included active case-finding and a section on integration into other child health services in their NSP; updating their LBTI treatment guidelines; adopting rapid diagnostics as initial test; use of new paediatric FL FDCs; as well as having an NTP focal person for paediatric TB; however only 70% have a national childhood TB working group and 60% have an NSP budget line earmarked for paediatric TB.

Fig 6. CaP TB Policy Guideline Outcome Indicators (% of countries)



M Finding 2. TB Speed completed research activities across its five studies, introducing innovative diagnostic approaches within study sites.

The project largely achieved its intended outcomes,²³ generating evidence across several target childhood TB diagnosis interventions to inform WHO guidance. The project contributed to creating an enabling environment through effectively engaging with WHO and other research institutions globally, resulting in increased interest by global actors. The project effectively addressed the innovation and availability barrier by introducing innovative diagnostic approaches and strengthening the capacity of health workers in supported facilities to deliver the required paediatric TB interventions within its research portfolio through trainings and supervision of research staff. The project demonstrated that these diagnosis interventions, though resource intensive, could be delivered at lower-level facilities. Many global and country-level respondents described this as the core achievement.

S Finding 3. The WHO enabler worked closely with both projects providing strategic guidance on introduction of new approaches and ensuring alignment on evidence generation efforts. The enabler team supported the design of the projects' research agendas to ensure alignment with WHO GTB's research needs and subsequently, the review of preliminary evidence towards the inclusion of results of Unitaid-funded innovations into development of WHO normative guidance; and dissemination of results within and beyond project countries (currently ongoing). The WHO enabler and TB Speed implementers expressed concerns about the use of Unitaid's logframe approach for performance management. The enabler grant implementers do not interact directly with country-level actors to collect primary data and have significant constraints in reporting indicators not already collected via existing routine sources. The performance measurement process needs to be adapted to accommodate these types of projects.

²³ TB Speed project results are treated as research results not project outcomes, and as a result cannot be used as performance measures for the project. This report therefore excluded TB Speed logframe indicators, as they are not a direct reflection of the effectiveness of the studies.

Effectiveness

Table 1: CaP TB Project Results: Outputs by Country

Key

Low population coverage

Low coverage & less than 70% of proportional target met

Countries Performance against targets	Children screened for TB (% of project target)	% Presumptive TB cases who are tested with Xpert+	Cases diagnosed with active TB disease (% of project target)	% TB index cases with successful contact tracing+	% TB cases on DS-TB treatment+	%TB cases who achieved treatment success+	%Eligible patients started on preventive therapy+	% Patients who completed preventive treatment+
Cameroon	>100%	94%	>100%	15%	99%	89%	46%	92%
CDI	>100%	84%	>100%	33%	95%	83%	47%	85%
DRC	>100%	60%	91%	67%	97%	81%	118%*	83%
Kenya	82%	63%	79%	32%	99%	87%	74%	94%
Lesotho	>100%	85%	83%	41%	98%	86%	77%	84%
Malawi	>100%	24%	97%	46%	97%	89%	46%	98%
Tanzania	>100%	34%	85%	14%	99%	95%	79%	99%
Uganda	>100%	62%	>100%	27%	100%	91%	49%	97%
Zimbabwe	>100%	83%	93%	15%	98%	86%	128%*	88%
India	96%	50%	73%	N/A	99%	85%	N/A	89%

The CaP TB results and targets varied by country especially results on the percentage of presumptive TB cases who are tested with Xpert and the percentage of eligible patients started on preventive therapy, where about half of the project countries are reaching less than 70% of the eligible population, as the use of Xpert was dependent on national regulations. The percentage of TB index cases with successful contact tracing was low across countries, with results ranging from 14% to 46%, and one outlier result, 67% in DRC. The substantial variation by country was attributed to varying national recommendations regarding contact tracing and COVID-19 movement restrictions. However, most of these results were above 70% of the target and represented improvements from baseline.

% Presumptive TB cases who are tested with Xpert: The proportional target was much lower in several countries as a result of the baseline at the start of the project, with Malawi's target set at 10%, DRC at 25% and Kenya at 47%. Other countries had targets above 60%. So even though the highlighted countries had a large proportion of the target population uncovered, only Tanzania and India were under 70% of their proportional target. Tanzania experienced national stockouts of GenXpert cartridges and long government verification processes of Xpert Ultra delaying rollout. In India, the COVID-19 second wave in 2021 seriously affected all sample collection, and the project closed out in August 2021, earlier than originally planned.

% TB index cases with successful contact tracing: All the countries' proportion targets were under 50%, with Tanzania and Malawi's targets being the lowest at 29%.

Most countries did not meet their proportional target, notably Cameroon, Tanzania, Zimbabwe, Uganda and Cote d'Ivoire, which only achieved 36%, 48%, 40%, 64% and 68% of their target respectively. The main challenge that affected this indicator across countries was COVID-19-related movement restrictions, with lower than anticipated index cases and limited or no access to contacts.

% Eligible patients started on preventive therapy: Targets here were also low, with most country targets under 50%, notably Uganda at 13% and Lesotho and Tanzania at 16%. So, even though the coverage is still somewhat low, all countries achieved over 70% of their proportional targets, with many achieving over 90%. These results represent improvements from very low baselines across countries.

+ indicators represent % of the eligible population and not % of the project target.

* Results over 100% or low proportions LBTI treatment are due to challenges estimating eligibility with a hybrid of the WHO approach and the projects data on HIV positive children not on LBTI treatment.

Effectiveness Innovation & Availability

To what extent has the project contributed to increased availability of better approaches for the diagnosis of TB in children in LMICs?

M Finding 4. TB Speed successfully generated evidence across several target childhood TB diagnosis interventions, including their effectiveness, to inform WHO guidance on improved childhood TB diagnosis approaches. The paragraphs below summarise the studies' objectives and results. Some of the studies were still being finalised at the time of this evaluation, and as a result, their findings are not included here.



Operational research to implement and evaluate new decentralised childhood tuberculosis diagnostic approaches are tested at district health system level and below

Interventions: GeneXpert Ultra, NPA and stool samples, standardised symptoms screening and chest radiograph interpretation.

Locations: Cambodia, Cameroon, Côte d'Ivoire, Mozambique, Sierra Leone and Uganda.

Preliminary findings:

- **Decentralised childhood TB diagnosis** to lower-level health facilities, including PHC level, **is feasible.**
- **High uptake of NPA and stool sample collection** methods at both levels
- **High levels of acceptance among health care workers**
- **Increased detection yield at district hospitals but not PHCs**
- There is need for continuous mentoring to increase clinicians' confidence in clinical and Chest X-ray reading skills
- The findings underscore the **importance of clinical diagnosis of TB at decentralised levels of care.**



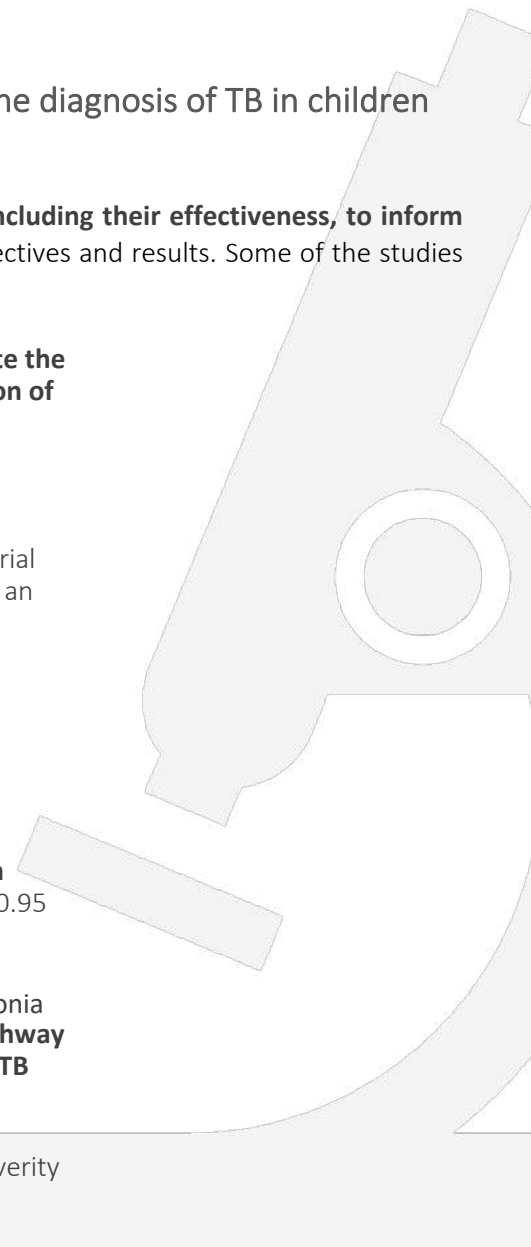
Cluster randomised clinical trial to evaluate the impact of adding systematic early detection of TB by Xpert Ultra on mortality and case detection among children with severe pneumonia.²⁴

Interventions: Cluster randomised clinical trial using Xpert Ultra, NPA and stool samples in an intervention group, compared to the WHO recommended standard of care.

Locations: Cameroon, Côte d'Ivoire, Mozambique, Uganda, and Zambia.

Preliminary findings:

- **The intervention was not associated with decreased mortality** [adjusted odds ratio 0.95 (95% CI 0.58-1.58).
- **Microbiological TB diagnosis remains important** in children with severe pneumonia because it can **simplify the diagnostic pathway and allow rapid initiation of appropriate TB treatment**
- **NPA tolerability in children with severe pneumonia was very good** despite the severity of their illness.





Effectiveness Innovation & Availability

To what extent has the project contributed to increased availability of better approaches for the diagnosis of TB in children in LMICs?



Cohort study to validate diagnostic tools and algorithms in highly vulnerable groups (HIV-infected and severely malnourished children) with presumptive tuberculosis. ²⁵

Interventions: Cohort study to validate diagnostic algorithms in HIV-infected children with presumptive TB and evaluation of diagnostic tests in severely malnourished children towards development of an algorithm.

Locations: Côte d'Ivoire, Mozambique, Uganda, and Zambia.

Preliminary findings:

- **The study confirmed the high sensitivity and specificity of the PAANTHER treatment decision algorithm for HIV-infected children with a sensitivity was 94.6% [90.4; 97.1] and specificity 58.2% [48.0; 67.8].**
- The use of the PAANTHER algorithm for TB diagnosis and treatment decision was also highly feasible in this population
- Only a few TB cases were missed by the score, and most children with detected TB initiated TB treatment within a day
- **The diagnostic model for children with SAM is also able to keep a specificity above 60% for a sensitivity of 85%.**
- Further analysis is in progress to compare the diagnostic accuracy of both algorithms to that of the WHO-suggested treatment decision algorithm and mortality outcomes, amongst others.



Microbiological and technological optimization study to identify and test simple and affordable specimen processing and collection methods for childhood TB diagnosis that can be used at lower-level health facilities in resource constrained settings. This also utilized the stool and NPA samples. ²⁶

Interventions: Identify and test simple & affordable specimen processing and collection methods for childhood TB diagnosis at lower-level health facilities in resource constrained settings.

Location: Uganda and Zambia.

Preliminary findings

- **Stool sample collection is feasible in children including highly vulnerable children.**
- **NPA sample collection showed higher feasibility than stool**
- **Ultra yield is low** with no major difference between the stool and NPA samples but was **increased when both samples were combined.**
- Results are also informing the **development of a manually operated nasopharyngeal aspiration device.**



Cost-effectiveness analysis of the proposed approaches and modelling of their market impact

- This was also conducted to further strengthen the evidence for feasibility of these approaches.
- The results were not available at the time of this evaluation.

25. TB-Speed preliminary technical report, July 21, 2022.

26. Manon Lounnas, Abibatou Diack, Mark P. Nicol, Sara Eyangoh, Eric Wobudeya, Olivier Marcy, Sylvain Godreuil, Maryline Bonnet, Laboratory development of a simple stool sample processing method diagnosis of pediatric tuberculosis using Xpert Ultra, Tuberculosis, Volume 125, 2020, <https://doi.org/10.1016/j.tube.2020.102002>. (<https://www.sciencedirect.com/science/article/pii/S1472979220301694>)



Effectiveness Demand & Adoption

How effective have the projects been in catalysing the update of global and national guidance and scale-up of decentralised and integrated models of care/ improved diagnostic and treatment products?

Finding 5. CaP TB contributed significantly to creating an enabling global policy and regulatory environment through evidence generation, global advocacy, capacity-building resources and new paediatric TB formulation's inclusion in global procurement lists. TB Speed primarily contributed through evidence generation.

Global Advocacy

For many years, childhood TB has been somewhat neglected in the global public health agenda, with policies and programmes heavily focused on adult TB and TB/HIV co-infection. These projects, especially CaP TB, have leveraged current global guidance (WHO post-2015 End TB Strategy, the Stop TB Partnership Global Plan to End TB 2016-2020, and the 2018 Roadmap for Childhood TB) to engage global actors to increase ownership, political and financial commitment towards childhood TB. CaP TB also collaborated with the Treatment Action Group (TAG) to disseminate advocacy reports that contributed to the development of the Childhood TB Roadmap. Both projects actively participated in relevant global meetings, including the UN High-Level Meeting on TB and the Union Conferences, to ensure key policies and declarations contained strong child-specific targets as well as to create more visibility for childhood TB interventions.

Evidence Generation & Global Policy

- Both projects introduced and generated evidence on several innovative models of care that cut across paediatric TB prevention, diagnosis and treatment, and these have informed the new WHO guidance and operational handbook for children and adolescents.

Capacity Building

- EGPAF supported the development of the new paediatric TB training package with the current WHO recommendations in 2021 in partnership with the Union. CaP TB adapted this training toolkit to each of the project countries' contexts, and it was utilised for trainings. It is also now available for other countries beyond the project locations. There is no evidence on if other non-project countries have utilised the package.

Commodity Adoption

- EGPAF also worked with the Global Drug Facility (GDF) to ensure that all key paediatric TB formulations, including single drug dispersible formulations, are included in the Expert Review Panel (ERP) and are thus quality approved for procurement by global sources, including the global fund.

- The close collaboration between CaP TB, TB Speed and WHO also informed WHO's launch of a tender for the supply of sample collection kits for sputum induction, nasopharyngeal aspiration and gastric aspiration in Q1 2021, with ongoing discussions with GDF to explore the possibility of including sample collection consumables in their catalogue.

Finding 6. The projects have increased the adoption and utilisation of improved diagnostic tools, child-friendly formulations, treatment regimens and models of care across project countries, as evidenced by revision of country guidelines, country procurements and service delivery standards.

There has been consistent underutilisation of many diagnostic tools and very limited coverage of paediatric TB services in LMICs globally. A landscape analysis of paediatric TB programmes in 12 African countries conducted in 2016 revealed that over 90% of the countries explicitly address childhood TB in their most recent NSP, showing a significant level of political will.



Effectiveness Demand & Adoption

However, a review of the budgets showed that just half had childhood TB activities listed as a separate line item in the NSP budget, with about 0.38-1.95% of the overall national TB budget allocated to childhood TB. The report also revealed dismal use of improved tools, technologies and treatment regimens that were already available, even when these were included in country guidelines and strategic plans.²⁷

S Policy Revision

The CaP TB project has made significant efforts towards improving the landscape. The project actively participated in TB guidelines and NSP revision processes in project countries. These engagements have resulted in the alignment of national policies to WHO recommendations and the inclusion of these new paediatric formulations FDCs (RH 75/50 and RHZ 75/50/150) and single dispersible formulations (INH and EMB); new TPT regimens – 3RH; diagnostic tools (MTB-Rif Ultra cartridges); models of care (screening integration, decentralisation and household contact tracing) into national paediatric TB policies, strategies, practice guidelines/algorithms, training materials, national registration and national essential medicines lists. There are, however, variations in the level of adoption across countries. See Table 2. Intervention Adoption

Matrix on page 29 for results across project countries. Country-level respondents, especially NTPs/MoH personnel, described the project as advocating for changes and providing consistent technical support for guideline revisions.

S Uptake of New Paediatric Formulations

Countries had already begun to procure the new paediatric formulations before the start of the projects, allowing for a quicker adoption of the new drugs than initially expected at country level. There was, however, a gap between availability of the FDCs in-country and actual utilisation; the new drugs were not always available at facility level; clinicians had not been trained, and many did not clearly understand the new dosing of drugs to weight bands; patients and civil society groups were not aware of the new formulations; and there were no job aids or IEC materials on the new paediatric formulations for health care workers and caregivers. CaP TB focused on addressing these and other gaps, and successfully increased uptake of these new formulations, quantifying demand, product transition planning, training to support appropriate use, introducing new formulations as part of the package of its new models of care, and documenting their impact. All ten CaP TB countries have registered these new paediatric First Line (FL) Fixed Dose

Combinations (FDCs) (RH 75/50 and RHZ 75/50/150) with their national regulatory authority* and are procuring them.

- Eight project countries procured EMB 100mg dispersible tablet for treatment of DS-TB in children. (Côte d'Ivoire and Kenya have not yet procured).

- Eight project countries procured INH 100mg dispersible tablet for administration of 6 or 9-month INH TPT regimen to children. (Kenya and Zimbabwe have not yet procured).

- Two countries (Malawi and Tanzania) have made the full transition from old paediatric medicines to these single dispersible formulations (INH and EMB). See Table 2. Intervention Adoption Matrix on page 29 for results across project countries.

S Capacity Building

A critical element of the projects' work towards achieving this result was the investment in designing and rolling out trainings. The project conducted trainings and supervision of HCWs and CHWs on paediatric TB management including management of childhood TB, prevention and treatment, contact tracing, advanced sample collection and transportation, drugs and regimens, and M&E. Models for delivery of training had to be adapted to country contexts, so there was quite some variability.

27. The policy and practice divide for childhood tuberculosis in Africa: a landscape analysis. 2016

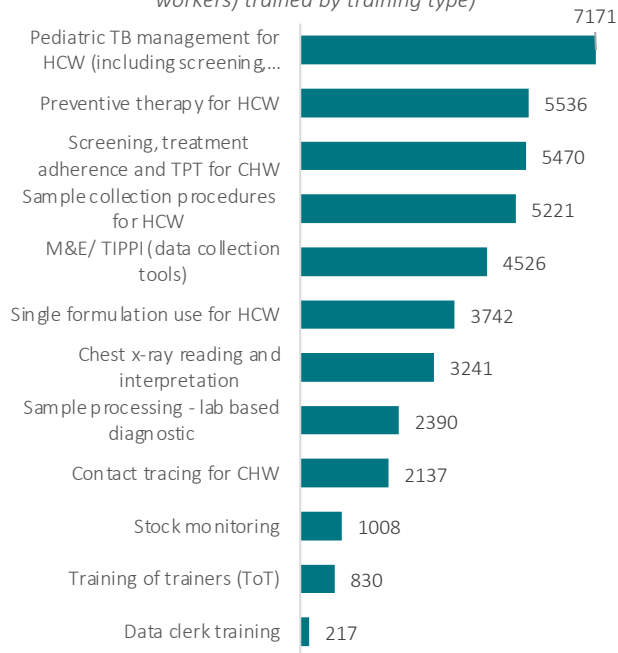
* Lesotho has no NRA and relies on other SADEC countries



Effectiveness Demand & Adoption

The common elements were delivery of classroom-based Training of Trainers (ToT) for selected staff and delivery of onsite training at facility level for other staff in order to ensure good coverage of training among front-line HCWs. At least one Health Care worker across 426 CaP TB implementation sites participated in the ToT. See Fig 7 below for health workers trained by training type. Health workers interviewed reported gaining new skills and providing services that previously required referrals.

Fig 7. CaP TB- Health Workers (including lay workers) trained by training type



Finding 7. The increase in adoption and utilisation of improved diagnostic tools, treatments and models of care has resulted in improved diagnosis, treatment and prevention of paediatric TB in high TB-burden settings.

Cap TB's multipronged intervention comprising the three models of care (integration, decentralisation and household contact tracing), improved childhood TB diagnosis, treatment and prevention, as evidenced from preliminary results from the studies INPUT, CONTACT and TIPPI described below²⁸:

§ Bacteriological confirmation in children Under-5 using alternate sample collection methods.

The project found that Implementation of sample collection procedures under routine conditions for children under five years old was feasible in the Sub-Saharan Africa context, with gastric aspirate and stool collection procedures found to be most suitable for primary level facilities. The introduction of these sample collection procedures contributed to significantly improving the number of children under five years with bacteriologically confirmed TB from 14 pre-intervention to 153 post-intervention across 55 sites, a 7-fold increase in average monthly rate/site compared to baseline.²⁸

§ Increased case finding through multi-site screening

The integration of paediatric TB screening in

facility-based non-TB entry points contributed to 89% of the children diagnosed with TB, with variability across entry points. The Out-Patient Department (OPD) and In-Patient Department (IPD) provided the highest relative contribution in most countries. Locations where sick children were attended to showed higher contribution. Household contact investigation also contributed to 11% of all cases identified.²⁸

Preliminary results from the INPUT study showed a statistically non-significant increase of 20% in TB case detection between the control and intervention arms. The results varied by country, with Cameroon showing a statistically significant 10-fold increase in case detection and Kenya showing no difference between control and intervention arms. Although the INPUT study failed to show a significant difference, it found that over 75% of children diagnosed with TB had pulmonary disease. Also, 90% of children with TB disease were diagnosed clinically, highlighting the importance of training on clinical diagnosis.²⁸

§ Improved access to TB Preventive Treatment

The project also reported excellent uptake of TPT among child contacts <5 years identified as eligible, with 98% uptake and a 91% completion rate, which contributed to a 3.8-fold increase in the number of TPT initiations among child contacts <5 years per facility/month across all countries, compared to baseline.²⁸



Effectiveness

Table 2. Intervention Adoption Matrix

Interventions		Status	Cameroon	Côte d'Ivoire	DRC	India	Kenya	Lesotho	Malawi	Tanzania	Uganda	Zimbabwe	Total	
Models of Care	Systematic paediatric TB screening in relevant non-TB entry points (OPD, IPD, MNCH, PMTCT, nutrition HIV) and in the private sector (India)	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
	Decentralisation-Capacity to manage paediatric TB at district level and lower	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
	Community-based House-hold contact investigation	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
Treatment Regimens	Shorter TPT regimens (3RH)	Included in National TB guidelines	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	7	
	Shorter TPT regimens (3HP)	Included in National TB guidelines	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	7	
Testing Algorithm	Rapid diagnostics as the initial test for presumptive TB cases	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
		Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
New Formulations	New paediatric TB FL FDC formulations (RH 75/50 and RHZ 75/50/150)	Procuring as first-line treatment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
		Registered by national regulatory authorities (NRA)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
		Included in EML	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	6	
	EMB Dispersible Formulation	Included in National TB guidelines	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	7
		Procuring	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	6
		Full transition to DT	No	No	Yes	No	No	No	Yes	Yes	No	Yes	Yes	4
	INH Dispersible Formulation	Included in National TB guidelines	No	Yes	Yes	No	No	No	Yes	Yes	No	No	No	4
Procuring		Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8	
Full transition to DT		Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	No	5	
Diagnostic Tools/Technology	Xpert Ultra	Included in National TB guidelines	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	
	X-ray equipment with optimised chest X-ray interpretation procedure	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	8	
	Advanced sample collection- Nasopharyngeal Aspirates	Included in National TB guidelines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	
	Advanced sample collection-Stool*	Included in National TB guidelines	No	No	No	No	Yes	Yes	No	No	Yes	Yes	3	
	Manually operated nasopharyngeal aspiration (MOAP) power free prototype	Under development by TB Speed												

*There was inadequate information on sample processing methods for stool samples at the time the CoP TB policy assessment was performed. This made NTPs more reticent to recommend use of stool because they did not know which processing procedures they would have recommended (studies were still ongoing).



Effectiveness Demand & Adoption

How effective were the projects engagement with national ministries of health (TB control programmes), civil society organisations & communities, towards increasing demand & uptake of diagnostic and treatment products?



AIDS Information Centre, Uganda (CAP TB CSO Partner)

④ Finding 8. The CaP TB project had productive relationships, with broad engagement with local actors at the national level, sub-national levels and within communities through its network of CSOs.

The project engaged local actors from design through implementation, extensively discussed under coherence. CaP TB advocated for key policy changes to support improvement of paediatric TB interventions through extensive interactions with stakeholders (MoH, other implementing and funding partners) at all levels. Implementers and country-level informants at national and sub-national levels verified the close working relationship they had with the project teams. These engagement activities ensured active participation and ownership of local actors through the life of the project.

CaP TB's successes in addressing the demand and adoption barrier are also attributed to the contribution of the ten national CSOs engaged. These CSOs supported both advocacy and policy change, and community awareness for paediatric TB. Some of the results achieved by the CSOs have been culled from the compilation of lessons learned from CaP TB's Advocacy Small Grants report (Civil Society Advocacy For Effective Childhood TB Response) published in January 2022.²⁹ These include:

- **Creating a platform for communities**, especially for children's voices to be heard, where experiences and concerns were shared

directly with the NTP, e.g., a champion facilitating the provision of child-friendly formulations in a health facility in Kenya and 1,100 Women champions successfully advocating for the adoption of systematic screening in Cameroon.

- **Increasing the agency of community actors** to engage high-level stakeholders. In Malawi, CHWs collected data through community-led monitoring that informed National TB TWG discussions. In DRC and Malawi, CSOs engaged parliamentarians with concrete and strategic demands in their policy advocacy papers.

- **Dispelling misconceptions and changing perceptions** about TB CHWs increased linkage to care in Zimbabwe, Cameroon and Uganda.

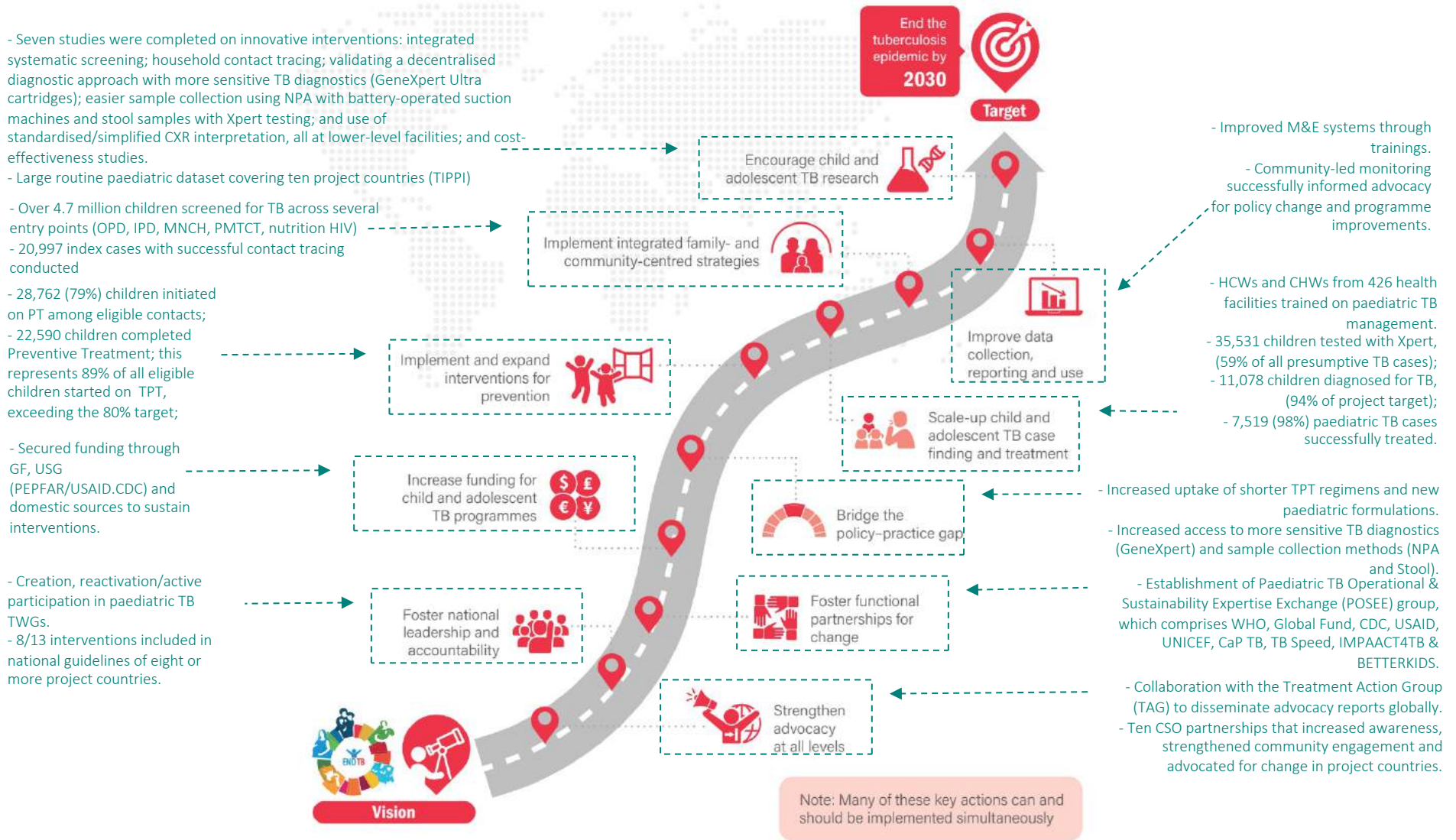
- **Increasing utilisation of media** to bring attention to paediatric TB. In Kenya, the CSO published stories on limited access to diagnosis and missed diagnosis for children in two newspapers with significant coverage. Radio jingles on paediatric TB through two radio stations covering southwestern Uganda.

- **Changing paediatric TB policies**, e.g., the elimination of medical consultation fees for paediatric TB in religious-led health facilities in DRC; incorporation of systematic screening in national guidelines and subsequent implementation in Cameroon; early development of stool-test algorithms for children in Kenya; and Increased budget for paediatric TB in Tabora district in Tanzania.

29. [Advocacy for Effective Childhood TB Responses: Lessons Learned from CaP TB Advocacy Small Grants Project - EGPAF \(pedaids.org\) January 2022](#)

Portfolio Contributions to the Road Map to end TB

Fig 8. Direct contributions from the projects to the Road Map to end TB



Effectiveness Supply & Delivery



To what extent did CaP TB improve supply and delivery systems to ensure that products reach those in need in a reliable and timely way? E.g., establishment (or integration) of functional and sustainable supply chain processes.

S Finding 9. The CaP TB project strengthened the market for new paediatric TB formulations through advocacy to phase out old formulations and the introduction of the new products within its models of care, which increased demand in project countries.

Due to the early adoption and procurement of FL FDCs by countries, the formulations were already available, existing side by side with older formulations. Procurement was already ongoing or being planned in 60 countries. In 2017, the percentage of paediatric reformulated FDC procured as a total of paediatric first-line drugs procured at national level in seven (Cameroon, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe) of the ten CaP TB countries was 100%. MacLeod's Pharmaceuticals Ltd Mumbai, India, was already manufacturing these FDCs. Both the supply and demand sides of the market were already highly sensitised and active, so the project was beginning at a very high baseline. It is, however, crucial to note that the procurement levels were not an indication of the actual use of the drugs with old formulations used concurrently in some countries, e.g., Malawi and Tanzania. As a result, the project supported efforts to phase out the older formulations and also further strengthened the

growth and sustainability of the paediatric TB market for these FDC formulations.

All project countries have now successfully transitioned to the new child-friendly flavoured FDCs. These improved formulations were also provided at all CaP TB-supported sites. WHO's recommendation of RH FDC for preventive therapy in 2018 also created additional transition support requirements. Prior to this, RH was procured solely for the continuation phase of active TB treatment. CaP TB supported NTPs to switch to the 3RH regimen as the regimen of choice for delivering treatment of LTBI to child contacts, and seven countries have also updated their LTBI guidelines accordingly. CaP TB also supported the adoption of dispersible EMB for the intensive phase of active TB treatment and INH for LTBI treatment when 3RH cannot be used. Four countries now procure EMB dispersible formulation exclusively, and five have transitioned to the dispersible INH formulation. See list of countries in Table 2. on page 29.

M Finding 10. CaP TB also utilised its partnership with GDF effectively, supporting national quantification process, as well as commodity distribution, monitoring and management at site level. There were, however, pockets of

stockouts across multiple countries.

CaP TB teams assessed national stocks of FL FDCs available at Ministries of Health at the end of 2018. The project also worked with NTPs to ensure adequate stocks for both LTBI treatment and treatment of active TB through providing data for quantification, monitoring stock levels, trainings, supporting quantification of products, engaging multiple manufacturers for quality sourcing and mapping of potential regional sources working closely with GDF. Country-level respondents reported that the projects supported strengthening commodity logistics and equipment maintenance at facility level as well as the provision of data to support national forecasting efforts. The project, however, experienced stockouts of paediatric FDCs at national and site levels in Cameroon and Uganda, impacting paediatric TB cascade of care in the NCE year due to transition to domestic funding or GF funding and delays in release of the funds from these sources for procurement. CaP TB also experienced breakdowns of GeneXpert devices impacting TB case detection, with the facilities reverting to other diagnostic tools to fill the gaps pending repairs.

Effectiveness Factors Influencing Programme Effectiveness

What were the main factors influencing the achievement of the intended outputs or overall outcomes?

**Most impactful factors*

Success Factors

- 1) **S** **Trainings, Supervision and Oversight***
- 2) **S** **Early and consistent engagement with WHO GTB and Scale Up Partners (GF and USG)***
- 3) **M** High External Validity – Multiple Project Countries
- 4) **S** Innovative Interventions Available to be Deployed
- 5) **M** Evidence-Based Programming – Baseline Assessments (Both), Pilot Phase Review and Robust Routine Monitoring (CaP TB)
- 6) **M** Task Shifting to CHWs (Cap TB)
- 7) **S** Close Working with Country Actors
- 8) **M** Skilled Project Staff with Local/Global Context Knowledge, Expertise and Relationships

- 1) **S** **Delayed ERC Approval (WHO & Local ERCs)***
- 2) **S** **COVID-19 disruptions to service delivery, study recruitment and programme management.***
- 3) **Programme Decisions & Design Flaws***
 - S** Inadequate time allocation for protocol development (TB Speed)
 - S** Late engagement of CSOs (CaP TB)
 - M** Skewed cost-effectiveness analysis
- 4) **S** Commodity/Equipment & Other Resource Constraints
- 5) **M** Human Resource Challenges: Strikes, High Attrition, Low Motivation
- 6) **M** Limitations of CaP TB's cost-effectiveness analysis
- 7) **M** Financial Transition Gaps (CaP TB)

Challenges

Finding 11. Factors that positively influenced achieving the projects' objectives included the potential for high external validity of projects' findings, the unique complementary interventions supported, evidence-based programming, task shifting to CHWs, robust quality assurance processes, skilled project personnel, and consistent engagement with local and global actors through the project life.

and implemented joint supportive supervision support. Country stakeholders described the increased confidence among health workers and CHW to provide paediatric TB diagnosis and treatment services. TB Speed organised monthly steering committee meetings and in-country monitoring visits to provide study oversight. The Scientific Advisory Board of TB Speed also applauded the quality of the studies and the low LFTU rate

already utilised some preliminary results from these projects and is poised to utilise additional research findings, depending on the final results.

S *Training & Supportive Supervision:* The projects provided extensive support to build the technical capacity of MoH teams and health workers. CaP TB established/revitalised/actively participated in paediatric TB Technical Working Groups, supported planning processes, co-created adapted training materials, conducted TOTs, step-down trainings

S *WHO GTB Engagement:* The continued and consistent engagement with WHO GTB has enabled seamless guidance and communication for the design of research studies, programme implementation and utilisation of findings for global guidance development. WHO GTB has

S *Engagement with Scale Up Partners:* The projects, especially CaP TB, worked closely with the two critical sustainability partners (The Global Fund and USG-PEPFAR, USAID, CDC) at both global and country levels; keeping them abreast of its implementation models, costs and outcomes, towards potential resourcing of paediatric TB in their upcoming grants. These actors were well informed about the projects' interventions and have also begun funding these innovations in some countries, with all countries already securing funds from GF, PEPFAR or domestic funding for selected interventions.



Effectiveness Factors Influencing Programme Effectiveness

What were the main factors influencing the non-achievement of the intended outputs or overall outcomes?

Finding 12. Factors that negatively affected the delivery of the projects' objectives included the COVID-19 pandemic, delays in preparing for and obtaining ethical approval, and resource constraints within country health systems.

contributed to the project. CSOs also felt that the funding was small compared to the expected outcomes, and this also limited the activities they could implement.

these could have been anticipated and planned for.

S *Delayed Ethics Review Processes:* Prior to the COVID-19 pandemic, the projects were already experiencing delays in completing ethical review processes. The protocols obtained initial WHO ERC approvals within 1-6 months, with two studies experiencing a 4-6month delay. Other delays resulted from amendments requiring back and forth with country IRBs. The CaP TB INPUT study took up to eight months to be approved after the first amendment. The study protocol was amended multiple times, and the fourth amendment took four and a half months. These significantly delayed implementation, also contributing to the need for the NCE.

S *Inadequate time allocation for protocol development:* TB Speed experienced significant delays developing some of its protocols. It took six and eight months to develop the output 2 – pneumonia and output 3 – HIV/SAM protocols. This created a cascade of delays resulting in a late start of project activities. The effects included a reduction in study duration for output 1, increase in timeline for outputs 2 and 3 – HIV only, staggered launch of studies in the different countries for outputs 1 and 3 and a reduction in the time available to complete data analysis. The protocols were delayed as there were many different actors involved in the process and a need to contextualise the protocols to each country's context. Specific outputs/studies also had unique requirements as described by implementers. The stepped wedge design and validation approach of output 2 required extensive discussions with the international research community. The design of output 3 was innovative and complex and required expert consultation; the project had to find a replacement for the GeneXpert Omni for Output 1. The reasons for delays are valid, but many of

M *Potentially skewed cost-effectiveness analysis:* Both projects' cost-effectiveness analysis was also limited, as project costs (such as M&E, research and project management) were embedded into intervention costs, and as a result, are not representative of the true costs of implementing these interventions within government structures, with government administrators as opposed to INGO staff. This has the potential to skew the study results to be cost-ineffective. The results of this study were not available at the time of this evaluation.

S *COVID-19 Pandemic:* The pandemic was the most critical factor that negatively impacted the projects' implementation through reduced patient attendance, shut down or partially functioning health facilities, inability to conduct supervisory visits, cancelled meetings and community activities. The projects experienced extensive delays and were unable to achieve some targets and enrolment numbers. However, as earlier mentioned, the projects adapted relatively well in dealing with COVID-19 and related disruptions, with final results satisfactory.

Programme Decisions & Design Flaws:

There were a few decisions made through the life of the projects that affected the projects' effectiveness.

S *Late engagement of CSOs:* Unitaid and CaP TB's introduction of CSOs mid-project, with very late contracting in some of the countries; hence, potentially decreased the impact that the CSOs

Impact

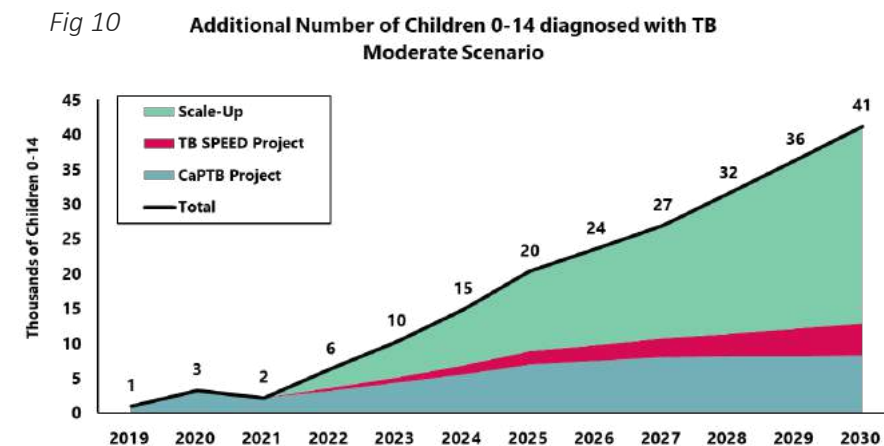
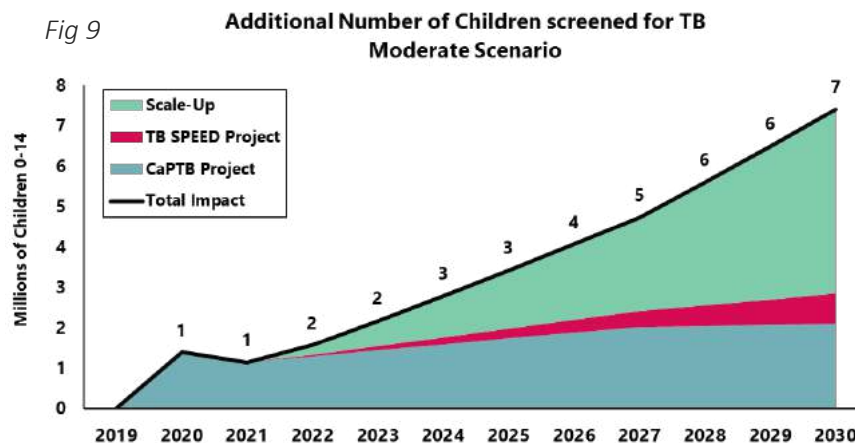
To what extent have the projects generated or are expected to generate public health and economic impact at the national and global levels?

The goal of the projects was to contribute to reduction in morbidity and mortality due to paediatric TB. The impact of the projects was estimated through modelling. The direct impact of the projects was calculated by estimating how many more children were impacted through project activities than may have been otherwise during project implementation years (2019-2021). With respect to indirect impact, it is unclear what combinations of tools and in what capacity they will be used for screening and diagnosis in countries, making it impossible to understand the expected indirect impact and associated costs during the scale-up period. The indirect impact estimates reported here are the potential progress that can be made over the next five years with up to 50% increase in screening in scale-up years as compared to project years.

M The potential impact of the projects was estimated as diagnosing and treating additional children for TB, as well as corresponding years of life lost due to premature mortality (YLLs) averted. Mobilized through projects' advocacy efforts and update of WHO normative guidelines, in a scenario where countries scale up screening by 50% in the next five years compared to project years, there is the potential that an additional 102,500 [37,100 - 267,500] children with TB will be diagnosed and an additional 106,100 [30,400 - 274,100] more children will complete TB treatment in the 14 project countries³⁰ and other countries in the WHO Africa region³¹ with high TB burdens. This increase in screening and diagnosis of paediatric TB could avert 4.3m [1.6m - 10.2m] YLLs. The impact model utilised inputs mainly from CaP TB's project results, as the project was more implementation-focused and less from TB Speed, being a research-focused project operating in very few health facilities. The results from the project cost-effectiveness studies were not available at the time of this evaluation.

30. 14 Project countries: Cambodia, Cameroon, Côte d'Ivoire, DRC, India, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Tanzania, Uganda, Zambia and Zimbabwe.

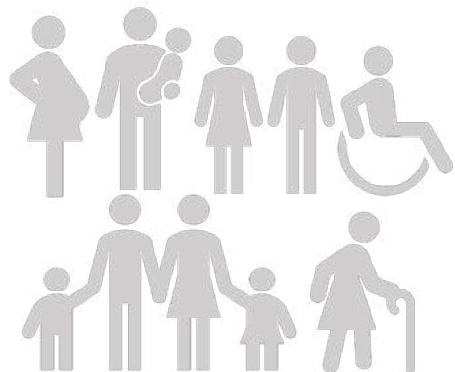
31. All other countries from the WHO Africa Region



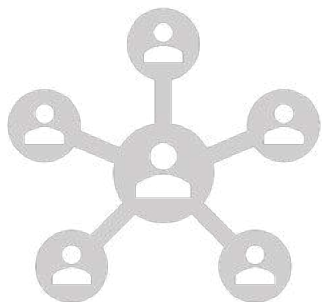
Impact



To what extent have the projects promoted equity?



What additional benefits has the health system experienced due to the introduction of the projects? What unintended effects have been experienced as a result of the project to either beneficiaries or the health system?



- M Finding 1. There was a strong equity focus in the design of the projects as noted in terms of how the projects targeted children and LMICs with a high burden of TB. Also the focus on lower level health facilities via the decentralisation work, which often caters to lower income groups, alongside its focus on even more vulnerable paediatric populations with severe pneumonia, HIV and severe acute malnutrition further reinforce the equity focus.**

The projects effectively deployed their interventions, targeting vulnerable children and lower-income communities. CaP TB successfully improved most of the project indices in implementation districts, as seen in the effectiveness and impact results. However, there is inadequate information on the extent to which the interventions closed equity gaps within countries, the extent to which gender of children is a prevailing equity concern, and if other variables such as geographic location, socioeconomic status, etcetera, were considered.

- M Finding 2: The strategic benefits and positive externalities produced by the projects are related to their integration in the health systems, working through Ministry of Health staff and structures. As a result, the projects did provide additional benefits to the health system beyond project implementation outcomes. These benefits are due to the integration of the projects' interventions in health systems and include:**

Human Resource Strengthening: Health care workers were trained in new diagnostic techniques and simplified screening tools for paediatric TB. These techniques are applicable and somewhat adaptable to other services, e.g., improved CXR capacity in lower-level facilities supported by TB Speed.

Equipment Procurement & Infrastructural Improvements: Some health facilities received additional equipment, including GeneXpert, oxygen concentrators, sample collection equipment and development of sample transportation networks, which are useful for other health service areas beyond paediatric TB. Other facilities were refurbished, while a few others were connected to national electricity grids.

Improved TB Data Quality: The comprehensive routine M&E system developed by the CaP TB project did impact the quality of TB data. Key informants reported improved documentation of TB data, which was not a primary objective of the projects.

Efficiency

Was the project time-efficient and cost-efficient? What factors have been considered to ensure that value for money has been achieved from an efficiency standpoint?

Overall, the projects were largely efficient, with TB Speed being slightly less efficient than CaP TB.

Both projects experienced external challenges that slowed the speed of implementation at inception (notably COVID-19). In addition, TB Speed experienced protracted delays in developing study protocols that already set the project behind schedule prior to COVID-19. Another critical factor for time-efficiency for both projects was ethics review processes with delays in approval of amendments due to WHO ERC delays and multiple iterations to local IRB in some countries. Some studies took up to eight months for approval. Subsequently, both projects applied for NCEs to utilise consistent underspends. The projects were largely cost-efficient, with negligible expenditure rates in the first year (2017) due to receipt of funds in the last month of the year. However, CaP TB and TB Speed expended 83% and 87%, respectively, by 2021. The projects delivered most of their planned activities across all outputs, with over 95%-spend on every output. The level of collaboration of project implementers with national authorities in project planning and implementation to promote integration into existing health systems was very high and created significant efficiencies. CaP TB's implementation partnership arrangement was fit for purpose and efficient. TB Speed's consortium was, however, too complicated with a larger number of members and partners jointly implementing.

S Finding 1. The projects were moderately time-efficient, with delays at inception towards finalising and approving research protocols as well as slow enrolments into services and studies markedly affected by COVID-19.

CaP TB

Project implementation started later than planned due to contract signing delays which were a prerequisite to recruitment of staff, as a result project activities kicked off in-earnest in Q1 of 2018. At inception, the project also required additional time to make revisions to research proposals, especially site selections in agreement with national authorities and corresponding budget realignments. During implementation, the project was behind schedule due to a number of factors including, delays in obtaining ethical approvals from the WHO Ethical Review Committee, which was further exacerbated by the COVID-19 pandemic. These factors all contributed to time inefficiencies that prevented the project from completing its studies within the original project duration. Unitaid thereby approved a 12-month extension mainly to complete the research studies (CONTACT, INPUT and cost-effectiveness) using a portion of the grant's remaining funds, extending the grant end date from 30 September 2021 to 30 September 2022. Furthermore, project activities were also cut short and terminated before September 2021, and the number of sites scaled down in a few countries, further reducing the time to achieve some of the direct impact targets under outputs 2 and 3.

TB Speed

TB Speed experienced delays in finalising its study protocols, with very ambitious timelines of less than six months to obtain ethical approvals for three studies. Also, coordinating across different organisations, across multiple countries was

challenging. During implementation, the projects were also behind schedule due to a number of factors, including delays in finalising agreements with partners, delays in obtaining ethical approvals from the WHO Ethical Review Committee, very late start to most studies, which was further exacerbated by the COVID-19 pandemic, and unavailability of GX Omni requiring a switch to Gene Xpert G1 edge. Output 3 staffing requirements were also underestimated in Zambia with both HIV and SAM interventions being implemented in the same sites, and this led to staff burnout which reduced their efficiency. Output 4 also experienced unique delays in enrolment due to the also protracted timeline to come to an agreement between University of Bordeaux, IRD, FIND and KNCV, due to the decision to collaborate on testing the three methods, further causing delays in commodity shipment to FIND. These factors all contributed to time inefficiencies that prevented the projects from achieving their objectives within the original project duration. The project addressed these delays by streamlining the study and reducing the planned duration from 30 months to 18 months (Output 1), and staggering the launch in different countries (Output 1 and 3), reducing the number of sites from ten to eight PHCs per country (Output 1), increasing the number of sites (Output 3), extension of study timeline (all Outputs) and a reduction of the data analysis period. Unitaid also approved a 12-month extension to complete all studies except Output 2, which concluded in June 2021, extending the grant end date from 30 September 2021 to 30 September 2022.

Efficiency

Finding 2. The projects were largely cost-efficient, with very low expenditure rates at inception, which improved as activities ramped up with over 80% of both project budgets implemented.

Fig 11. CaP TB Expenditure as % of annual budget, by year

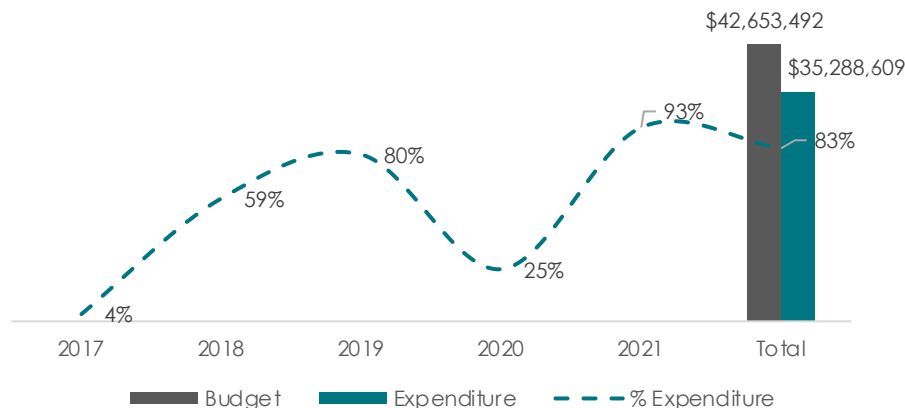
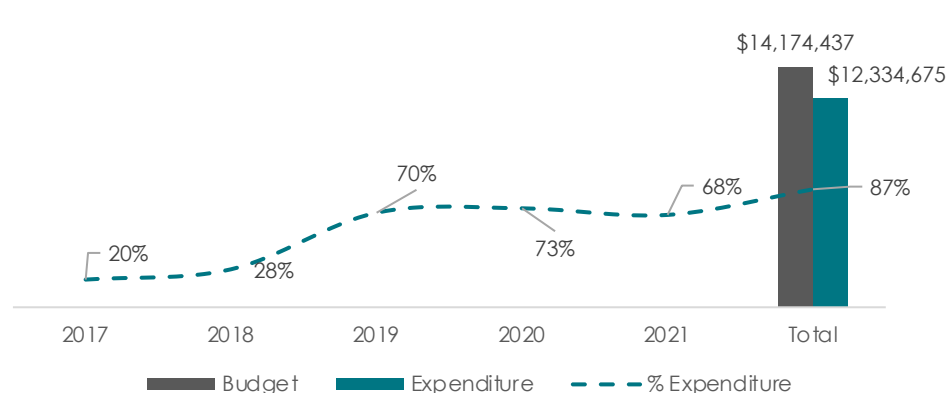


Fig 12. TB Speed Expenditure as % of annual budget, by year



CaP TB’s budget was US\$ 36,346,541, initially for four years of implementation, and this was further stretched through the no-cost extension year. The project’s absorptive capacity increased annually from a 3.5% burn rate in 2017 to 93% in 2021. See figure 11. The lower budget consumption in its initial years was due to receipt of Y1 funds at year-end, the inability to recruit personnel or execute subcontracts in Y1, procurement delays and late M&E protocol approval. The COVID-19 pandemic further impacted project expenditure, with only 25% of the budget expended in 2020. The consistent underspend through the project life created a surplus for the extension year. As of December 2021, the budget execution was 83%, with expenditure expected to continue till project closure. The project teams consistently monitored project expenditure; however, external factors had a significant effect on the projects’ burn rate.

TB Speed’s budget was initially US\$14,670,470 million for four years of implementation and further stretched through the no-cost extension year. The project’s absorptive capacity increased annually from a 22% burn rate in 2017 to 100% in 2021. See figure 12. The lower budget consumption was due to late receipt of funds in November 2017, too late to transfer funds to sub-grantees coupled with University of Bordeaux’s administration processes creating a bottleneck, delays in finalising the protocols, starting the studies, recruiting study personnel and procuring the materials and equipment. Subsequently, lower patient costs and other associated commodities, lower cost of external professional services, and the impact of COVID-19 through travel restrictions also affected the projects’ burn rate. As of December 2021, the budget execution was 87%, with expenditure expected to continue till project closure. Project budget and expenditure monitoring seemed more reactive with missing budget items and some wrongly categorised costs, which were subsequently corrected.

* Expenditure rates here are based on reported rates in each annual report



Efficiency

Finding 3. The projects delivered most of their planned activities across all outputs, with mild underspend mostly due to COVID-19 restrictions.

Both projects' expenditure by output as of December 2021 showed underspend across all outputs. See figures 13 and 14. CaP TB's expenditure by output was 97% or more across all outputs and successfully delivered all its activities, with a few targets unmet. TB Speed had slightly lower expenditure rates, between 85% and 98%. The lowest expenditure rates were on TB Speed's Output 1 (86%) due to the late start of this study, lower recruitment rates in all countries, and underspend on external professional services. TB Speed's Output 4 (85%) also underspent by 15% due to lower recruitment rates, thus lower patient costs. The project has, however, delivered most of its planned activities across all outputs, with some inefficiencies earlier discussed.

Finding 4. The cost-effectiveness of these interventions is yet to be proven; though stakeholders anticipate that the intervention will be value for money based on design projections. The cost-effectiveness studies will, however, provide evidence to back this claim.

At inception of CaP TB, the project utilised the programmatic budget and estimates of YLS as a measure of value for money, with an estimate of \$134.25 per YLS. The project also cited evidence from literature to back the claim of the project's potential cost-effectiveness, with CEA study still in progress. However, the design of this study includes the full costs of an INGO project, which are likely to skew the results towards not being cost-effective. The factors the CaP TB project considered to achieve value for money started from the design of the project included leveraging existing resources at EGPAF, other partners/past projects and within project countries; these included building on EGPAF's and SAATHI's existing footprint in the ten implementation countries; the Unitaid Point-of-Care Early Infant Diagnosis (POC EID) project procurements and existing Xpert POC

Fig 13. CaP TB Expenditure as % of total budget, by output

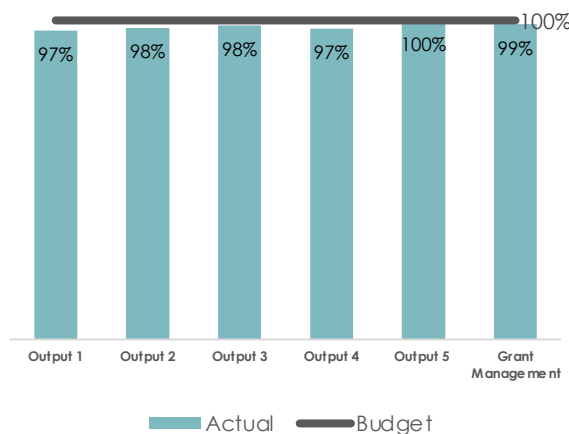
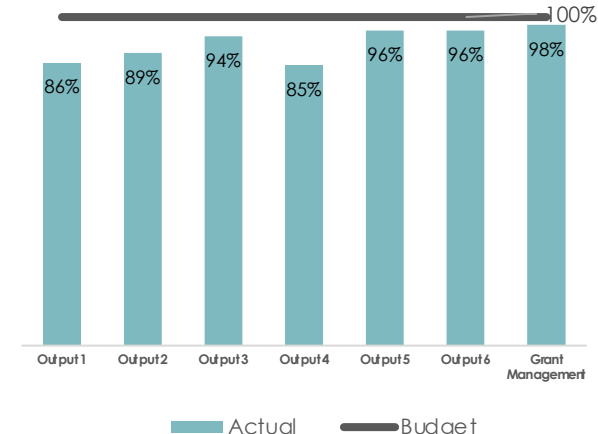


Fig 14. TB Speed Expenditure as % of total budget, by output



capacity; utilisation of onsite trainings; conducting awareness creation and other community interventions through CSOs; as well as using local suppliers for procurement where feasible. The project also reported additional price savings from reduced training expenditures where platforms already existed with trained staff. Furthermore, the project intervention initiating LTBI treatment in project locations is also expected to avert costs of full treatment and hospitalisations in future years. Many stakeholders reported the need for more investments in paediatric TB, indicating that the funding size of CaP TB was appropriate to its scope, but also due to the expected impact of its interventions it would be cost-effective in the long run. Respondents also reported the need to increase investments in paediatric TB as there is an enormous need to improve services for children and very few funders supporting these

interventions.

TB Speed is also conducting a cost-effectiveness analysis of its proposed diagnostic approaches and modelling their market impact to further strengthen the evidence for feasibility of these approaches. The results of both cost-effectiveness studies were not available at the time of this evaluation but are expected to be released by the project late 2022. Implementers described TB Speed as value for money, indicating that for the size of the project, it was at minimal cost compared to other research activities of similar scope, especially with the added responsibilities and costs of implementing in the COVID-19 pandemic context. Considering the geographical scope, the number of interventions being tested, and the somewhat minimal staffing structure of the TB Speed project compared to the budget, it is expected to be cost-effective.





Efficiency

How well did the grant implementers collaborate with national authorities in project planning, implementation and assessment to promote integration into existing health systems?

S Finding 5. The projects collaborated very well with national authorities, from obtaining national authorisations to co-creation and close working on implementation and sharing evidence and learning via various platforms.

Collaboration with NTPs and MoHs

Both projects worked through MoH staff and had very close working relationships with NTPs, as evidenced by:

- ✓ Securing the required project authorisations from national authorities. (Both Projects)
- ✓ Co-creation of projects, participation in baseline assessments and site selections, site networks, ensuring appropriate decentralisation of services, sample transportation/processing, and efficient patient referral. (Both Projects)
- ✓ Active participation of NTPs in project Country Project Committees and regional trainings. (TB Speed)
- ✓ Active participation, including establishment/revitalising paediatric TB technical working groups (TWGs) in all countries. (CaP TB)
- ✓ Supporting revision of the national paediatric TB guidelines, national strategic plans, algorithms, training curricula, SOPs and job aids. (Both projects)
- ✓ Accelerating updates and amendments to EMLs. (CaP TB)
- ✓ Supporting national authorities to transition to Xpert Ultra cartridges. (Both Projects)
- ✓ Adaptation of clinic registers to report on screening and contact tracing in collaboration with the MoH and NTP. (CaP TB)
- ✓ Trainings and close supervision of HCWs and CHWs jointly with MoH staff on paediatric TB management, including advanced sample collection and contact tracing. (Both projects)

- ✓ This close collaboration and utilisation of MoH personnel and structures integrated project activities into national MoH agendas and capacity-building at implementation and will ease transition and scale-up of these models of care post-project life.
- ✓ Experiences gained and lessons learned by both projects were also shared regularly via national and international platforms.

Collaboration with Global Actors

The projects also worked closely with global actors. CaP TB actively contributed to creating and leading the Paediatric TB Operational and Sustainability Expertise Exchange (POSEE) group. The POSEE played an essential role in updating Global Fund’s modular framework and developing a costing tool that has been integrated into WHO’s One Health TB module companion Book, which is the tool that WHO is supporting and proposing for the development of NSP budgets and budgets for GF proposals. The POSEE group has now evolved to become a TaskForce of the Child and Adolescent Working Group, with EGPAF’s representative serving as the coordinator. TB Speed also engaged at global level with an increased focus on other scientific leaders leading to its collaboration with FIND and KNCV. Both projects also engaged effectively with the WHO enabler, as evidenced by ongoing uptake of their study results.



Efficiency

To what extent was the implementation arrangement (including consortium structure) optimally designed to ensure efficient delivery of the project objectives?

S Finding 6. CaP TB had a complementary implementation partnership arrangement. The TB Speed consortium and partners though complementary, were too many to be efficiently managed with several administrative challenges and a need for more complex coordination structures.

CaP TB

Implementers: EGPAF (lead grantee) and SAATHI (consortium member leading implementation in India)

EGPAF implemented activities in nine African countries with its successful track record of implementing HIV and MNCH programmes across the continent. The consortium comprised one sub-grantee, SAATHI (a reputable and well-established national non-governmental organisation, with footprints in 14 Indian states, implementing HIV, TB projects and research for almost two decades). The choice of SAATHI was both pragmatic and efficient, as it would require significant resources for EGPAF to set up operations in a large country with more contextual differences than the African countries EGPAF had previously served. SAATHI, however, already had the necessary relationship with the Ministry of Health and very strong linkages with professional associations and private sector; it was already an actor with vast experience in the TB space. The consortium coordination structures were effective with a clearly documented MOU between the organisations, co-creation of key technical, data management and reporting tools, SAATHI’s participation in regular global project team meetings/key governance meetings, regular financial and programmatic report inputs from SAATHI with EGPAF maintaining the overall project management, financial and project reporting responsibilities alongside oversight of SAATHI’s implementation. Key informants, including EGPAF and SAATHI personnel, reported that the relationship was both effective and efficient.

TB Speed

Implementers: University of Bordeaux (lead grantee) and consortium members: Institut de Recherche pour le Développement (IRD); Makerere University - Johns Hopkins University Research Collaboration, Uganda (MUJHU); Therapeutic Solidarity and Initiatives for Health (Solthis); PAC-Cl, Côte d’Ivoire; Instituto Nacional de Saude, Mozambique (INS); Institut Pasteur, Cambodia; and University of Zambia (UNZA).

Technical partners: Adera, Epicentre, MSF Logistique, TeAM/SPI, CAMTech and the University of Sheffield.

The TB Speed consortium and partners comprised 14 organisations carefully selected to enable implementation in the different countries (as the university does not have in-country presence in any of the locations) and to provide complementary expertise required for the project to implement key interventions within the research context. However, the number of internal actors was too many for the size and scope of the project; hence, it created a need for extremely complex coordination structures to manage project resources, including staffing, finances and project activities. The project addressed this by setting up several coordination bodies, meetings and events, including project coordination committees, a scientific advisory board and executive committee meetings.

The organisational procedures and bureaucracies were also different for each of the partners, creating some bottlenecks and delays at project start-up and throughout implementation, including delays in protocol development and procurement processes due to different institutional requirements.

Scalability & Sustainability

Global Environment Inputs

Overall, the projects have contributed significantly to creating an enabling environment, especially through evidence generation and dissemination, but also through demonstration of the feasibility of the projects' interventions and effective global and local partnerships, resulting in an immediate interest in the adoption and scale-up of some of the projects' interventions.

Both projects successfully generated and disseminated knowledge and evidence on their intervention sets, and created sustainable access conditions, as the evidence has already informed the new WHO consolidated guidelines on tuberculosis (Module 5: Management of tuberculosis in children and adolescents). Both projects introduced new innovative delivery models, and CaP TB also strengthened the supply base for new paediatric formulations, earlier described under effectiveness. The projects aligned very well with local and global stakeholders, leveraging extensive existing relationships with NTPs, funders and other programme implementers. CaP TB successfully updated policies and guidelines, developed and deployed training packages, and secured some scale-up funding for most countries. The scalability conditions target were not fully met in a number of defined areas, most notably the inadequacy of transition and scale-up funding. There are also still concerns about the ability of countries to scale up without technical support due to the technical nature of these services and the level of planning, supervision and staffing implementers utilised to support implementation in the smaller geographical focus of the projects.

Sustainable access conditions

Align and coordinate with global donors & partners

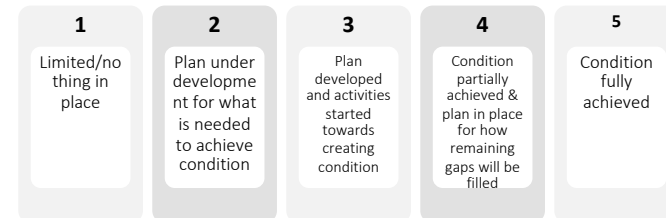
Generate & disseminate knowledge & evidence

- ◆ Project start (2017)
- ◆ Project end (2021/22)
- ◇ EOP Target

* denotes conditions that are highest priority for change

How have the projects contributed to an enabling global environment for the scale-up of TB diagnostics and treatment?

Fig 15. Scalability Matrix- Baseline, targets and final status of global conditions – CAP TB



Scalability & Sustainability

Status rating	Description of status rating
5	Condition fully achieved
4	Condition partially achieved & plan in place for how remaining gaps will be filled
3	Plan developed and activities started towards creating condition
2	Plan under development for what is needed to achieve condition
1	Limited/nothing in place

Finding 1. The projects successfully introduced, generated and disseminated evidence on several innovative models of care, diagnostic tools and processes; accelerated the adoption of guidelines and policies at national and global levels, including WHO normative guidance.

S 4

Evidence on Delivery Models

At baseline, there was no evidence of the impact of integrated approaches, household contact tracing and initiation of TPT on improving TB diagnosis and treatment for children. Through its TIPPI protocol (routine service delivery data), CaP TB collected data to showcase trends on the impact of these approaches with results and lessons disseminated through several national and global platforms. TIPPI data, in addition to preliminary data from the INPUT study, have informed the inclusion of the interventions into other projects and have also informed WHO guideline updates.

TB Speed

At baseline, there was also no evidence on validating a decentralised diagnostic approach using more sensitive TB diagnostics (Xpert Ultra cartridges) and the use of easier sample collection using NPA with battery-operated suction machines and stool samples with Xpert testing. During the course of implementation, other similar initiatives sprang up, including the stool processing methods by FIND and KNCV, which were incorporated into Output 4 for a joint study.

WHO Enabler

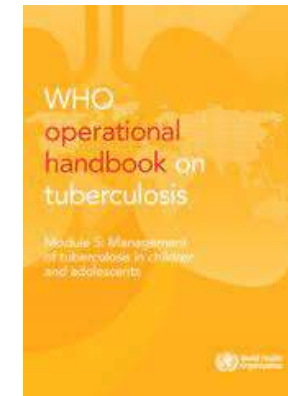
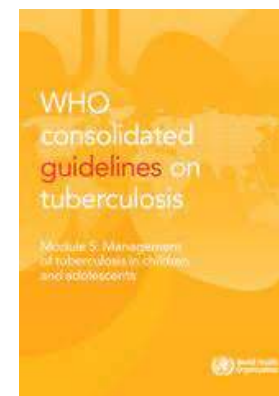
The WHO enabler team supported research design efforts on both projects towards alignment of research questions with WHO GTB's research agenda. The WHO enabler team and the POSEE group actively collaborated in the review of evidence generated from the projects. Interviews with POSEE members and the WHO enabler team did corroborate the extensive collaboration with the projects in reviewing and disseminating evidence on these models within and beyond project countries. Dissemination is currently ongoing through regional and global platforms.

Normative Guidance

Paediatric TB guidelines that existed at the start of the project needed to be updated with these interventions; however, further evidence on operationalising was needed. CaP TB's contribution to the new WHO consolidated paediatric TB guidelines includes preliminary findings on costs of integrated and family-centred models of care and data on coverage of child contacts initiating TPT treatment from its TIPPI, INPUT and CONTACT studies, as well as its compilation of lessons learned shared with the guideline development committee. The operational handbook also featured the project's private sector experience in India. Additional evidence yet to be released is expected to inform future information needs by national and global actors and further reinforce the evidence utilised. The CaP TB project leads also served as external reviewers of these updated guidelines.

The project has also contributed to the new WHO consolidated guidelines and operational handbook on tuberculosis. Current inclusions to WHO Guidelines include evidence on diagnostic accuracy of Xpert Ultra from gastric and stool; acceptability and feasibility of NPA and stool; head-to-head comparison of stool processing methods; and evidence on acceptability and feasibility data of the decentralised diagnostic approaches. The operational handbook also featured experiences from the TB-Speed decentralisation and pneumonia studies. Further findings to be disseminated from the project are also well positioned for introduction into WHO guidelines. Most respondents referred to informing normative guidance as the most important contribution of this project.

The enabler team also facilitated the inclusion of results of the projects into the development of WHO normative guidance, convening the Guideline Development Group (GDG) with project inclusions in both the 2021 and 2022 guideline updates. See page 44 for details on the projects' inclusions into the 2022 WHO consolidated paediatric TB guidelines.



Scalability & Sustainability



Table 1. Contributions to Normative Guidance

WHO Guidelines³²

WHO Operational Handbook³³

CaP TB

Pico Question 6 - Models of care: provision of preliminary findings on **cost-effectiveness of integrated and family-centred models of care** and **data on coverage of child contacts initiating TPT**

CaP TB contributed to the following sections:

Section 2: TB screening and contact Investigation

Box 2.2 Paediatric TB Operational and Sustainability Expertise Exchange budgeting tool for household contact investigation.

Box 2.4 The Catalyzing Pediatric Tuberculosis Innovation project's approaches to contact investigation, including lessons learnt, based on TIPPI data

Box 2.6 The Community Intervention for Tuberculosis Active Contact Tracing and Preventive Therapy study, based on CONTACT data

Section 6: Models of care for TB care for children and adolescents

Box 6.3 Finding the missing children affected by TB: preliminary data from the Catalyzing Pediatric Tuberculosis Innovation project experience in sub-Saharan African countries (unpublished data, 2021).

Box 6.8 The Catalyzing Pediatric Tuberculosis Innovation project: enabling access to public paediatric TB medicines for private-sector patients in India – translating policy into action.

Also contributed to:

Annex 4. Standard operating procedures for sample collection methods

Annex 1. Selected resources on child and adolescent TB

TB Speed

Pico Question 2 - Diagnosis:

Contribution to the **meta-analysis on diagnostic accuracy of Xpert Ultra from gastric and stool;**

presentation of data on acceptability and feasibility of NPA and stool and of interim results of pooled analysis from the FIND and TB-Speed head to head comparison of stool processing methods.

Pico Question 6 - Models of care:

presentation of acceptability and feasibility data of the decentralised diagnostic approaches

TB-Speed made substantial contributions to the following sections of the handbook:

Section 4: TB diagnostic approaches for children and adolescents

Shared NPA & stool procedures, results of the market screening for electrical suction pumps for NPA – recommendations for the use of stool as a non-invasive specimen for bacteriological confirmation of PTB and rifampicin resistance in children are an important new development. See Box 4.2 Experiences from the TB-Speed Decentralisation and Pneumonia studies.

Section 6: Models of care for TB care for children and adolescents

Provided description of the decentralisation models of care and brochure of the course of chest X-ray interpretation in children (see Box 6.4 TB-Speed project: strengthening paediatric TB services for enhanced early detection (unpublished data, 2021)) and reference in section 4.3.7 for use of chest X-ray

Section 7: Special considerations

Shared findings of TB-Speed Pneumonia study (Box 7.8 Findings from the TB-Speed Pneumonia study) to inform management of TB in children with severe pneumonia)

Other contributions to Annex 1. Selected resources on child and adolescent TB

32. WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

33. WHO operational handbook on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Scalability & Sustainability



Status rating	Description of status rating
5	Condition fully achieved
4	Condition partially achieved & plan in place for how remaining gaps will be filled
3	Plan developed and activities started towards creating condition
2	Plan under development for what is needed to achieve condition
1	Limited/nothing in place

Finding 2. CaP TB successfully deployed appropriate delivery models, ensuring incorporation in guidelines, supported transition preparedness, and made marginal progress in obtaining regulatory approvals, competitive pricing and increasing the supply base for new dispersible paediatric formulations.

Appropriate Delivery Models **S 4**

At the projects' inception, global and country-level data revealed low rates of paediatric TB diagnosis, with minimal initiatives specifically focused on addressing this challenge. The projects introduced integrated and decentralised models of care, which have been well-documented through the studies and disseminated to local and global scale-up and sustainability partners. NSPs and guidelines have been adapted to include these models, the models are featured in the recent WHO recommendations, and some of the models/interventions are now included in GF grants or USG awards in project countries. Some successful activities were not transitioned due to limited funding. Scale-up of the model of care at national level is expected to be a challenge in several countries, due to the limited funding from partners, but also due to the level of planning, supervision and staffing implementers utilised to support implementation in the smaller geographical focus of the projects, compared to the larger scope of the countries.

Regulatory Approvals **M 4**

There were already two quality assured (QA) dispersible RH products, one QA dispersible RHZ, and one QA dispersible Ethambutol (EMB) product,

with dispersible INH submitted to WHO PQ and awaiting approval at the projects' inception (PQ approval obtained in March 2021). Further, eight countries had already registered RHZ and RH, but only three had registered EMB. CaP TB focused on advocacy to manufacturers to submit dossiers and provided support for rapid national registration of the FDCs and other dispersible formulations. The project achieved registration/approval in the remaining two countries – Cameroon and Lesotho*. The project, working closely with GDF, also increased the number of countries that registered dispersible ethambutol to four countries (three registered and Lesotho*), with one application still in progress in Tanzania. The six other project countries have, however, not registered dispersible EMB. Though these products are not yet approved by NRA in several countries, they have already been included in national treatment guidelines and are already being procured.

Affordable Pricing **S 4**

The pricing for dispersible FDCs, INH and EMB are higher than previous products on the market. The price difference is viewed as minimal for FDCs (approximately \$4 to \$5 for an 84-tablet pack of the new FDCs compared to \$2 for the old FDCs)²⁷ with the price per treatment course still quite low. However, the increase is more significant for EMB (\$25 for a 100 tablet pack of the new formulation compared to approximately \$4 for the old tablets),²⁹ with country stakeholders indicating some reluctance in procuring due to the higher

price. The CaP TB project working closely with GDF, successfully increased the countries procuring from three at baseline to six at the end of 2021; also, three countries successfully phased out the old formulations. The remaining four countries have not placed orders, however, the second recently prequalified supplier for EMB will increase competition to potentially reduce the price. Eight countries have also procured the newly prequalified dispersible INH.

Adequate Supply Base **S 4**

There were no supply shortages at the global level for paediatric TB products experienced through the life of the project. However, the single supplier for dispersible RHZ and EMB poses a risk to supply security; further, the inclusion of at least one more supplier of both products will also increase competition and potentially improve pricing, as earlier discussed. CaP TB, in partnership with GDF, advocated for manufacturers, specifically Lupin, to accelerate submission of its RHZ dispersible formulation, but this was not achieved. Although the CaP TB increased demand in the pilot sites, these are too small to create sizeable procurement volumes. As a result, the market for child-friendly TB drugs is still weak; thus, there are not a lot of incentives for manufacturers to produce the drugs. The expected scale-up of the models of care with these new formulations, with many countries procuring FDCs prior to the project, creates the expectation for increased procurement volumes.

*Lesotho uses WHO prequalification or registration in the neighbouring countries was sufficient due to lack of its own NRA 29. GDF Medicines catalog May 2022



Scalability & Sustainability

Status rating	Description of status rating
5	Condition fully achieved
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3	Plan developed and activities started towards creating condition
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Finding 3. The projects’ strategic priorities and recommended approaches were well aligned with donors. Implementation processes have also been coordinated closely with strategic planning/budgeting cycles and procurement plans of these donors resulting in immediate uptake of some interventions.

Strategic priorities/needs S 4

The projects were already aligned by design, with project research questions aligning almost seamlessly with the WHO guideline research agenda and some interventions mirroring WHO TB roadmap milestones. However, during implementation, strategic alignment was achieved through incorporation of interventions in NSPs and guidelines, inclusion of paediatric TB interventions into Global Fund TB info note and modular funding framework, and input into USG COP21 and COP22 technical guidance. This resulted in some interventions being transitioned to NTP and local actors with GF/USG or domestic funding in all countries.

Recommended approaches/tools S 4

The TB Speed project developed training materials for simplified chest X-ray reading and procedures for specimen collection and processing methods. These have been published on the project website. EGPAF also supported the development

of the new paediatric TB training package with the latest WHO recommendations through a sub-contract with the Union; these will also support transition and scalability. CaP TB’s input into PEPFAR COP guidance includes providing child-friendly TPT (dispersible INH or 3RH for children on EFV), which was not included in previous COP guidance.

Planning/budgeting cycles S 4

The project teams, working closely with the POSEE taskforce, developed a budgeting tool for sample collection that was incorporated in the WHO One-Health TB Module Companion Book to support countries in their budget forecast for the preparation of the GF concept notes. The budgeting tool has been shared widely, and CCMs and GF consultants have been sensitised on the use of this tool. This contributed to the paediatric TB innovations in GF concept notes and USG proposals and their resulting grants.

Procurement S 4

The design of the projects in terms of countries selected represented regions that were likely to procure internationally quality-assured products (except India). This has already created a platform for sustainable, scalable impact of FDC formulations in the project countries and regions. CaP TB worked with GDF to ensure that all new

paediatric TB formulations were included in the Expert Review Panel list. CaP TB also worked with GDF to support countries in quantifying their needs for these formulations, and strengthen procurement processes and stock monitoring. CaP TB also supported the introduction of Ultra in DRC, CDI, Malawi, Cameroon, Tanzania and Uganda. Both projects closely collaborated with WHO to include consumables and reagents needed for sample collection procedures in the WHO Field Respiratory Sample Collection Kit and influenced WHO’s tender for the supply of sample collection kits in Q1 2021. Lastly, the projects identified suppliers for sample collection products and SI devices procured in several countries. The new formulations and diagnostic equipment are now being purchased by GF grants.

Investment case/global advocacy S 3

CaP TB also collaborated with TAG to develop and disseminate advocacy reports. These contributed to the development of the Childhood TB Roadmap. In addition, the project also produced two policy landscape analyses in 2018 and 2021 that will support further advocacy.

Scalability & Sustainability



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To what extent have the projects helped established country readiness for scale-up of TB diagnostics & treatment?

Finding 4. The CaP TB project achieved a high level of ownership among country stakeholders, as evidenced by the inclusion of some project interventions into national strategic plans, national policies now aligned with WHO recommendations and scale-up partners already funding activities across countries. All countries have also achieved a partial rating on 90% of the readiness criteria. See Table 3 below.

of engagement was high due to existing relationships between MoH and EGPAF. Six of ten project countries fully achieved this scalability indicator. The project shared several publications during these engagements, including the policy & preparedness assessment report to help countries see improvements made and take action to address remaining gaps.

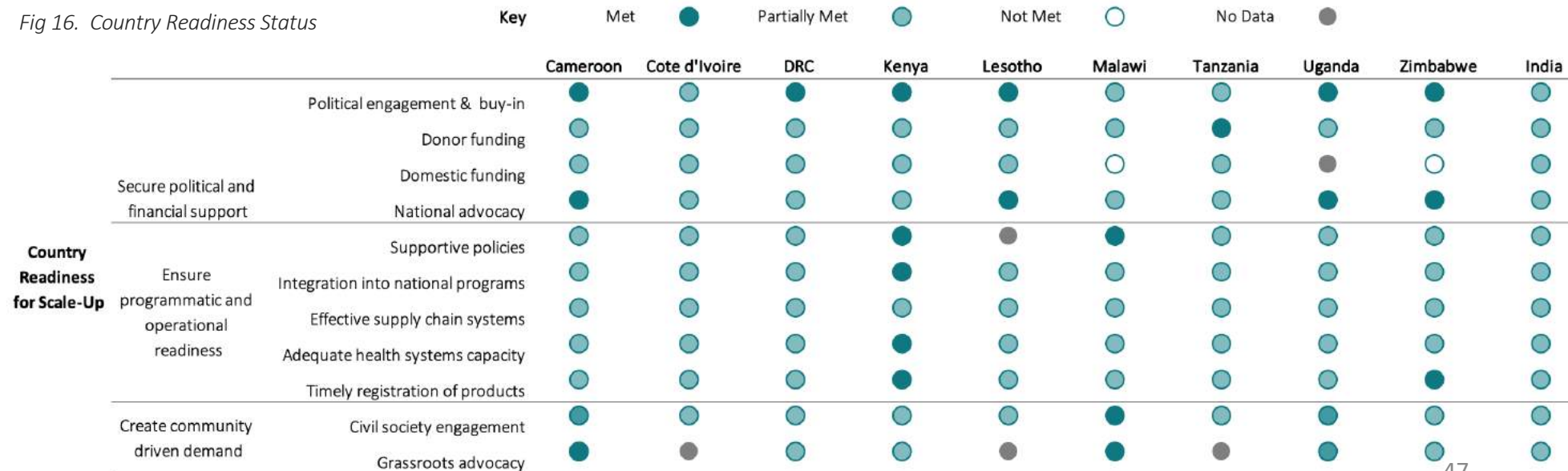
Political engagement & buy-in S 4

National advocacy and supportive policies S 4

The CaP TB project closely engaged with NTPs from design, through implementation and dissemination of research studies, with close-out activities currently in progress. This consistent engagement was done to share project achievements/research findings, facilitate buy-in, and promote country adoption of strategies in national guidelines and national health sector plans, as well as the commitment to continue implementation post-project. The level

CaP TB actively participated in TB guidelines and TB national programme review in supported countries, with many elements within the project now included in national guidelines as earlier tabulated on page 29. These engagements have resulted in the alignment of national policies to WHO recommendations and the inclusion of these new paediatric formulations such as 3RH, diagnostic tools (MTB-Rif Ultra cartridges) and models of care in relevant policy documents.

Fig 16. Country Readiness Status





Scalability & Sustainability

Donor and domestic funding M 4

The Cap TB project worked with international partners at the global level, such as USG and the Global Fund and their country-level representatives, to absorb the activities into the donor-supported country operational plans. Funding has been secured for continuation of key paediatric TB innovations through inclusion in GF grants applications/programming, USG grants (PEPFAR/ USAID/CDC) and national budget in Tanzania. *See Fig. 14 overleaf for donor coverage by country.* There are limitations in funding for some of the elements initiated under CaP TB (i.e., consumables for sample collection in Malawi, Cameroon, DRC; CXR support in Cameroon, Kenya, Malawi, and DRC; cough monitors in India, Kenya and Malawi; paediatric TB M&E in Cameroon, Côte d'Ivoire, DRC, Kenya and Malawi). The project has also experienced gaps created through delays due to transition to other partners, including MoH's replacement order for paediatric TB drugs in DRC, delay of USG follow-on award in Tanzania and a delay in GF funding disbursement, leading to gaps in Côte d'Ivoire. Key informants also reported that there would be funding gaps post-project with significant financial support from outside sources required due to NTP's current allocations being insufficient to fund these approaches. TB Speed also engaged actively with the Global Fund HQ and regional managers towards synchronising evidence generated with the timeline for development of concept notes with the project's

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progress presented to WHO and GF meetings. Domestic funding is limited in most countries and primarily focused on health systems structures, with some countries relying extensively on donor funding to implement paediatric TB services, e.g., Malawi and Zimbabwe.

Finding 5. CaP TB has also contributed towards strengthening country health systems for delivery of paediatric TB services, from integrating the interventions into national coordination processes with TOTs and ongoing onsite trainings, to supporting quantification and supply planning through GDF and utilisation of CSOs to increase awareness and advocate for policy change.

Integration into national programmes S 4

Starting with obtaining project authorisation from MoH and NTP, to co-creation of projects, participation in baseline assessments and sites selection, projects being implemented through national health systems, regular coordination meetings through TWGs, revision of national paediatric TB guidelines, national strategic plans, algorithms, training curricula, SOPs and job aids and M&E tools and extensive trainings and supportive supervision. The project made extensive strides towards integrating project interventions in national programmes.

Effective supply chain systems S 4

CaP TB improved demand forecasting in collaboration with the GDF, and it also increased diagnosis and linkage to care using innovative models of care. These two achievements lay the

foundation for a more stable market for FDCs and other paediatric formulations. Both projects are also creating a market for sample collection consumables, with the projects actively working with WHO to define the items to be included in the WHO tender for the supply of sample collection kits for sputum induction, nasopharyngeal aspiration and gastric aspiration in Q1 2021, and conversations with GDF to explore the possibility of including sample collection consumables in their catalogue.

Adequate health systems capacity S 4

CaP TB conducted a myriad of systems strengthening activities, already described in earlier sections, from adapting the Union Childhood TB training toolkits for countries, to conducting TOTs and trainings and supervision of HCWs and CHWs on paediatric TB management, including management of childhood TB, prevention and treatment, contact tracing, advanced sample collection and transportation, drugs and regimens, and M&E. These trainings are also available to non-project countries.

Civil society engagement and grassroots advocacy S 4

CaP TB effectively utilised CSOs to improve project design, increase awareness and demand for access to improved childhood TB diagnosis and management, and to effect policy change.

Scalability & Sustainability

Fig 17. CaP TB Transition Funding Source

Key Fully (All project interventions included) ●

Partially (Some project interventions included) ●

Not Funded (No project interventions included) ○

Post-project funding source	Cameroon	Cote d'Ivoire	DRC	Kenya	Lesotho	Malawi	Tanzania	Uganda	Zimbabwe	India
Domestic Funds	●	●	●	●	●	○	●	●	○	●
Global Fund	●	●	●	●	●	●	●	●	●	○
PEPFAR/USAID/CDC	●	●	●	●	○	●	●	○	○	○

Cameroon

- ✓ National strategic plan budget is earmarked for paediatric TB
- ✓ MoH/NTP agreed to take over most of CaP TB activities
- ✓ Global Fund grant includes paediatric TB innovations
- ✓ CaP TB interventions included in EGPAF PEPFAR project
- ✗ Some interventions not covered by MoH/partners, e.g., Access to CXR, consumable for sample collection, 3RH.

Côte d'Ivoire

- ✓ GOVCDI funds have contributed to the procurement of Ultra cartridges, paediatric FDCs, dispersible H100, and X-ray film.
- ✓ 2021-2023 Global Fund budget included some paediatric TB interventions.
- ✓ CDC / PEPFAR COP 20 included some paediatric TB interventions.

DRC

- ✓ PNLT partners have continued their support to PNLT in different areas.
- ✓ Global Fund grant includes paediatric TB innovations.
- ✓ IHAF (EGPAF USAID project) will support the paediatric TB working group for one year as this was not covered by GF.

Kenya

- ✗ Currently, Paediatric TB allocation is insufficient at 10% of the total budget.
- ✓ Global Fund grant includes most CaP TB innovations.
- ✓ Two new EGPAF-led projects by USAID and CDC will take over some of CaP TB activities, including TB screening, diagnostic workup, sample networking, treatment monitoring, contact tracing and treatment interrupters follow-up.
- ✗ Some interventions not covered by MoH/partners, e.g., x-ray subsidies/vouchers.

Lesotho

- ✓ The GF grant is the main source of funding for CaP TB activities continuation implemented by the MoH.
- ✗ Some interventions not covered by MoH/partners: TB/HIV collaborative activities, active TB case finding in communities and use of mobile CXR.

Malawi

- ✓ The GF grant is the main source of funding for CaP TB activities continuation.
- ✓ USAID-TIFA-TCG agreement is scaling up CaP TB innovations to more peripheral sites.
- ✓ Ongoing discussions for inclusion in PIVOT -CDC project especially case finding models and BMGF project.

Tanzania

- ✓ All CaP TB activities are included in new USAID C3HP award.
- ✓ CaP TB interventions are included in plans of 14 global fund-supported councils.

Uganda

- ✓ Global Fund grant (Detect TB project) includes paediatric TB drugs procurement.
- ✗ GF grant does not include some CaP TB interventions.
- ✓ PEPFAR project funding covers some TB elements
- ✗ Government funding is primarily via Human Resources.

Zimbabwe

- ✓ Global fund CR19 2021 application was approved
- ✓ Infectious Disease Detection and Surveillance (IDDS) funded by USAID committed to supporting the national roll-out of the use of stool on X-pert platform for diagnosis of TB in children.
- ✓ CHAI will support the implementation of short LTBI regimens, which include 3RH and 3HP in some previous CaP TB sites.
- ✗ Domestic resources cover mainly Human Resources and some programme coordination.
- ✗ One previous CaP TB region, Bulawayo, is not covered for continuation.

India


- ✓ In 2020, NTEP has progressed with the integration of paediatric TB with other child health programmes of Rashtriya Bala Swasthya Karyakram (RBSK) – School health and young children health programme, and Rashtriya Kishor Swasthya Karyakram (RKSK) – adolescent health programme, and also with Health and Wellness primary care centres, based on CaP TB Ahmednagar learnings,
- ✓ NTEP also launched a national level training on integration.

Scalability & Sustainability




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To what extent have the core elements of the intervention been transitioned to ensure that the benefits of the intervention will continue beyond the life of the investment?

Finding 6. Most CaP TB project countries transitioned project interventions to GF-supported programmes, and many also transitioned to USG-funded programmes. The project has also capacitated the NTPs with relevant programmatic tools to aid implementation with a successful transition process. TB Speed also implemented transition plans with most transition initiatives limited primarily to research sites.  4

Beyond integration of project interventions into health systems, the CaP TB project also developed and implemented transition plans in collaboration with NTPs/MoH and local actors in the ten project countries. Due to the NCE, transition activities were completed 12 months prior to the new end date, with the project now focused on completing studies in the three remaining countries. Key informants stated that core elements of the interventions had already been “transitioned” since they were integrated into the health system already. They also acknowledged that not all interventions were covered.

TB Speed also initiated transition activities early on, with capacity-building efforts already completed and the transfer of project resources and equipment to NTPs and project sites planned. Respondents, however, felt a strong need for further advocacy to promote project research findings.

Finding 7. The number of interventions tested and/or deployed by these projects were somewhat overwhelming for simultaneous implementation in small pilot locations, and will undoubtedly be cumbersome for countries to scale up. Funding support has mostly been obtained through the Global Fund, often implemented directly by NTPs. There will be need for technical support for countries that are scaling up these interventions to ensure the quality, or prioritisation of the most critical interventions per the country context to be implemented in a phased manner.  4

The projects have successfully implemented planned activities towards transition and continuity of project interventions at global and country levels. The number of interventions being transitioned is many, some of which are highly technical and required extensive training for health workers across countries. Funding support needs to be complemented with technical support to scale-up these interventions. In cases where only funding is provided, scale-up will be cumbersome, and quality may be compromised, especially for larger-scale implementation. Country stakeholders, as well as implementers, cited the need for technical support for the scale-up of these technical approaches at a countrywide scale.

Learning

Lessons on Diagnosis

1 Utilise diagnostic tools as a first step, not rule-out test: The projects showed that access to Xpert testing alone does contribute to improved diagnosis of TB in children; however, it is highly critical to note that a negative Xpert result can not rule out TB in children and clinical diagnosis is of key importance. Xpert testing also builds clinicians' confidence in their clinical diagnosis.

2 Clinical diagnosis is still the mainstay: With different diagnostic tools and sample collection processes deployed and tested on these projects, implementers report that clinical diagnosis remains the mainstay, and its deployment in a decentralised/integrated manner was the most valued innovation of the projects.

3 Prioritisation of X-ray machines and alternative sample collection consumables in procurement is necessary: The projects experienced challenges in increasing access to X-ray and consumables for alternative sample collection. There were limited numbers of X-ray machines in countries, often located at higher level facilities, and consumables for alternative sample collection methods were simply unavailable in many countries, as they were not standard items procured previously. These need to be prioritised in planning processes for scale-up of diagnostic approaches.

Lessons on Systems Strengthening

4 Preliminary results dissemination boosted advocacy efforts: The early dissemination of preliminary findings simplified the advocacy process towards national policy and guideline updates and funding opportunities. For example, the early incorporation of project interventions into GF and USG funding applications, as well as immediate revision of country guidelines to include the projects' innovations.

5 Trainings, site support, and supervision are necessary to reinforce skills: The strong capacity-building efforts of the programme were critical for the implementation and roll-out of paediatric TB services, especially onsite training, as it enabled full coverage of all HCWs at facility level. The trainings were complemented by regular supportive visits and job aids due to the somewhat technical nature of the interventions.

6 Systematic screening in child health services requires task shifting or additional workforce: The introduction of systematic TB screening for children at non-TB entry points increased case detection. This approach increases the workload of personnel at these other service delivery points and does require task shifting to other cadres, e.g., CHWs or additional manpower dedicated to screening, as seen in most of the project countries, especially at MCH and OPD.

Lessons on Community Engagement

7 CSO grants contributed to improving project outcomes, especially policy change and sustainability: CSOs can make concrete contributions to advocacy efforts that contribute to policy change, scalability and sustainability, not just increasing awareness and addressing misconceptions about paediatric TB in their communities. They also made concrete contributions to advocacy efforts that contributed to policy change, scalability and sustainability. They engaged in-country stakeholders: advocating to policymakers; amplifying community voices and strengthening the agency of CHWs. This resulted in the adoption of systematic screening, adoption of a stool sample algorithm, removal of user fees and increased budgets in different countries; discussed in more detail under demand and adoption.

8 A collaborative relationship between implementing partners, CSOs, and communities amplifies advocacy results: The synergy from leveraging each of these actors was one of the success factors of the advocacy approach. CSOs were the lead actor as they are intricately connected with their communities, with a better understanding of how things work and what solutions are contextually appropriate. CSOs, CHWs and Community Champions received technical support on paediatric TB from CaP TB through training. CaP TB also created credibility for CSOs through their relationship. Community TB champions serve as the unbiased voice of the project, speaking out on community needs as community members.

9 Community-led monitoring improved advocacy efforts, allowing for ownership of observations/results and evidence-based tasks: The CaP TB project supported the development of a monitoring system owned by community actors. These actors also had the autonomy to lead monitoring activities in their communities, creating the ideal conditions for ownership of observations and increased use of data. Subsequently, CHWs and other actors utilised these data to inform their advocacy efforts.

10 Early engagement of CSOs is important to increase local ownership and optimise sustainability contributions: Small grants to CSOs were initiated only mid-way through the CaP TB project; if these organisations had been engaged earlier, there would undoubtedly have been increased local ownership and further contributions towards sustainability.





Risk Mitigation

How effectively have strategic, implementation and sustainability/scalability risks been identified and managed over the course of implementation?

The projects did a thorough risk assessment at design stage, identified relevant strategic, implementation and scalability risks and effectively addressed most risks. The table below summarises how these risks were addressed.







Table 3. Risk Mitigation, Resolution and Impact

	Project Experience	Impact	Resolution	Management
Implementation Risks	<i>Complex consortium:</i> The TB Speed consortium was a large and complex consortium, comprising consortium members and technical partners as described earlier. The project experienced some inefficiencies as a result.	Medium	The management structures and processes put in place enabled improved coordination but didn't completely eliminate the inefficiencies.	
	<i>Contextual variations/inadequate scoping:</i> The TB Speed project discovered many contextual differences in implementation areas, including other similar initiatives in project locations (decentralisation efforts) and different baselines for project indicators from what was originally projected, requiring many amendments to study designs.	Medium	The study increased the sample size for Output 1 and adjusted the study durations for Output 2. It also amended the study protocol of Output 1 to adjust for countries with partly decentralised childhood TB services (Mozambique, Uganda and Sierra Leone). Though the amendments were made, they were an indication of inadequate country scoping and baseline assessments, which should have revealed these gaps earlier.	
	<i>Delays in GeneXpert Omni release:</i> The GeneXpert Omni device release was delayed, and the projects had to deploy an alternative.	None	This challenge was anticipated early on, and a clear mitigation plan had been established, which was to replace the device with other Gene Xpert devices. In addition, the projects also created or strengthened existing sample transfer networks and procured a few GeneXpert IV devices allocated based on forecasted needs and distance between sites and Xpert capacity.	
	<i>Challenges Leveraging PEPFAR projects:</i> EGPAF's PEPFAR-funded project ended in two regions where the project overlapped with CaP TB.	None	CaP TB, however, continued work in these regions with changes to the project's resource allocations to cater for the deficit created. This did not negatively impact project activities as the CaP TB team had already envisaged this possibility.	
	<i>Stock shortages of FDCs and GeneXpert Cartridges:</i> National and site level stock-outs of paediatric FDCs were experienced in Cameroon, CDI, India, Kenya, Lesotho, Uganda, Zimbabwe and GeneXpert cartridges in Tanzania, Kenya, and DRC.	High	This impacted the paediatric TB cascade of care, with services delayed due to the absence of commodities in some project locations. CaP TB addressed this by working with country stakeholders to improve stock monitoring processes, and the projects also procured some commodities for supported sites to fill the gap.	

Risk Mitigation



	Project Experience	Impact	Resolution	Mgt
Implementation	<i>COVID-19 Outbreak:</i> This was an unexpected risk that significantly impacted both projects' activities, ranging from cessation of study enrolment activities for about 3-6months to research quality concerns due to phased reopening in different countries with COVID-19 becoming a new confounding factor.	High	TB Speed developed remote monitoring processes to manage research teams and gradually restarted activities with additional resource requirements for biosafety measures, including the provision of PPE, developing a protocol for investigating exposure to health care workers and guidance for safety (patients, staff). Reports from advisory groups such as the TB Speed SAB commend the quality of research conducted within this challenging environment, indicating that quality was maintained. The CaP TB team monitored the situation closely, regularly collecting data on the situation and its impact. They also provided PPE for health services in project locations. Both projects obtained NCEs, as earlier mentioned, to complete research activities.	
	<i>Delayed study protocol approvals:</i> This was the most likely implementation and scalability risk identified by the projects. Delayed approval would create a cascade of delayed implementation, delayed evidence generation and delayed stakeholder buy-in, which is a critical factor for potential scale-up. The projects both experienced these delays, as a result of several factors, most notably protocol development delays for TB Speed and WHO ERC approval timelines.	Medium	These delays also contributed to the need for a no-cost extension of both projects, as earlier described. The projects also proactively shared preliminary findings and routine data with key stakeholders, especially NTPs, POSEE and WHO, leading to immediate utilisation of project results in WHO guidance even for evidence that is yet to be published. NTPs are also supportive of and interested in taking up these interventions and potentially scaling them up.	
Sustainability	<i>Inadequate Transition Funding:</i> MoH/NTP budgets for paediatric TB are very limited, about 10% or less of the entire TB budget in project countries. There are also a few countries where the entire budget is completely donor-funded, so transition funding was important to sustain activities.	Medium	The Cap TB project worked with international partners at global level such as USG (USAID, PEPFAR.CDC) and the Global Fund and their country-level representatives for absorption of the activities into the donor-supported country operational plans. Funding has been secured for the continuation of key paediatric TB innovations through inclusion in GF grants applications/programming, USG projects or domestic funding in all project countries. There are still gaps in funding for some project commodities/interventions, e.g., consumables for sample collection, cough monitors (lay workers conducting TB screening) and paediatric TB M&E., which could not be fully resolved.	
	<i>Insufficient Technical and Human Resources for Scale-Up:</i> The pathway to scale-up and sustainability is not very strong. The programmatic and technical teams required for implementing these approaches at scale will be more than the teams that NTPs currently have.	High	Implementers have effected changes in policies and guidelines, tested and deployed operational processes and tools, and in all countries, a level of funding has been established. However, planning for a full national scale will be a huge jump that most countries may not be able to make on their own without some additional technical support. This could not be addressed by the projects but can be supported by other implementers and funders taking over these services in countries.	



Conclusions & Recommendations

- Conclusions by DAC criteria
- Recommendations by stakeholder category
 - ❖ MoH/NTPs
 - ❖ Donors/Policy Makers
 - ❖ Unitaid



Conclusions

The main conclusions of the evaluation are as follows:

The projects were relevant as they were responsive to the needs of the beneficiary countries and the global TB response as a whole. With the high burden of TB, high mortality rates, underestimated prevalence due to weak diagnosis, sample collection challenges and limited health worker capacity in paediatric TB services, the projects were much needed. In addition, there has been limited funding for interventions/research focused on childhood TB. Also, with new diagnostic tools and child-friendly medicines on the market, there were a number of innovations that were ready to be tested operationally or deployed. The projects were composed of a selection of interventions and research questions that included these new innovations and addressed the major priorities in the childhood TB space at global and national levels. Respondents at all levels agreed that projects with a paediatric TB focus are just as critical because of the dire need and limited actors focusing on this area.

The projects were externally coherent and made significant efforts to ensure alignment of global and country priorities and partners. They were also internally coherent with each other, as well as WHO, through its enabler grant. They

were complementary to other Unitaid projects, with negligible overlaps. The projects were coherent by design and implementation approaches, ensuring alignment with global and country priorities and partners, through close working relationships with key global actors especially convening the POSEE group. The CaP TB project also consistently engaged the two critical sustainability partners (The Global Fund and USG through PEPFAR, USAID, and CDC). At the country level, both projects worked closely with National TB programmes and Ministries of Health. CaP TB engaged more with other implementing partners and advocacy actors, while TB Speed actively engaged the scientific community. The projects were complementary to other Unitaid projects with CaP TB's global and national advocacy efforts creating momentum around new formulations and regimens that other Unitaid paediatric TB projects leveraged (IMPAACT 4 TB and BENEFIT KIDS).

The projects were largely effective and achieved their intended outcomes; generating evidence across several target childhood TB diagnoses and treatment interventions to inform WHO guidance; introducing and deploying innovative diagnostic tools, models of care and new treatments; and creating an enabling policy and regulatory environment for adoption and scale-up of these interventions. The projects addressed key access barriers, successfully introducing and generating evidence

on these child-friendly interventions (Innovation & Availability). They strengthened the capacity of health systems (including health workers and community actors) to deliver these interventions through extensive trainings and supportive supervision and created an enabling policy and regulatory environment for adoption and scale up; including the development of training materials and budgeting tools available globally (Demand & Adoption). Lastly, they collaborated with NTPs and GDF to strengthen supply chains, including supporting product switches to the new paediatric formulations (Supply & Delivery).

The potential impact of the projects was estimated as diagnosing and treating additional children for TB, as well as corresponding YLLs averted. If countries scale up screening by 50% in the next five years compared to project years, there is the potential that an additional 102,500 [37,100 - 267,500] children with TB will be diagnosed, and an additional 106,100 [30,400 - 274,100] more children will complete TB treatment in the 14 project countries and other countries in the WHO Africa region with high TB burdens from 2019-2027. This increase in screening and diagnosis of paediatric TB could avert 4.3m [1.6m - 10.2m] YLLs. The results from the cost-effectiveness studies being conducted by both projects were not available at the time of this evaluation.

Conclusions

The projects were largely efficient, with TB Speed being slightly less efficient than CaP TB.

Both projects experienced external challenges that slowed the speed of implementation at inception (notably COVID-19). In addition, TB Speed experienced protracted delays in developing study protocols that already set the project behind schedule prior to COVID-19. Another critical factor for time-efficiency for both projects was ethics review processes with delays in approval of amendments due to WHO ERC delays and multiple iterations to local IRB in some countries. Some studies took up to eight months to be approved. Subsequently, both projects applied for NCEs to utilise consistent underspends. The projects were largely cost-efficient with negligible expenditure rates in the first year (2017) due to receipt of funds in the last month of the year. However, CaP TB and TB Speed expended 83% and 87%, respectively, by 2021. The projects delivered most of their planned activities across all outputs with over 95% spend on every output. The level of collaboration of project implementers with national authorities in project planning and implementation to promote integration into existing health systems was very high and created significant efficiencies. CaP TB's consortium arrangements were fit for purpose and efficient; however, TB Speed's consortium was too complicated with a larger number of members and partners jointly implementing.

The projects have contributed significantly to creating an enabling environment, especially through evidence generation and dissemination, but also through demonstration of the feasibility of the project's interventions and effective global and local partnerships, resulting in an immediate interest in adoption and scale-up of some of the projects' interventions.

Both projects successfully generated and disseminated knowledge and evidence on their intervention sets and created sustainable access conditions, as the evidence has already informed the new WHO consolidated guidelines on tuberculosis (Module 5: Management of tuberculosis in children and adolescents). Both projects introduced new innovative delivery models, and CaP TB also strengthened the supply base for new paediatric formulations, earlier described under effectiveness. The projects aligned very well with local and global stakeholders, leveraging extensive existing relationships with NTPs, funders and other programme implementers. The CaP TB project successfully updated policies and guidelines, developed and deployed training packages, and secured some scale-up funding for most countries. The scalability condition targets were not fully met in a number of defined areas, most notably the inadequacy of transition and scale-up funding. There are also still concerns about the ability of countries to scale without

technical support due to the technical nature of these services, and the level of planning, supervision and staffing implementers utilised to support implementation in the smaller geographical focus of the projects.

“ The decentralisation of diagnosis was the biggest innovation. It was a bold initiative and it worked. ”

Country level respondent



Recommendations

National TB Programmes /Ministries of Health

- 1) **Identify opportunities to integrate these interventions into future requests for donor-funding and country budget lines**, as most countries have only secured partial scale-up funding.
- 2) **Implement complementary health systems strengthening efforts to increase the effectiveness of TB diagnosis services:**
 - In integrating TB screening for children at non-TB entry points, assess HRH requirements, with considerations for task shifting this role to CHWs.
 - In decentralising diagnosis services, capitalise on adapting existing sample transportation networks for TB samples as an alternative to making significant investments in equipment.
 - Strengthen diagnosis capacity holistically, with focus on improving provider skills; developing infection control plans; creating functional sample transportation networks; developing procurement plans for equipment and consumables; and infrastructure upgrades where needed.
- 3) **Implement community-based services and advocacy efforts through organised community structures such as CSOs.** These ensure increased acceptance among several stakeholder groups, including policymakers, as well as effective and sustained linkages between communities and health facilities.

Donors & Policy Makers

- 1) **Continue funding support to scale up these paediatric TB innovations per recent WHO guidelines, as childhood TB is still severely underfunded.** Investments should include the deployment of rapid molecular diagnostic tests that are suitable for point-of-care in LMIC settings and continue to support the development of diagnostic innovations that will overcome some of the performance and affordability issues with current diagnostic tests.
- 2) **Fund technical support to complement existing financial support for scale-up in project countries**, as a countrywide scale of these technical approaches will be challenging without additional support for planning, supervision, and monitoring.

Unitaid

- 1) **Prioritise streamlined consortium structures**, with a goal to select organisations/consortiums with a relatively wide set of competencies and/or operational scope.
- 2) **Directly engage with scale-up partners at Afl development stage, ensuring alignment from inception and through project life and beyond.** The heavy reliance of Unitaid's catalytic approach on other funders who support implementation at scale, required this level of alignment.
- 3) **Safeguard resources allocated to research dissemination, especially dedicated time for evidence dissemination** and provide resources for advocacy towards the adoption of the study findings. With research results only finalised at the end of the project, there is need to ensure the evidence is well disseminated.
- 4) **Consider intervention-focused evaluations that may cut across multiple projects in a specific portfolio rather than evaluating a portfolio of complex projects/interventions.** The former will produce succinct findings and more actionable recommendations. It will also increase the accuracy of impact estimates with strong assumptions.



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Appendices

Paediatric TB Portfolio Joint End-of-Grant Evaluation Report

Catalyzing Pediatric Tuberculosis Innovations (**CaP TB**) &
Strengthening Paediatric TB Services for Enhanced Early Detection (**TB Speed**)

11 Aug 2022

by **BroadImpact**
Development & Business Consulting





Appendices

- Country Case Studies (Cameroon, DRC, Uganda, India, Cambodia & Zambia)
- Documents Reviewed
- Interview Guides
- List of Participants



Cameroon Case Study



Health worker at St Martin de Porres Hospital, Cameroon, CaP TB implementing site

Paediatric TB Context

Cameroon has a population of approximately 27 million people. The country's TB epidemic is widespread, with an estimated TB incidence of 179 cases per 100,000 people. A total of 46,000 people developed TB in 2020, 5,100 of whom were children. Of this number, only 22,056 were notified. This means that almost 23,944 (over 50%) of Cameroon's TB cases were missed in 2020, including 3,943 children.¹ Children under the age of 15 account for only 5% of Cameroon's notified cases, compared to an expected 10-15% for high TB incidence countries like Cameroon.² With 16,600 TB-related deaths in 2020, the disease is the sixth leading cause of death among communicable, maternal, neonatal & nutritional diseases in Cameroon. TB is a major cause of mortality among PLHIV, and Cameroon ranks among the top 30 countries with the highest burden of HIV and TB coinfection globally.³ An estimated 24% of TB patients are co-infected with HIV.¹ Cameroon's response to the TB epidemic is coordinated by the National TB Programme (NTP) with support from partners such as CHAI, EGPAF, WHO, USAID, CDC and Reach Out Cameroon. The NTP's biggest donor is the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF), which together with other donors, contributes 93% of the overall funding available for TB control. Domestic funding accounts for the remaining 7%. The NTP supervises diagnostic TB testing and provides free TB treatment at 261 health facilities throughout the country. TB control efforts have been successful in gradually declining TB incidence from 260 per 100,000 inhabitants in 2010 to 174 in 2020. TB treatment coverage, however, remains relatively low, at 48%. The NTP's priorities include increasing active and latent TB case detection and therapeutic success rates among high-risk groups, particularly children and scaling up the use of molecular diagnosis for early detection of TB and drug resistance.

Projects Scope

The CaP TB project was implemented by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in the Central, Littoral and Western regions of the country and included the CONTACT, INPUT, and TIPPI studies. The project introduced the following approaches – Integrated TB care in MNCH, HIV, Nutrition SDPs; community-based household contact tracing, screening, and initiation of preventive therapy, including task shifting; 3RH regimens; Xpert Ultra and alternative sample types- NPA and Stool.

1. WHO Global Tuberculosis Report 2021
2. Catalyzing Pediatric Tuberculosis Innovation (CaP TB) in Cameroon accessed at https://www.ped aids.org/wp-content/uploads/2018/05/2018_CaP_TB_Cameroon-2.pdf on the 13th January 2022)
3. Global Burden of Disease Study. Global Health Metrics | Volume 396, Issue 10258, p1204-1222, October 17, 2020



Cameroon Case Study

The TB Speed project was implemented by Institut de Recherche pour le Développement (IRD), who conducted three studies in Cameroon. The study on decentralised diagnostics approaches (Output 1); Early TB screening for children with severe pneumonia (Output 2); and optimising specimen processing tools (Output 4). The evaluation findings include:

Key Findings

Finding 1. The projects' early engagement with the MoH (Department of Disease Control and Division of Operational Research) and WHO enabled these key actors to contribute significantly to the project and research design.

Cap TB held kick-off meetings, a joint planning workshop, and the development of a site review tool to gather information that assisted in defining paediatric TB patients' pathways for screening and initiation on TB treatment as well as the paediatric TB policy landscape analysis. TB Speed also had introductory meetings, further consultations and data collection to inform protocol development.

Finding 2. The projects coordinated very well with the MoH, with improved coordination across TB implementing partners and other stakeholders. The TB Speed project lead was past Chief of TB Services at MoH, allowing for in-depth knowledge of MoH systems and an almost

seamless relationship with MoH stakeholders. CaP TB improved coordination by facilitating the creation of the TB TWG and conducting joint monitoring visits and data quality assessments with the MoH. Many key informants described the involvement of key stakeholders at all levels, from central to the health facility in the project; especially NTP's close coordination with the projects as a key success factor, and this facilitated the national adoption of some CaP TB approaches and strategies and their inclusion in the NSP. An example cited by many informants was NTP's adoption of free TB testing, which has increased demand and uptake of TB diagnosis among children.

Finding 3. The successful revision of national TB guidelines to include relevant paediatric TB innovations is attributed to the intensive support provided by CaP TB project. The project provided evidence on the effectiveness of its interventions; supported the review/validation of TB indices, programmatic tools and training materials in line with WHO's latest recommendations. The 2020-2024 national TB strategic plan now includes: Adoption of Xpert Ultra cartridges, increase of budget allocation for paediatric TB drugs, 3RH for LTBI, and free access to all diagnosis tools (Xpert and CXR).⁴ The National Operational Plan for paediatric TB was

also revised accordingly, with algorithms, treatment and laboratory registers and other M&E tools updated. CaP TB also supported NTP to translate TB guidelines from French to English to meet Cameroon's bilingual needs.⁵

Finding 4. The projects increased health worker capacity significantly, which contributed to increased availability of better approaches for the diagnosis of TB in children. The Cap TB project capacitated a national pool of trainers, training over 1000 MoH staff (Medical Doctors, Nurses, and Lab. Technicians) in paediatric TB management, clinical diagnosis algorithm, including CXR, advanced sample collection and M&E tools training. Key informants reported that these trainings have contributed to a reorientation in the mindset of the HCWs, making them more aware of the intricacies of diagnosing TB in children and intensified case-finding. They also reported challenges with poor HCW attitudes associated with an expectation of financial incentives and an initial shortage of human resources on the TB Speed project, which was resolved by hiring additional consultants to support coordination at the regional/site level.

4. Plan Strategique National 2020-2024 du Programme National de Lutte Contre La Tuberculose du Cameroun (2020-2024)

5. CaP TB Scalability Report 2021



Cameroon Case Study

Finding 5. The CaP TB project increased access to paediatric TB services by deploying a number of simple and effective context-based solutions to address health system inadequacies.

The project deployed sample transportation networks between hubs (sites with GeneXpert, that are fully equipped to process samples) and spokes, with reimbursement of transport to MoH staff where there are no bikers available to transport samples. There was also the implementation of a performance-based incentive programme (POA) in which health workers were motivated to improve performance through cash-based incentives that could be earned when targets were met. These strategies boosted screening and overall TB cascade indicators at supported sites.

Finding 6. The CaP TB project increased demand for paediatric TB services by deploying a number of simple and effective context-based solutions to address patient-related factors.

These include the provision of CXR subsidies (vouchers) for presumptive TB children with negative GeneXpert results, using community relay agents and CSOs as linkage agents who physically guide patients through the referral process. Key informants reported a drastic increase in patient attendance and paediatric TB case notification, attributing these to decentralisation and community engagement. They also reported that community engagement was improved by working with CSOs. A few respondents reported that the duration of CSO

engagement was short, which was true due to late engagement by Cap TB. Respondents also reported increased acceptability of approaches such as NPA, decentralisation of care to district levels and general awareness in communities of service availability and access, with referrals now being done by word of mouth from one community member to another.

Finding 7. Dispersible Paediatric FDCs and single drug dispersible formulations (INH and EMB) have been procured and available in-country via MoH procurements with government funding.

EMB dispersible formulations and 3RH are also available via Global Fund. CaP TB supported NTP in quantifying TB drugs, manage stocks and revise its stock with management guidelines. All key informants reported that the CaP TB project was involved in the procurement and distribution of RH to support the piloting of 3RH regimen for preventive treatment in 50 sites. This support catalysed the adoption and scale-up of 3RH by the country. Key informants also reported that the use of government funding, and consequently, the country's PSM system resulted in supply chain disruptions due to delays in the mobilisation of domestic funds. Respondents acknowledge the support provided by the project, but report that supply chain strengthening is still needed.

Sustainability Outlook

By the end of 2021, Cameroon reported some progress in establishing conditions for country

level scale-up of CaP TB, having most conditions of political and financial support, operational readiness and community-driven demand partially or fully met. The project disseminated results through annual meetings, national TB programme evaluation, national World TB Day, and regional workshops where project findings, challenges and lessons learned were shared. Further, CaP TB actively participated in reviewing the paediatric TB section of the Global Fund 2021-2023 HIV-TB concept note to ensure that key paediatric TB project innovations were included, such as intensified case finding in all entry points, switch to Ultra cartridges and introduction of 3RH.

The transition plan for CaP TB was shared in 2019, and this was refined through the life of the project, with MoH and NTP defining and agreeing on the key priority interventions to be handed over to NTP and national partners. Some activities have already been implemented, including the revision of the national TB guideline to include key interventions on paediatric TB management, revision of the NTP registers to capture the whole TB cascade, decentralisation of the TB treatment to non-TB service delivery points, use of the TOT approach and use of mentors trained for CaP TB project to mentor paediatric TB activities. NTP is now leveraging other resources to scale up these approaches introduced and funded by CaP TB.

Cameroon Case Study



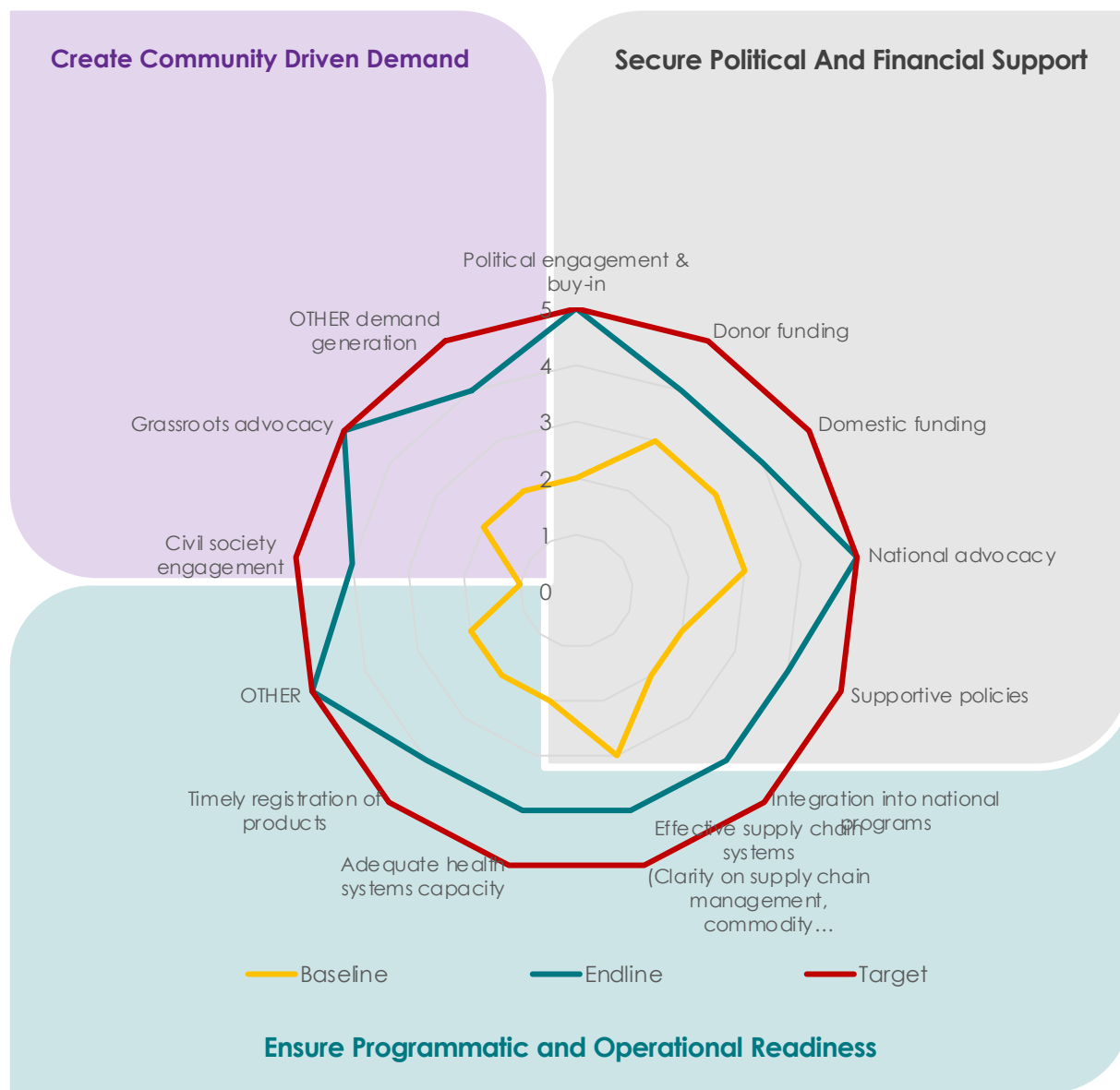
Examples of this include sustaining free TB testing in CaP TB facilities and scaling this up to all of Cameroon's 305 diagnostic and treatment facilities through Global Fund support. Global fund support is also being used under NFM3 to scale up the intensified TB Case-finding intervention, notably, the recruitment of TB mentors at some selected health facilities and coordination of the sample transportation system. The Contributing to the Elimination of Tuberculosis in Africa (CETA) project is also expected to sustain some of the CaP TB interventions.

Most key informants reported that the CaP TB project catalysed the update of the national TB guidelines to align with the latest WHO recommendations. The project also ensured that the guidelines were available in both French and English to meet Cameroon's bilingual needs. Some informants also mentioned that the project played an important role in updating the country's algorithms, treatment and laboratory registers and M&E tools to ensure that adequate paediatric information is routinely collected.

Outstanding Challenges

- National integrated committee under MoH to oversee quantification of TB, HIV and Malaria drugs and other commodities, though strongly recommended to the country during the GDF training in 2019, was not created.
- FDCs are now being procured using government funding, and consequently, the country's PSM system is sometimes interrupted due to delays in the mobilisation of domestic funds.
- There is a funding gap in procurement of sample collection materials, as this is currently not covered by the NFM3 grant. Also, printing and distribution of routine data collection tools have only been partially taken over by the NTP.

Fig 1. CaP TB Scalability Matrix- Country Preparedness



DRC Case Study



Paediatric TB Context

In the DRC, Tuberculosis is associated with a high socioeconomic and health system burden, with DRC being one of the 30 countries that bear 87% of the global TB burden.¹ According to the WHO, Tuberculosis is the second leading cause of death among communicable, maternal, neonatal and nutritional diseases. In 2020 alone, an estimated 286,000 people developed TB (8% with HIV co-infection) and 38,000 (14%) were children. In the same year, only 70% of the total number were started on TB treatment.² This evidence reveals significant challenges in the diagnosis, promotive and curative capacity of the DRC Public Health System in direct contrast with available resources. The country relies heavily on technical and financial support from partners, including EGPAF (through the CaP TB) and International Union Against Tuberculosis and Lung Disease (through its USAID-funded Challenge TB project). There has been increased emphasis on improving TB detection and TB treatment services at community level (including for Paediatric TB) during the recent revision of National TB policies as part of the government vision to eliminate TB by 2030.



Nurse utilising GeneXpert at Saint Sacrement Health Care Facility, Kinshasha, DRC

Project Scope

The CaP TB project was implemented in 10 out of the 32 districts of the capital, Kinshasa. The project introduced innovations aimed at improving Paediatric TB notification and treatment such as the integration of TB screening in all childhood care entry points at facility level; community-based household contact tracing, improved clinical and bacteriological diagnosis using a diagnosis decision tree which included CXR, GeneXpert Ultra, and child-friendly sample collection techniques. The treatment innovations were mostly based on the initiation of preventive therapy with the 3RH regimen using new paediatric FDCs formulations.

Key Findings

Finding 1. Early engagement of a broad range of key stakeholders by the project largely contributed to securing a large “buy-in” into the project implementation approach. An array of high-level stakeholders were engaged at inception, including the MoH Director of the NTP and paediatric services lead, the TB coordinator for the province of Kinshasa, the National Coordinator of Club des Amis Damien (CAD), the representative from the Global Fund, and the WHO-DRC country office.

1. DRC NTP, DHIS2 system: carte score 018 DRC, 2018

2. WHO TB Dashboard 2020



DRC Case Study

Finding 2. The project successfully engaged civil society organizations and the communities in which it was implemented. This engagement was two-fold:

1. Advocacy: Here, four CSOs were trained in advocacy specific to Pediatric TB and received funding to engage key decision-makers on improving budgetary allocation to TB programmes and removing financial barriers in accessing adequate diagnostic. This was done under the context of an ongoing campaign on access to Universal Health Coverage, especially for children under five. The project obtained commitment letters from parliamentarians, health care facility managers and other key decision-makers.

2. Clinical Activity implementation: At community level, the project identified index cases, conducted sample transportation to sites having GeneXpert machines, and supported adherence for patients receiving both preventive and curative treatments.

Finding 3. The project developed training materials and modules, which were later on validated by the MoH. These are now being used as reference documents in Paediatric TB trainings. The MoH, with support from CaP TB, conducted training for a pool of Trainer of Trainers among the ministry’s TB technical staff.

Thereafter, training of health providers in TB clinical management was cascaded down to all the pilot sites using an “onsite training” approach, which proved to be cheaper than the traditional residential approach. The trained healthcare providers mentored other healthcare providers based in non-TB entry points.

Finding 4. The CaP TB project increased the Paediatric TB notification rate by improving healthcare providers’ clinical skills, as well as the availability and affordability of various technologies supporting both clinical and bacteriological diagnosis. CaP TB developed and implemented a CXR access improvement plan based on a diagnosis decision tree, including CXR, the provision of vouchers for eligible children, and signed contracts with selected sites for X-ray services. The project also defined a patient flow and trained a CXR focal point in each site. In order to facilitate timely access to bacteriological diagnosis facilities, the project also provided transport costs reimbursement to CHWs for sample transportation from spokes to the Hub with Xpert and for advanced sample collection procedures.

Finding 5. CaP TB significantly contributed to improving the national TB policy by providing expert contributions to Paediatric aspects of the policy. The policies updated include:

- The national paediatric TB guidelines and corresponding job aids, algorithms, and training materials, in line with the latest WHO recommendations on paediatric TB management 2018-2020;
- Update of the GeneXpert guidelines with the latest WHO recommendation regarding Ultra cartridges. Development of the Latent TB Guidelines, with the introduction of 3RH regimen;
- Update of the preventive TB register and appointment card. Revision of the MDR TB guide (introduction of TB drug second line dispersible formulations for children)
- The 2021-2023 NTP strategic plan with key elements of CaP TB transition plan included.
- DRC advocacy plan developed with local CSOs and the NTP.

Outstanding Challenges

- Relatively low to non-availability of X-ray services.
- Despite the success in securing commitment from parliamentarians and other key decision-makers, the allocation of domestic funding to the TB control programmes is still pending.



DRC Case Study

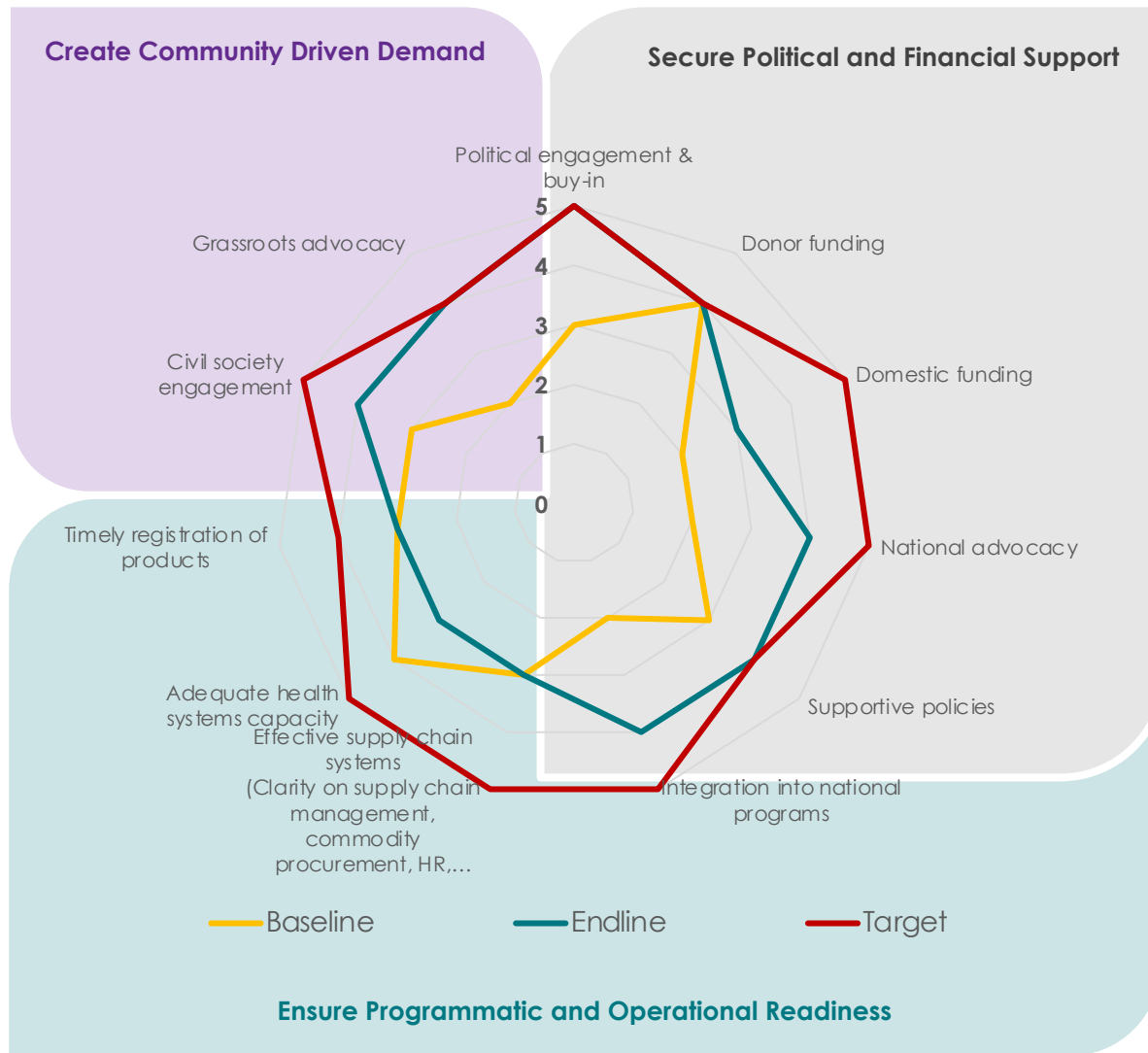
Sustainability Outlook

The project conducted a series of dissemination activities including: Paediatric TB Working Group Meetings, CaP TB annual meeting with the NTP and key stakeholders, the Union Conference, World-TB Day, the AFRAVIH virtual meeting, a regional CSOs paediatric TB advocacy workshop and NTP advocacy, communication and social mobilisation working group meetings.

The changes to national guidelines, strategic plans and other key documents throughout the life of the project are an indication of how project interventions have been well integrated into existing policies. CaP TB also supported the development of the 2021-2023 NTP strategic plan and advocated for key elements of CaP TB transition plan to be included. These are integration of TB screening, sample collection materials provision, contact tracing, GeneXpert initial test, sample transportation, 3RH regimen for LTBI and tools adaptation.

In terms of scale-up funding, the MoH increased its TB domestic funding allocation from 2% to 10% for TB drugs starting in 2019. CaP TB participated in the Global Fund concept note development process and ensured paediatric TB innovations were included, such as GeneXpert as a first-line test, trainings on sample collection procedures and clinical diagnosis, intensification of TB screening in TB and non-TB entry points, procurement of Ultra Cartridges, procurement of additional GeneXpert machines, reinforcement of sample transportation financial support, use of contact tracing register, 3RH for TPT). Club des Amis Damien (CaP TB's CSO partner) has continued to implement CaP-TB activities and they have scaled up beyond the initial intervention sites.

Fig 1. CaP TB Scalability Matrix- Country Preparedness



Uganda Case Study



Madhvan Children's Hospital, Uganda

Paediatric TB Context

TB remains a public health problem in Uganda and is listed as the fourth cause of death among communicable, maternal, neonatal and nutritional diseases. In 2020, an estimated 90,000 people were estimated to have fallen ill with TB, while 16,100 are estimated to have died.¹ While men make up the biggest proportion of TB case notifications (57%), children account for only 12% of the total cases notified. The proportion of notified paediatric TB cases remains relatively stable; however, this is low compared to the expected 15% of all incident TB cases, with a decline observed over the 2019-2020 financial year.² The National TB and Leprosy Programme (NLP) recognises the urgent need to understand and address the drivers of this trend. The key challenges currently include; social stigma and disruption of service delivery due to the COVID-19 pandemic, sub-optimal TB screening at facility level, weak sample referral systems, long turnaround time at GeneXpert testing sites and inadequate utilisation of data for programme improvement.³ Through the new strategic plan 2020/2021-2024/2025, the NLP aims to address the critical challenges associated with TB control in Uganda with the overarching goal to reduce TB incidence by 20% from 200 to 160/100,000 population by the year 2024/25.^{4,5}

To achieve this, the NLP will focus on strengthening community systems to reach high-risk populations and scale-up TB Preventive Therapy (TPT), as well as enhancing public-private collaboration, improving access to diagnostic and treatment services, including the adoption of new technologies and medicines, optimising information management with a focus on digital technologies and strengthening supply chain management systems. Additionally, the programme aims to strengthen leadership and accountability, multisectoral collaborations and resource mobilisation mechanisms.

1. "UGANDA TB Dashboard - Stop TB Partnership." https://www.stoptb.org/static_pages/UGA_Dashboard.html. Accessed 13 Dec. 2021.

2. Global tuberculosis report 2020 - WHO | World Health Organization." 15 Oct. 2020 <https://www.who.int/publications-detail-redirect/9789240013131>. Accessed 13 Dec. 2021.

3. Uganda National TB and Leprosy Program July 2019 – June 2020" <https://www.health.go.ug/cause/uganda-national-tb-and-leprosy-program-july-2019-june-2020-report/>. Accessed 13 Dec. 2021.

4. 4th national tuberculosis and leprosy annual stakeholders' conference'. " 9 Dec. 2021, <https://www.youtube.com/watch?v=JdoNbiYGrE>. Accessed 13 Dec. 2021.

5. Uganda Tuberculosis Roadmap Overview, Fiscal Year 2021 - USAID." 23 Nov. 2020, <https://www.usaid.gov/global-health/health-areas/tuberculosis/resources/news-and-updates/global-accelerator-end-tb/tb-roadmaps/uganda>. Accessed 13 Dec. 2021.



Uganda Case Study

Projects Scope

The CaP TB project was implemented in 40 sites located in Southwestern Uganda. The project introduced the following approaches: integrated TB care in MNCH, HIV, Nutrition SDPs; community-based household contact tracing, screening, and initiation of preventive therapy, including task-shifting; 3RH regimen; Xpert Ultra and alternative sample types- NPA and Stool.

The TB Speed project was implemented by MUHJU, which conducted three studies in Uganda. The study on decentralised TB diagnostic approaches (Output 1) was conducted at facilities in Kanungu, Rakai and Mbarara districts. Early TB screening for children with severe pneumonia (Output 2) was conducted at the national referral hospital, Mulago and Jinja Referral Hospital and the study on validation of diagnostic tools and algorithms in highly vulnerable groups with presumptive TB (Output 3) was conducted at the national referral hospital, Mulago.

Key Findings

Finding 1. The projects' engagement with the National TB and Leprosy Programme was consistent and effective through the life of the project; they worked with an extensive network of community actors, including CSOs, CHWs and

TB linkage facilitators. The project teams collaborated with the NTLP from the initial baseline assessment, protocol writing, site selection and implementation. The projects were implemented in collaboration with other stakeholders through the different platforms that provide technical assistance for the pediatric and adolescent TB response, such as the pediatric TB technical committee. This created opportunities to increase visibility for the project activities and initiated conversations on the potential scale-up of some of the core project interventions. The project worked with a network of community actors, including CSOs, CHWs, and TB linkage facilitators, which facilitated advocacy and increased demand for the project interventions.

Finding 2. The projects implemented a comprehensive capacity building package that included training, mentorship and quality improvement processes, with an average of 250 health workers trained annually. The training focused on clinical diagnosis and management of paediatric TB, advanced sputum collection (GA, NPA and SI), CXR reading and interpretation, screening, contact tracing and TPT. The training package also included a component of adult TB which had a positive impact on adult TB case detection as well as improved uptake of TPT

among people living with HIV/AIDS. CaP TB's capacity-building approach included.

Finding 3. CaP TB leveraged the USAID/RHITES-SW project for commodity logistics support and enhancing sample transportation networks through motorcycle maintenance support.

Finding 4. CaP TB supported relevant policy revisions. The project contributed to the 2020 HIV/AIDS consolidated guidelines which recommend the use of 3RH and 3HP for children under 15 years and children two years and older, respectively. The projects also supported the revision of the NSP 2020/21-2024.

Outstanding Challenges

- Screening with X-ray is still inadequate due to challenges in setting up the required structures.
- Quality of diagnosis is still compromised at a few sites due to delays in training and delivery of equipment.
- Considerable limitations to scale up due to delay in implementation. Informants stated that most of the implementation was done in the last two years of the project.

Uganda Case Study

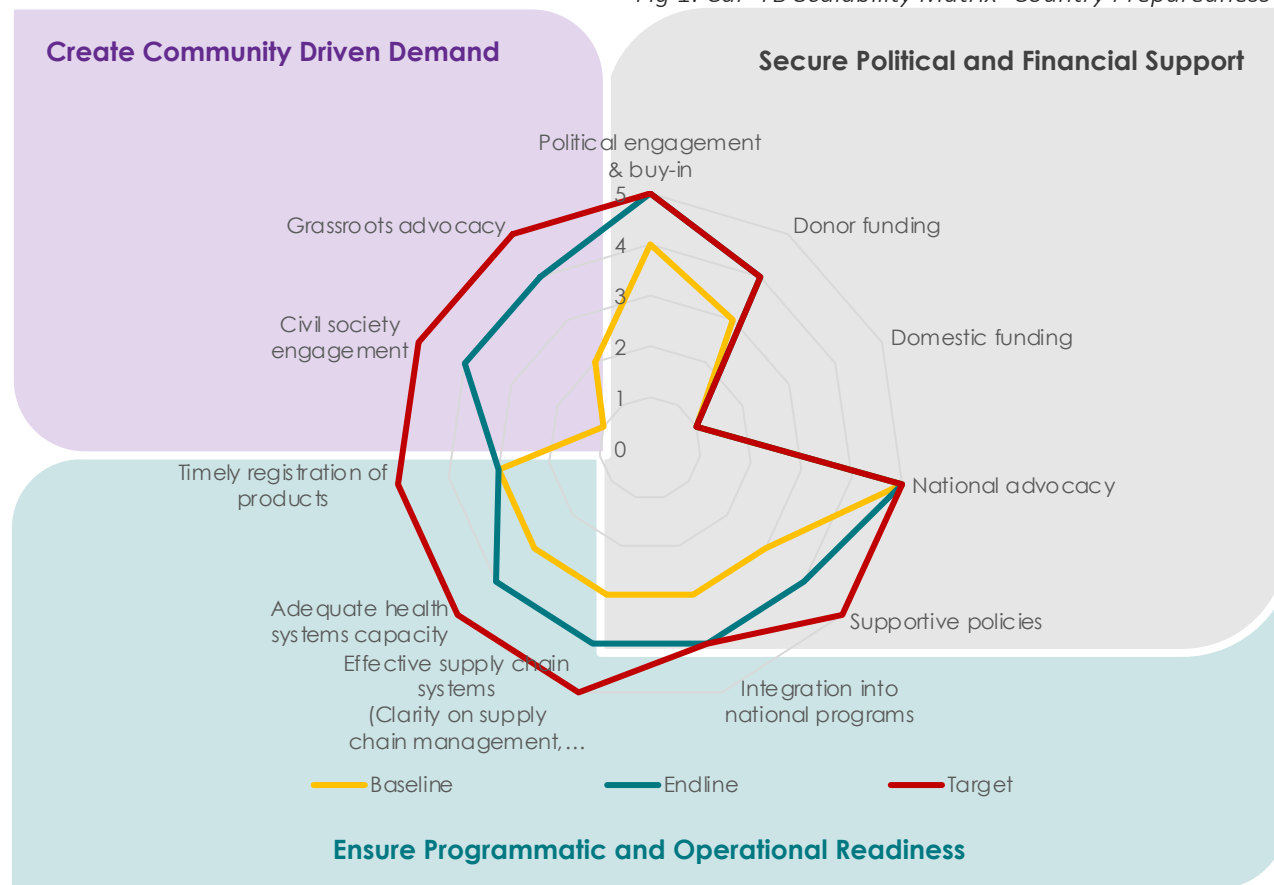


Sustainability Outlook

Key national stakeholders were involved from the design stages of the projects as co-decision makers and have been updated regularly on project results through paediatric TB committee meetings (this group reviews evidence and provides guidance for national guidelines and scale-up). As a result, feels a deep sense of ownership of the projects' interventions. NTLP leadership reported utilising the CONTACT study to push for policy changes around introducing household contact tracing as well as the inclusion of RH and TPT in their national guidelines. Project findings have been disseminated via several platforms/for a, including the paediatric TB technical working group, Regional TB performance review meetings organised by National and Regional TB and Leprosy Programme representatives, and ongoing project-led rounds of learning sessions to collate best practices on paediatric TB.

Key informants described the conversations around scale-up and sustainability as involving many partners and donors, especially through the paediatric and adolescent TB working group. The NTLP is aware of the high-impact interventions that can be tapped into and is developing a package that will be disseminated at facility level. Some of the key elements that will be sustained include; the equipment procured by the projects, screening tools and models for mentorship. Key informants mentioned that TB linkage facilitators/cough monitors and procurement of TB stamps are some of the core elements that have already been transitioned to USAID/PEPFAR funding. TB SPEED has also developed a sustainability action plan based on simple tools that will be shared with the NTLP.

Fig 1. CaP TB Scalability Matrix- Country Preparedness



Advocacy to include a separate budget line for paediatric TB in GF concept notes was successful, with GF concept notes approved in 2020. The funding covers GeneXpert ultra-cartridges and contact tracing, but not Dispersible child-friendly TB drugs formulation (RH, RHZ, EMB, INH). Further, CaP TB team has mapped all the key partners that could potentially take over paediatric TB activities, which were poised to receive USAID funding linked to EGPAFs Technical Assistance work with USAID: Uganda Protestant Medical Bureau, Mbarara Regional Referral Hospital and The AIDS Support Organization (TASO). These have been engaged through a series of introductory and project dissemination meetings. Dispersible child-friendly TB drugs formulation were classified as “above allocation” by GF, and these need to be procured via other funding sources.

India Case Study



Paediatric TB Context

In India, an estimated 333,000 children in the age group 0–14 years become ill with TB each year, with a slightly higher burden among males.¹ Pulmonary TB is the most common form in children, but extra-pulmonary TB forms a more significant proportion of cases reported. About 6% of the cases reported to the National TB Elimination Programme (NTEP) are from children up to 14 years of age. In 2019, the NTEP reported 150,000 TB cases of children aged 0–14 years, indicating a gap of 55% in TB notifications in this age group. To address the gaps in Paediatric TB coverage, the National TB Elimination Programme (NTEP) is working closely with the Child Health and Adolescent Health programmes of the Ministry of Health and Family Welfare (MoHFW). The NTEP aims to provide universal access to TB control services, including screening, diagnostics, treatment, and infection control.²

Project Scope

The CaP TB project was implemented in Andhra Pradesh (AP), Telangana (TS), and Maharashtra (MH) by SAATHII with emphasis on the private sector in urban and peri-urban settings. The project introduced the following approaches: integrated TB care in MNCH, HIV, Nutrition SDPs; reverse contact tracing of contacts of paediatric cases, screening, and initiation of preventive therapy, including task shifting; 3RH regimens; TruNat or Xpert Ultra and alternative sample types – NPA and Stool.

Key Findings

Finding 1. The CaP TB project in India demonstrated the integration of paediatric TB services in the private health sector through evidence generation and catalysing scale-up. CaP TB helped bridge the gap with the private sector to close the gap in diagnosis of paediatric TB. The project also leveraged the new private sector engagement policy.

Finding 2. The project supported trainings to disseminate “RNTCP Updated Paediatric TB Guidelines 2019” in collaboration with Indian Academy of Paediatrics (IAP) at national, state and district levels, building a pool of ToTs to conduct cascade trainings. CaP TB ensured alignment with MoH, the Indian Academy of Paediatrics (IAP) and other TB programme implementers: GF-funded Joint Effort for Eliminating TB (JEET) project partners, Clinton Health Access Initiative (CHAI), FIND, PATH, TB Alert and CSOs. CaP TB supported the development of the updated 2019 Paediatric TB guidelines led by the RNTCP (Revised National Tuberculosis Control Programme) and the Indian Academy of Paediatrics (IAP).

Finding 3. Improving sample transportation at project sites using Field Treatment & Prevention Coordinators (FTPC). The intervention supported the sample collection procedures at CaP TB sites through a fixed cost reimbursement for Induced Sputum, Nasopharyngeal aspirate, Gastric aspirate

and FNAC. Supporting sample transportation within the private sector with linkages to Government facilities.

Finding 4. Increased TB screening and detection rates in supported sites. A rapid response system was established to inform CaP TB field staff of all PR-TB cases to be evaluated for TB as they are found, with a one-day follow-up target. The intervention supported NTP staff to undertake reverse contact tracing of paediatric index cases identified in CaP TB sites through facility, community and phone-based contact tracing. Improved programme monitoring using power BI dashboards to analyse site-level performance.

Finding 5. SAATHII CaP TB worked with CTD on data sharing to integrate CaP TB MIS with the national MIS (Nikshay). This ensured that increased the use of Government procured FDC drugs and reduced utilisation of private sector FDCs with suboptimal dosage as per WHO recommendations through advocacy efforts via meetings with DTO, DMHO and IAP stakeholders.

1. <https://tbfacts.org/tb-statistics-india/>

2. Hazarika, Indrajit. “Role of Private Sector in Providing Tuberculosis Care: Evidence from a Population-based Survey in India.” *Journal of global infectious diseases* vol. 3,1 (2011): 19-24. doi:10.4103/0974-777X.77291

India Case Study

Sustainability Outlook

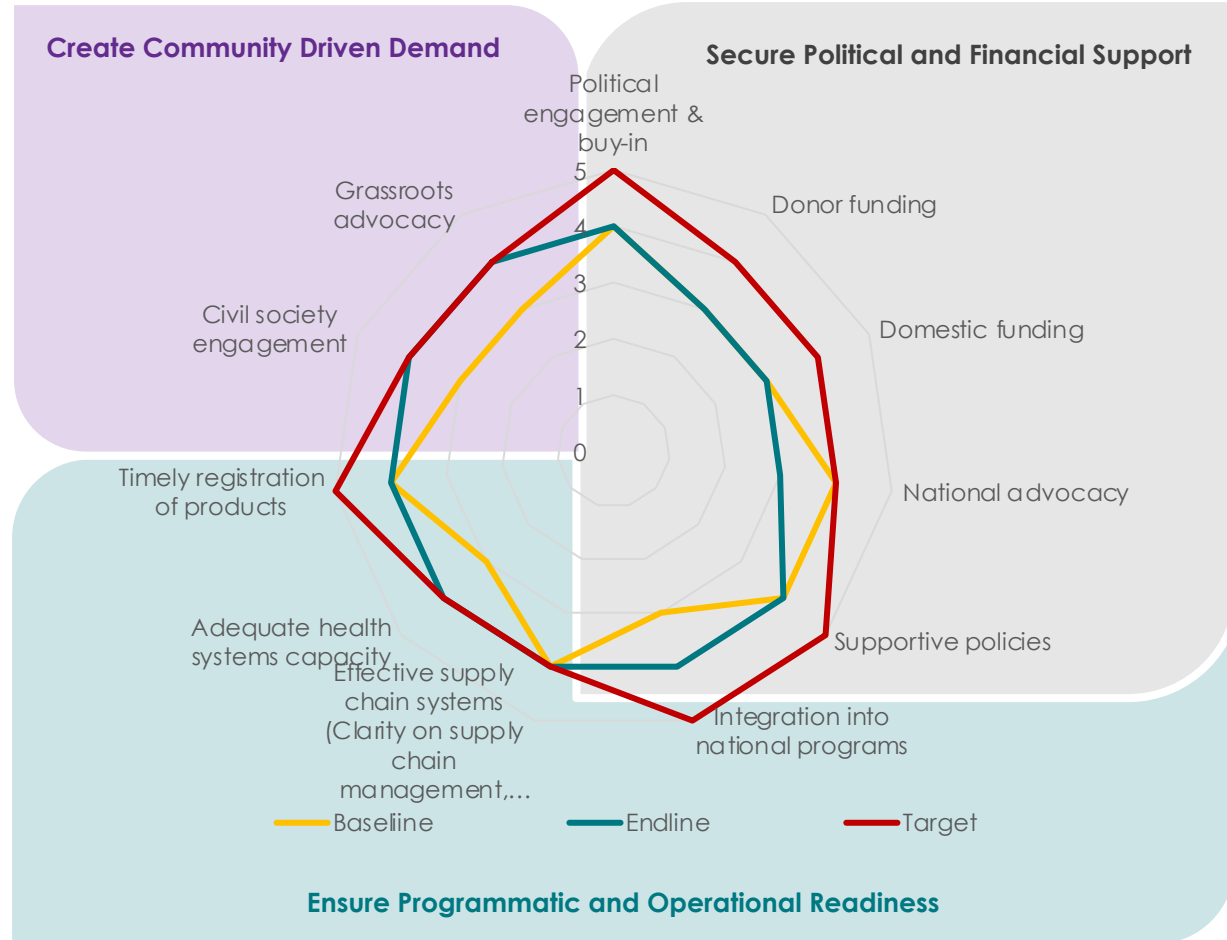
Transition plans were created early in the life of the project, with SAATHII identifying the Global Fund-supported JEET private sector consortium, the World Bank-supported National Technical Support Unit (TSU), upcoming NTEP-supported PPSA projects and the Indian Academy of Paediatrics, as sustainability partners. The project organised regular meetings and shared project reports with NTP and other relevant national authorities to present project updates. The team also developed and distributed regular newsletters targeting key stakeholders (MoH, donors, CSOs) on project activities, and worked with journalists on media stories to highlight project interventions.

In 2020, NTEP progressed with the integration of paediatric TB with other child health programmes such as the Rashtriya Bala Swasthya Karyakram (RBSK), school-health and young-children-health programme, and Rashtriya Kishor Swasthya Karyakram (RKSK) adolescent health programme, and also with Health and Wellness primary care centres, based on CaP TB Ahmednagar learnings. NTEP also launched a national-level training on integration.

Outstanding Challenges

- The NTP conducted an initial trial using Ultra cartridges in Mumbai in selected hospitals, but there are no specific guidelines or other official communication on Ultra introduction.
- Provider and caregiver reluctance to initiate IPT with 6H for eligible contacts due to perception of resistance. The alternative 3RH is recommended by NTP but still waiting for approval from the MoH.

Fig 1. CaP TB Scalability Matrix- Country Preparedness





Cambodia Case Study

Paediatric TB Context

Tuberculosis (TB) is a severe concern in Cambodia. In the past two decades, the country has made notable progress in TB control. In 2016, the TB incidence was approximately half of what it was in 2000, with a similar decline observed in the TB mortality rate. Cambodia also recorded a TB treatment success rate of 94%, one of the highest among the 30 countries with a high TB burden in 2017. However, the successes are encumbered by a significant proportion of undiagnosed cases. It is estimated that 40% of TB cases go undetected in Cambodia. Each missing case continues to perpetuate the transmission of TB and contribute to the current TB burden, compounding the challenge to end TB. In 2020, 46,000 developed TB symptoms, and 9,600 were children. An estimated 1,100 people with TB were co-infected with HIV, and 3,300 people died due to TB. Although the detection rate of smear-positive TB cases has declined in recent years, the total number of TB cases continued to rise, partly due to the increased focus and capacity to diagnose smear-negative TB.

Projects Scope

The TB Speed project was implemented by Institut Pasteur, working hand in hand with the NTCP in Cambodia. The study on decentralised diagnostics approaches (Output 1) was implemented in Angroka and Batheay.

Key Findings

Finding 1. The project attracted a high level of interest amongst childhood TB stakeholders on the projects' interventions. This resulted in increased awareness, alignment and coordination with stakeholders. There were regular country project committee meetings, HIV/TB TWG and quarterly national interagency meetings that the project use to effectively engage TB stakeholders, including MoH, GF, CDC and other implementers, identifying alignment and synergies. Respondents described the projects' close working relationships with the NTP and other actors.

Finding 2. The TB speed screening algorithms were incorporated into national training curricula for clinicians. The project ensured extensive human resource training and capacity building across the cascade of care. TB workshops and mentoring on paediatric TB screening and diagnosis were conducted at project sites. This increased HCWs' competence and confidence in diagnosis.

Finding 3. TB Speed promoted the decentralisation of diagnostic approaches, enabling small PHCs have the global package to diagnose and treat TB. This was achieved by capacitating the national programme for the diagnosis of TB in children by creating tools, providing training, providing CXR machines, and other supplies to the government. Respondents reported that decentralising TB screening and diagnosis has been on the NTP's radar for long but was finally implemented with this project.

Finding 4. The intervention introduced Xpert Ultra and alternative sample types, including NPA and Stool, to optimise the specimen processing.

Respondents reported that TB Speed provided easier tools that could be decentralised to lower-level facilities, showing health care workers at these lower levels that TB diagnosis is possible, quick, easy and feasible.

Finding 5. The childhood TB management national guideline was revised with input from the project. NTP co-designed the project activities to ensure that interventions were in line with the national standards and goals, and to make them practical, implementable, and replicable.

Sustainability Outlook

There was very limited focus on sustainability at country level due to the nature of the project. However, the project increased political will for paediatric TB interventions from the central government. Country respondents have high expectations for the final results of the study, and expect to continue these interventions if results are favourable.

The technical capacity to implement the interventions were transitioned to MoH facilities and staff through capacity building provided during implementation, with additional equipment to be donated to the government at closeout.

1. World Health Organization. *TB country profile: Cambodia*. Geneva: World Health Organization; 2019.

2. Stop TB Partnership, United Nations Office for Project Services (UNOPS). 90–90–90. *The tuberculosis report for heads of state and governments*. Geneva: Stop TB Partnership and UNOPS; 2017.

Zambia Case Study



Paediatric TB Context

Tuberculosis is a major public health concern in Zambia, as it is the third cause of death among communicable, maternal and neonatal and nutritional diseases.¹ Globally, Zambia is ranked 21 among the 30 HBCs.² There were an anticipated 59,000 new TB cases in 2020, and only 40,000 (68%) were diagnosed and commenced on treatment. However, for paediatric TB, only 50% of the anticipated cases were diagnosed and commenced on treatment.¹ A Ministry of Health report in 2019 revealed that 33% of TB patients diagnosed between January and August 2019 were not notified to the NTL.³ These figures show a major gap in TB case identification and notification which is more pronounced in the diagnosis and treatment of TB in children. Zambia's NSP for TB prevention, care, and control 2017-2021 envisions a TB-free Zambia by 2030 by providing equitable access to cost-effective, high-quality TB services. The NTL hoped to reduce the number of TB deaths by 40% by 2021 (as compared to 2015).⁴

Projects Scope

The TB Speed project was implemented in two tertiary hospitals based in Lusaka Province and the Copperbelt Province. In Zambia, the TB Speed project implemented four studies: Early TB detection strategy in children with severe Pneumonia; Diagnostic tools and algorithms in

HIV-infected and severely malnourished children; Specimen processing and collection methods optimisation; and Cost-effectiveness of the proposed diagnostic approaches

Key Findings

Finding 1. TB Speed engaged early with the MoH, WHO and USAID, organising consultative meetings at the project's inception, and active participation in the weekly TB situation room subsequently. There was, however, very limited sub-national level engagement. The project team coordinated ongoing data management and monitoring during a weekly TB situation room meeting where key project stakeholders participated in data review and decision-making on research activities. The project's engagement with MoH was good at national level, but it had very limited engagement at sub-national level, civil society organisations and communities. Sub-national level TB focal points reported little or no engagement with the project. These stakeholders viewed the project as a hospital-based research project. Country-level implementers also reported that the scope of the project did not include community engagement.

Finding 2. The project introduced innovations in the two teaching hospitals supported through its research studies. There were, however, concerns from respondents about the project meeting its objectives. The project introduced

new tools, technology and algorithms; however, respondents were unsure of the status of these activities, stating that sample size targets were unmet, with the project being severely set back by COVID-19. They also described other realisations during implementation, such as the very low number of paediatric HIV cases due to the success of the national PMTCT programme and the existing decentralisation of HIV programmes to lower-level facilities, which affected the enrolment rates significantly.

Finding 3. The project provided implementation sites with all necessary logistics to support improvement in clinical and bacteriological diagnosis as well as the prompt treatment initiation.

The project provided TB management skills training to healthcare providers, including midlevel providers, and equipment to facilitate digitalisation of X-ray images for quality assurance. With regards to bacteriological diagnosis, the project donated GeneXpert machines and laboratory consumables, and timely transportation of samples for processing.

1. WHO TB Dashboard 2020

2. World Health Organization. Global Tuberculosis Report, 2020

3. Ministry of Health. A report on under reporting of TB patients in Zambia, 2019)

4. Zambia National Strategic Plan 2017-2021

CaP TB

Grant agreements, amendments and reprogramming reports
 Unitaid (2021) Grant Amendment to extend the duration of the grant by 12 months (NCE)
 Unitaid (2019 Jan) Minor reprogramming
 Unitaid (2017) Grant Agreement (original)

Reports

2021 Annual report
 2020 Annual Report
 2019 Annual Report
 2018 Annual Report
 2017 Annual Report

Logframe

Impact models/estimations

Reports/Research/Investment cases
 Advocacy for Effective Childhood TB Responses: Lessons Learned from CaP TB Advocacy Small Grants Project - EGPAF (pedaids.org) (2022)
 Union conference presentations (2021)
 Integrating paediatric TB services into child healthcare services in Africa: study protocol for the INPUT cluster-randomised stepped wedge trial (2020)

Other briefs and information

Supporting community and civil society advocacy to scale up quality childhood tuberculosis services - EGPAF
 It is Time to Ensure No Child is Left Behind: Budgeting Tools for Paediatric and Adolescent TB Interventions
 GDF Medicines catalog May 2022

TB Speed

Grant agreements and amendments

Unitaid (2021) Grant Amendment to extend the duration of the grant by 12 months (NCE)
 Unitaid (2017) Grant Agreement (original)

Reports

2021 Annual report
 2020 Annual Report
 2019 Annual Report
 2018 Annual Report
 2017 Annual Report

Logframe

Impact models/estimations

Evaluation Reports and EVAs
 Mid-term evaluation of the TB pneumonia study (output 2) commissioned by Expertise France/5% Initiative and conducted by AEDES (2021)

Reports/Research/Investment cases

TB-Speed preliminary technical report (2022)
 TB-Speed Pneumonia Study Group (2021). Impact of systematic TB detection using Xpert Ultra on nasopharyngeal aspirates and stool samples on mortality in children with severe pneumonia.
 Union conference presentations, including early results of pneumonia study (2021)
 Contribution to WHO guidance on paediatric TB diagnosis (June) (2021)
 Impact of systematic early tuberculosis detection using Xpert MTB/RIF Ultra in children with severe pneumonia in high tuberculosis burden countries (TB-Speed pneumonia): a stepped wedge cluster randomised trial (2021)
 Laboratory development of a simple stool sample processing method diagnosis of paediatric tuberculosis using Xpert Ultra (2020)
 TB-Speed Study Group (2020). Laboratory development of a simple stool sample processing method diagnosis of paediatric tuberculosis using Xpert Ultra.
 Tackling mortality due to childhood tuberculosis, The Lancet Public Health, 380 (2018)

WHO TB enabler

Unitaid (2020) - Internal evaluation of WHO enabler (TB component)

WHO TB enabler reports (annual and SAR 2021)

WHO TB enabler project plan and logframe

Other Relevant Documentation

WHO (2022) Consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents.

WHO (2022) Operational handbook on tuberculosis. Module 5: management of tuberculosis in children and adolescents.

WHO (2021) Global TB report

Unitaid (2019) Disease Narrative for Tuberculosis

WHO/Unitaid (2018). Roadmap towards ending TB in children and adolescents

WHO (2018) Latent tuberculosis infection: updated and consolidated guidelines for programmatic management

WHO (2015) Global TB report

Unitaid (2018) Impact Story: Improving use of Tuberculosis Diagnostics

Unitaid (2019) Impact Story: Childhood Tuberculosis

Unitaid (2018) Multi-disease diagnostic landscape for integrated management of HIV, HCV, TB and other coinfections

Unitaid (2017) Tuberculosis Diagnostic Landscape – 5th Edition.

Unitaid (2015) TB Diagnostics Market in Select High-Burden Countries: Current Market and Future Opportunities for Novel Diagnostics.

Unitaid STEP TB Evaluation

USAID (2016) The policy and practice divide for childhood tuberculosis in Africa: a landscape analysis

Unitaid (2014) Tuberculosis Medicines Technology and Market Landscape.

Interview Guides



Grantees & Consortium Members interview/discussion guide	 Lead Grantees.docx
Ministry of Health/NTP (National Level) interview/discussion guide	 National MoH Respondents.docx
Ministry of Health/NTP (Sub-national level) interview/discussion guide	 Sub-National MoH Respondents.docx
Civil Society/Community Groups interview/discussion guide	 Civil Society.docx
Health Workers interview/discussion guide	 Health Workers.docx
Donors, Scale-up Partners & Other Global Stakeholders interview/discussion guide	 Donors_Other Stakeholders.docx
Unitaid Secretariat interview guide	 Unitaid.docx

Participants –Global & Non-Case Study Countries

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25	Global Fund	Senior TB advisor	Anna Scardigili
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28	PACCI, Côte d'Ivoire;	Principal Investigators	Raoul Moh
29	Therapeutic Solidarity and Initiatives for Health (Solthis).	Principal Investigator	Guillaume Breton
30	University of Montpellier, IRD, Cameroon, Uganda	Principal Investigator	Maryline Bonnet



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Participants- Uganda



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12	EGPAF	PI -Contact study	Daniel Atwine
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India

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3	TB Speed Country Team-IRD	Co-Investigator	Dr Bonnet
4	TB Speed Country Team-IRD	Former director of NTP-MOH Advisor / <u>Co PI TB-Speed</u>	Dr MAO Tan Eang
5	CDC	CDC representative	Dr Hy Chhaly



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