DECEMBER 2021

THE CATALYZING PEDIATRIC TUBERCULOSIS PROJECT IN KENYA 2021

Implemented by The Elizabeth Glaser Pediatric AIDS Foundation

Elizabeth Glaser Pediatric AIDS Foundation
Fighting for an AIDS-free generation

Unitaid
Innovation in Global Health

THE CATALYZING PEDIATRIC TUBERCULOSIS PROJECT IN KENYA 2021

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ACRONYMS

ADR	adverse drug reaction
APOC	adolescent package of care
CHAI	Clinton Health Access Initiative
CHV	community health volunteer
CLO	community liaison officer
CSO	civil society organization
CXR	chest X-ray
DS TB	drug-sensitive TB
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
ERC	ethical research committee
FDC	fixed-dose combination
GFATM	Global Fund to Fight HIV, TB and Malaria
HCW	health care worker
ICF	intensive case finding
INH	Isoniazid
INPUT	the Integrating Pediatric TB Services into Child Health Care Services in Africa study
IPD	inpatient department
IRB	Institutional Review Board
KNH-ERC	Kenyatta National Hospital Ethics and Research Committee
LTBI	latent TB infection
M&E	monitoring and evaluation
MNCH	maternal, newborn and child health
MOH	Ministry of Health
MTB	Mycobacterium tuberculosis
NACOSTI	National Commission for Science, Technology, and Innovation
NTP	National TB Program
OPD	outpatient department
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PSSG	psychosocial support group
RHZ	rifampicin, isoniazid, pyrazinamide
SOP	standard operating procedure
TAG	technical advisory group
TIPPI	Evaluation of the Catalyzing Pediatric TB Innovations Project
TPT	TB preventive treatment
TWG	technical working group
TX	treatment
WHO	World Health Organization

EXECUTIVE SUMMARY

Catalyzing Pediatric Tuberculosis Innovation (CaP TB) is a UNITAID-funded project that ran from 2017 to 2021. Managed and implemented by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the project covered 10 countries, including Kenya. TB remains a major public health concern in this nation – being the leading cause of death of both children and adults.1 Even so, there is evidence to suggest that a significant number of children go undiagnosed and untreated. Accordingly, CaP TB sought to address existing baseline gaps with informed interventions.

Moreover, the project served to center the pediatric TB agenda at the 10 facilities in Turkana County and the 24 in Homa Bay. This, too, served to address various gaps, including: (1) limited integration of TB screening into other services, leading to missed opportunities for identification; (2) limited capacity for pediatric TB diagnostic services (e.g., the use of GeneXpert, clinical-radiological evaluation); (3) low pediatric TB case finding; (4) insufficient number of GeneXpert and uncoordinated sample networking – especially for diagnostics; (5) low awareness of TB communities; and (6) delayed TB contact tracing activities and TB preventative treatment (TPT) enrolment.

Fundamentally, the project aimed to increase pediatric case detection, initiation on TB treatment, and TPT through integrated and decentralized models of care, while introducing improved diagnostics and treatment for latent and active TB and employing household contact tracing.

All photos: Kevin Ouma 2021

CAP TB ACHIEVEMENTS BY OBJECTIVE

OBJECTIVE 1:

create an enabling policy and regulatory environment at the global and national levels

Through the Ministry of Health's (MoH) TB Technical Advisory Group (TAG), the CaP TB team helped revise the pediatric TB training curriculum for national health care workers (HCWs). The project also supported the development of the National Strategic Plan for TB (2019–2023), which included childhood TB priorities informed by CaP TB implementation. In collaboration with the National TB Program (NTB), CaP TB helped revise the latent TB infection (LTBI) policy document, the integrated TB guidelines, standard operating procedures (SOPs), and HCW training resources.

The project relied on civil society organizations (CSOs) to create an enabling policy environment. Accordingly, the team strengthened the capacity of the Stop TB Partnership—a local CSO—to use small grants to engage policymakers and decisionmakers at various levels. This bred robust, community-based advocacy, created demand for national TB policy reforms, and expanded pediatric TB care.

OBJECTIVE 2:

introduce effective and innovative models of care to improve pediatric TB case detection

The project adopted activities and tools that served to detect potential TB cases as early as possible. One example of this is the intensified case finding (ICF) screening forms: simple questionnaires used to screen for TB signs and symptoms. There were also Pediatric Service Optimization forms used only for children with confirmed symptoms of TB to allow documentation of the diagnostic work. These changes improved TB screening services for clinic attendees at targeted service delivery points, resulting in greater uptake, as demonstrated in the graph below.

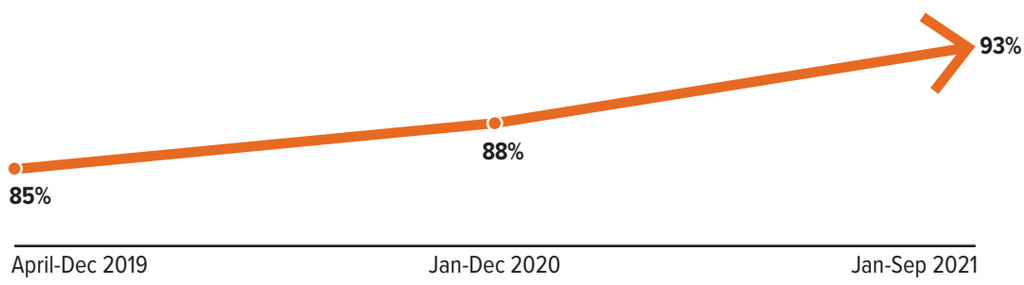


FIGURE 1: Screening trends from project start (April 2019) to third quarter of final project year.

Lay workers were engaged to support clinics with active TB screening for children. Known as “cough monitors”, they were stationed at triage desks and worked as first screeners in all facility entry points. This improved clinicians’ responsiveness regarding the diagnostic workups needed to further evaluate children with TB symptoms.

In order to improve access to laboratory based diagnosis for children, the project supported use of the rapid molecular assay Xpert MTB/RIF as the initial test on pediatric patients identified as presumptive TB. Molecular assays such as Xpert MTB/RIF have the advantage of being more sensitive compared sputum smear microscopy and allow the simultaneous detection of TB and resistance to a common TB drug, rifampicin. Diagnostic efforts were supported by advanced sample collection procedures (including gastric aspiration, nasogastric aspirate, and sputum induction), installation of a 2 modular Genepert machine at Lopiding Sub county hospital, and a robust sample networking system. The latter used motorcyclists to speed up testing and results retrieval to foster timely clinical decision making and treatment.

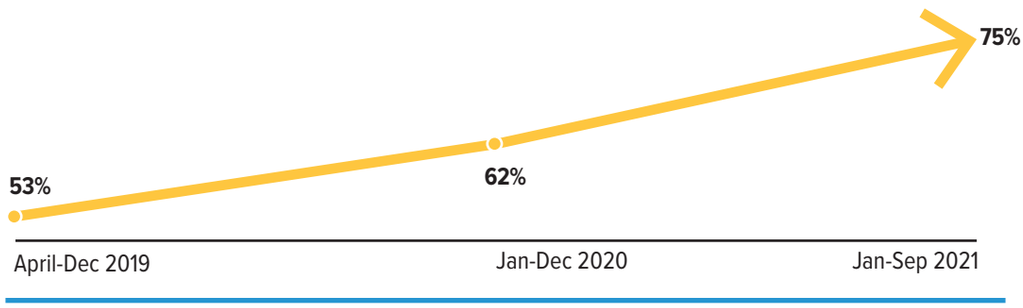


FIGURE 2: proportion of children with presumptive TB who accessed GeneXpert testing

While it is important to improve access to laboratory-based diagnosis for children in order to obtain bacteriological confirmation of TB disease whenever possible, the performance of currently available diagnostic tests, including the rapid molecular assays, remains limited in children. Therefore, a negative Xpert MTB/RIF test should not rule-out active TB disease. In the presence of TB signs and symptoms, all children with a negative test should be further evaluated through CXR and clinical assessment. In order to support the clinical-radiological diagnosis of pediatric TB, the project also introduced the electronic transmission of radiographic images. Teleradiology allows for X-rays taken in distant areas (spokes) to be checked by expert radiologists in another location, who then transmit the results via email within two hours. Additionally, X-ray payment vouchers were introduced to aid families that needed more than transport reimbursement to cover the cost of attending referral centers. This helped raise the uptake of radiological services from 53% to 75% and enhanced the quality of X-ray reporting. The project also implemented a training program for front-line health workers aimed at building capacity to diagnose and manage pediatric TB. This multipronged approach including improved access to laboratory based diagnosis and improved capacity for clinical-radiological diagnosis and these above factors led to increased pediatric TB diagnosis in Turkana and Homa Bay Counties.

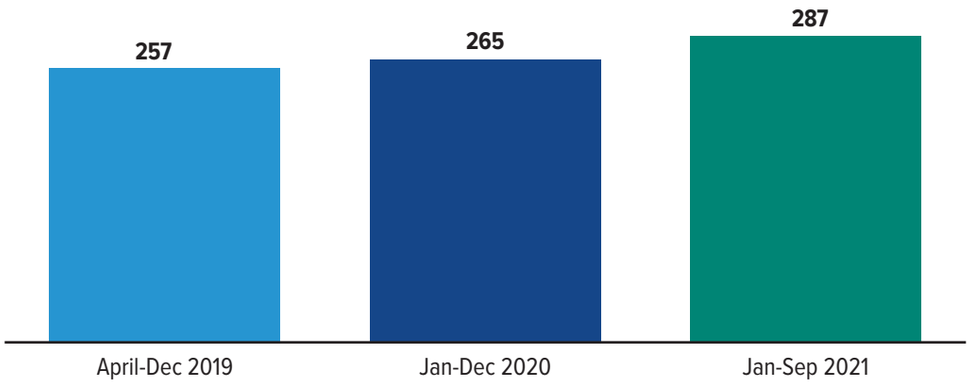


FIGURE 3: number of pediatric TB cases diagnosed over time

OBJECTIVE 3:

increase uptake of, and access to, improved pediatric treatment for active and latent TB infection

The engagement of trained community health volunteers (CHVs) and cough monitors strengthened community-based TB contact investigation and management. Thus, it improved TPT coverage among child contacts and children living with HIV. Treating people with latent TB is a key component of disease control. Regular, low-cost preventive medication serves to avert TB cases in children at risk of contracting the disease, along with children and adults living with HIV. The World Health Organization (WHO) recommends 3RH regimen for children < 15 years and recommends TPT for all contacts irrespective of age. Isoniazid (INH) is recommended for children who are newly diagnosed, and those living with HIV.

FIGURE 4: proportion of eligible pediatric clients initiated on TPT

Introducing and adopting facility-based psychosocial support groups (PSSGs) for index clients and children on TPT has improved adherence to TB treatment and TPT. Of the children initiated on TPT during the Cap TB implementation period, 94% completed treatment while 84% were successfully treated for drug-sensitive tuberculosis (DS TB).

OBJECTIVE 4:

generate novel evidence of cost-effectiveness

The project collected and analyzed data to inform programmatic improvements (e.g., completion rates of patients on shorter therapeutic regimens compared to those on longer ones, etc.). This was done in accordance with the pre- and post-monitoring and evaluation protocol approved in the US and Kenya and rendered results on the cascade of care from screening to treatment initiation and completion. It also gave us evidence around the yield of case finding approaches. Project data will also be disseminated through publications in 2022.

OBJECTIVE 5:

effectively transition activities to national entities to ensure sustainability

The involvement of the NTB, other implementing partners, CSOs, and the local authorities in the two counties has ensured that the activities commenced during the project (i.e., pediatric technical working group [TWG], TB screening, laboratory networking, and 3RH for children) will sustainably continue after closeout.

PROJECT OVERVIEW AND BACKGROUND

The CaP TB project aimed to reduce illnesses and deaths associated with childhood TB by overcoming critical access barriers and catalyzing the uptake of key childhood TB products and innovative models of care. These models were developed, implemented, and documented to catalyze their wide-scale, sustainable uptake to improve case detection and treatment for children with active and latent TB.

Due to a shared goal to eliminate HIV in pediatric and adult populations, EGPAF and Kenya's MoH share a history of close, extensive collaboration. Accordingly, Cap TB leveraged the network built through EGPAF's expansion of pediatric HIV testing and diagnosis to optimize: (1) access to TB case finding, testing, and diagnostics, and (2) novel and effective treatment of active and latent TB infection among vulnerable and high-risk populations. Project implementation began with 15 health facilities (3 Turkana, 12 Homa Bay) in October 2018; it expanded to 34 facilities by the close of 2021. The 10 implementation sites in Turkana County were chosen due to high TB burden, while the 24 in Homa Bay were selected due to high HIV / TB coinfection.

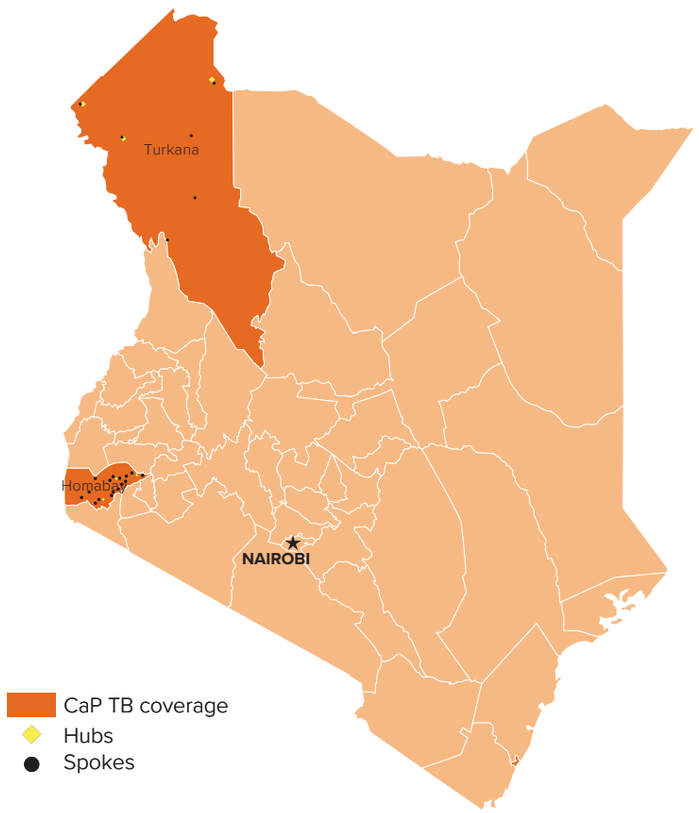
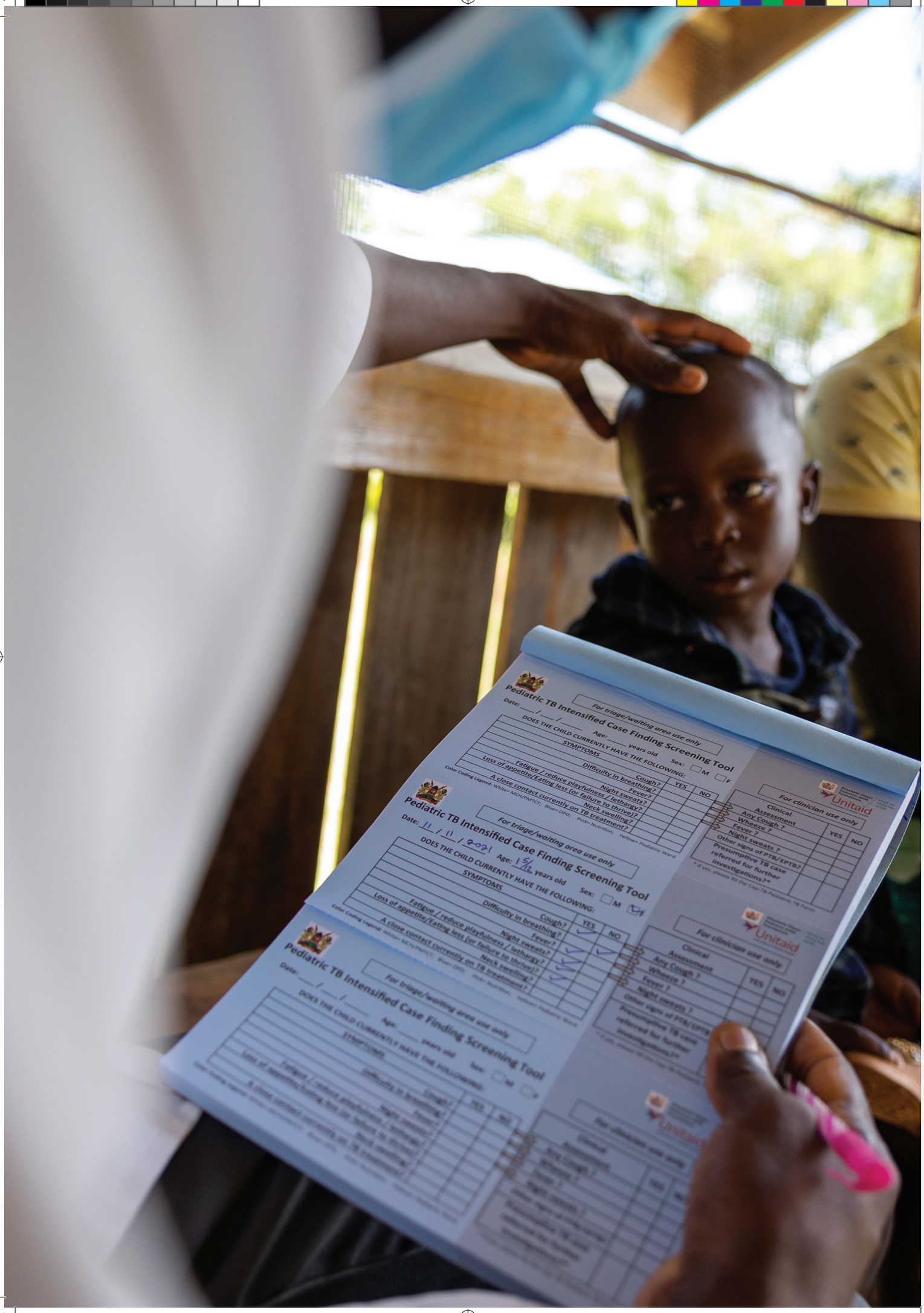


FIGURE 5: location of CaP TB coverage sites (Turkana and Homa Bay Counties)


Pediatric TB Intensified Case Finding Screening Tool
For triage/waiting area use only
Date: __/__/__
Age: ___ years old
Sex: M F
DOES THE CHILD CURRENTLY HAVE THE FOLLOWING:
SYMPTOMS
YES
NO
Cough?
Difficulty in breathing?
Fever?
Night sweats?
Loss of appetite/Eating less (or failure to thrive)?
Fatigue / reduce playfulness / lethargy?
Neck swelling?
A close contact currently on TB treatment?
For clinician use only
Clinical Assessment
Any Cough ?
Wheeze ?
Fever ?
Night sweats ?
Other signs of PTB/EPTB?
Presumptive TB case referred for further investigations?*
Unitaid

PROJECT MILESTONES

2018

- CaP TB Program inception
- Entry and introductory stakeholder meeting
- Baseline assessment at 30 facilities (15 for the Evaluation of the Catalyzing Pediatric TB Innovation Project: A Pre-and Post-Implem entation Assessment [TIPPI], 15 for the Integrating Pediatric TB Services into Child Health Care Services in Africa [INPUT] study) in May
- Engaging and training cough monitors and key HCWs
- HCW training

2019

- Both protocols approved by Kenyatta National Hospital Ethics and Research Committee (KNH-ERC)
- Baseline data collected from 15 sites
- Prospective data collection commenced on April 1st

2020

- Expanded to 37 facilities; 3 of these (Homa Bay) were turned into COVID centers

2021

- Transition activities
- Sharing best practices
- Project closeout

METHODS

A baseline assessment was completed in May 2018 to investigate gaps in pediatric TB service delivery. More specifically, the evaluation served to collect retrospective patient-level data from the clinic records of children aged 14 and under. This information enabled a comparison of standards of care before and after project implementation.

Before the baseline assessment, the Cap TB team obtained ethical approval for TIPPI across 10 countries. It also obtained a multi-country protocol from Advarra (an institutional research board in the US), the WHO's ethical review committee (ERC), Kenyatta National Hospital, and the National Commission for Science, Technology, and Innovation IRBs for Kenya.

EGPAF staff developed a questionnaire and disseminated it in 15 pilot health facilities. Results showed limited integration of TB screening at service delivery points, which led to missed identification opportunities. Case finding and active screening among children below 14 were low. This may have been due HCWs' and CHVs' limited knowledge about TB screening and diagnosis and childhood TB case management. The survey also showed that HCWs had limited capacity to diagnose children using Xpert MTB/RIF — a new test contributing to the rapid diagnosis of TB disease and drug resistance as initial diagnostic test for children and limited capacity for clinical radiological diagnosis.

Challenges in TB case management included limited access to (and utilization of) pediatric TB services at health facilities. Such human resource constraints kept task shifting (allowing lay workers to perform simple tasks, like TB screening, so clinicians can oversee diagnostics and treatment) to a minimum. Finally, the community had minimal TB knowledge, particularly concerning prevalence and the signs or symptoms of TB in children.

The project engaged 76 cough monitors who were trained in TB screening before being deployed to the targeted health facility entry points. Screening was successfully integrated into the HIV clinics, outpatient departments (OPD), maternal and neonatal child health (MNCH) departments, nutrition departments, and pediatric in-patient departments (IPD) at all the implementation facilities. This was achieved using CaP TB ICF and CaP TB optimization forms. A cough monitor was allocated to each triage desk, where they supported active TB screening for children while clinicians or nurses conducted further screening to confirm presumptive TB and initiate diagnostic workup. The CaP TB team also designed a color-coded ICF screening tool for the various entry points.

Various cadres of HCWs received training for pediatric TB diagnosis and management, including nurses and clinical, pharmaceutical, laboratory, and nutrition officers. The program began to collect data for monitoring indicators in 2019 and donor targets came into effect in April that year for all 15 of the facilities supported at that time. The project also began using a CaP TB pediatric service optimization form for data collection. The tool compiled data of children with TB symptoms at the various entry points to track diagnostic workup and treatment information. It also acted as a screening tool at the HIV clinic and during contact tracing for TPT eligibility.

Power Apps forms were used to enter ICF data into an online database, while data from the CaP TB pediatric optimization forms were entered into an excel database and later analyzed using Power BI. The data were used during quarterly progress review meetings, and when working innovations and lessons learned where shared with the NTP and other TB stakeholders

KEY INTERVENTIONS UNDER CAP TB

FACILITY-BASED

- Systematic pediatric TB screening in relevant non-TB entry points (OPD, IPD, MNCH, nutrition, and HIV) at all supported facilities
- Pediatric TB management training for HCWs from all relevant entry points
- Capacity building for pediatric TB management at subcounty level and below

TREATMENT

- Shorter TPT regimens (3RH)
- New pediatric-friendly dispersible single formulations
- Dispersible anti-TB FDC DS-TB (2RHZ, 4RH)

CASE FINDING

- Household contact investigation

DIAGNOSIS

- Xpert / MTB RIF
- Xpert ultra has been procured and distribution is ongoing
- Clinical-radiological – chest radiograph and algorithm
- Sputum collection procedures - gastric aspiration, nasogastric aspirate, and sputum induction

RESULTS BY OUTPUT

OUTPUT 1:

create an enabling policy and regulatory environment at the global and national levels to support the introduction and scale-up of effective, innovative diagnostic and treatment interventions for pediatric TB

The CaP TB Project has helped to create an enabling environment at the national and subnational levels. Working closely with national and county governments (and other stakeholders), the project helped develop a strong policy framework for childhood TB. These efforts ensure that practices and policy decisions are informed by lessons learned. Moreover, the close, collaborative nature of this work fostered synergy, which (1) facilitated the integration of project activities into existing work, (2) bolstered collaboration with implementation partners, and (3) ensured sustainability by advocating for successful strategies to be integrated into national plans.

The CaP TB Kenya team successfully organized three national TAG meetings to discuss innovative CaP TB approaches, LTBI, shorter regimen introduction, baseline facility assessment, and project status updates. To come to a consensus on priority areas for childhood TB, the project supported four pediatric TB TWG meetings at the national level and six at county level. This resulted in policy changes to implement and scale-up new shorter regimens for TB prevention. The TWG meetings also served as platforms for partners share experiences, including best practices and new information, while the TAGs helped the government inform implementation, share new guidelines, and provide strategic direction. The project also supported the revised pediatric TB training curriculum for HCWs and participated in two national strategic planning meetings for TB, which engaged core issues in pediatric TB.

Following the release of the WHO LTBI treatment guidelines, EGPAF held discussions with the NTP to consider how to proceed. It was agreed that CaP TB would pilot the shorter (3 month) treatment regimen for latent TB infection (3RH) in three facilities (Turkana and Homa Bay) by June 2019. The project would support expansion once the NTP was ready for rollout. The CaP TB Kenya team aided the writing and revision of the latent TB infection policy document and guidelines, which serve to inform Kenya's in its management of LTBI. The NTP policy was released in March 2020, and the project helped the review team complete the guidelines, SOPs, and a slide deck for the HCW training rollout.

After 3RH was piloted, CaP TB shared lessons learned about the use of the shorter TB preventive regimen (e.g., improved adherence and better treatment outcomes than 6INH) with the NTP. This knowledge then informed the scale-up process in all the CaP TB sites. The NTP availed enough 3RH tablets for expansion to in 34 sites, including locations that were not under the CaP TB project. The NTP also issued a circular about 3RH to prepare HCWs for scale-up in September 2020.

In March 2020, the CaP TB project convened a dissemination meeting with the Turkana County MoH, elected officials, and the NTP. This was an opportunity to disseminate innovative care models and spotlight progress and challenges in the project's implementation in the county. The overarching goal was to inspire commitment among stakeholders: prompting them to address challenges in the fight against childhood TB.

The project commemorated World TB Day during its implementation period. Activities took place in both counties and highlights included TB screenings and supplying information, education, and communication materials and health education to the community. The team also published a story titled "It's time we stopped new TB infections in children" on the WHO website in March, 2020. It chronicled successes in providing the shorter 3RH regimen for TB preventive treatment.

EGPAF-Kenya held a consultative meeting with the Clinton Health Access Initiative's team for the Increasing Market and Public health outcomes through scaling up Affordable Access Models of Short Course preventive Therapy for TB (IMPAACT4TB) project. More specifically, Cap TB Kenya sought to determine how it could collaborate with IMPAACT4TB to: (1) pilot LTBI management, and (2) identify potential avenues to jointly engage national and county stakeholders (National TB Program (NTP), WHO, Stop TB Partnership, United States Agency for International Development(USAID), Centers for Health Solutions [a local NGO], and CSOs, among others) to influence policy and programming.

The CaP TB team both joined and supported a meeting about pediatric TB and HIV that saw participation from 14 CSO representatives. Attendees identified programmatic gaps and agreed on important priorities for pediatric HIV and TB in Kenya's 2021-2023 grant application with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). The group also developed a priority charter to help CSOs engage disease-specific constituency meetings. That engagement increased CSO advocacy around childhood TB issues, thereby enabling inclusion in the GFATM application. When the Country Coordinating Mechanism takes such action at the national level, the impact reverberates in the global advocacy landscape. Accordingly, this work contributed to ongoing global advocacy for childhood TB resources.

The CaP TB Kenya team also helped strengthen the capacity of the Stop TB partnership: a Kenyan CSO that required assistance to respond to an advocacy award from Unitaid. The small grants award facilitated community-led advocacy and demand creation for national policy reforms to implement and expand pediatric TB care through: screening, diagnostics, adherence support, treatment of active TB, TB preventive therapy, and adding GeneXpert Ultra to the TB diagnosis module under Kenya's TB guidelines. The country will begin using GeneXpert Ultra once the available stock of GeneXpert MTB/RIF cartridges is exhausted.

OUTPUT 2:

introduce effective and innovative models of care to improve pediatric TB case detection

Collection of project data was made possible through the use of project specific forms (the ICF and CaP TB pediatric optimization forms). Data collection started in April 2019, upon

approval by Kenyatta ERC of the TIPPI protocol. In April 2019, the Kenya team adopted the ICF and CaP TB pediatric optimization (carbonated) forms. Following this development, TB screening was successfully integrated in to OPD, MNCH, nutrition, HIV and pediatric IPDs at implementing facilities. Each triage desk was assigned a cough monitor to support active TB screening for children while clinicians or nurses conducted further screening to confirm presumptive TB and initiate diagnostic workup. This ensured optimized screening of all children at all entry points, as shown in the chart below.

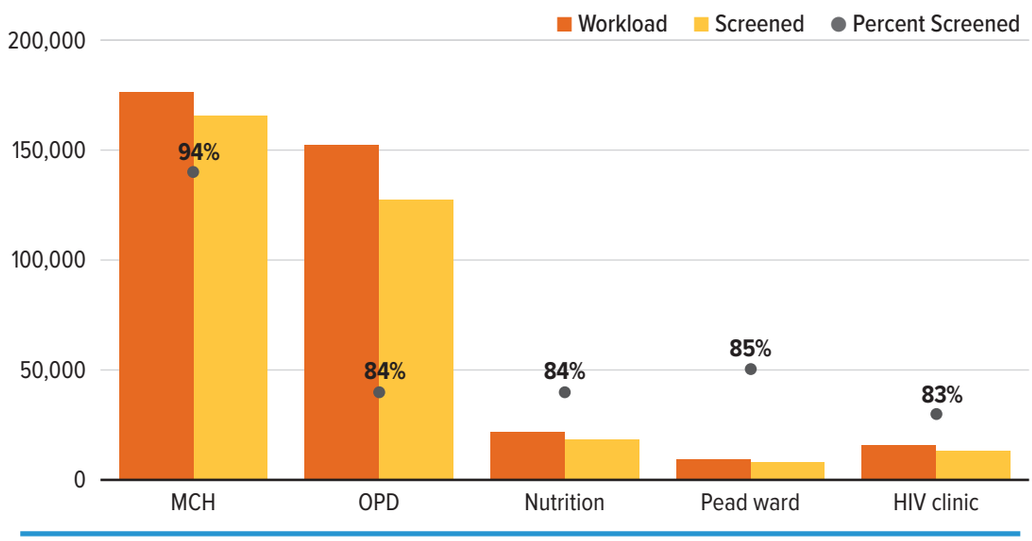


FIGURE 5: TB screening uptake across various entry points

It is difficult to diagnose TB in children, and this presents a challenge to most health care providers. Very young children often cannot produce sputum for testing, as they tend to swallow the specimen instead. For children who are not able to spontaneously expectorate and produce a sputum sample, collection of alternative sample types such us gastric aspiration, nasopharyngeal aspiration or induced sputum is required. However implementation of those sample collection procedure has been limited under routine clinical conditions. Even when a sample is taken for Xpert MTB/RIF diagnosis, the quantity of TB bacteria in their samples is often lower than that of adults, making it harder to detect. The current guidance on TB testing in Kenya recommends GeneXpert as the preferred test for TB diagnosis in children. Accordingly, the CaP TB project took a significant role in improving the implementation of this guideline. On and off-site capacity building and strengthening sessions were used to help HCWs obtain quality sputum specimens from children and enhanced the availability of consumables for sample collection. The specimen collection procedures implemented by the Project were sputum expectoration for older children and gastric aspiration at all levels of the health facilities whereas sputum induction and nasopharyngeal aspiration were done at the Referral Hospitals (hubs). These efforts generated progress in the uptake of Xpert MTB/RIF testing. The figure below shows a high of 75% presumed tested with Xpert MTB/RIF at project implementation sites, against a target of 45%:

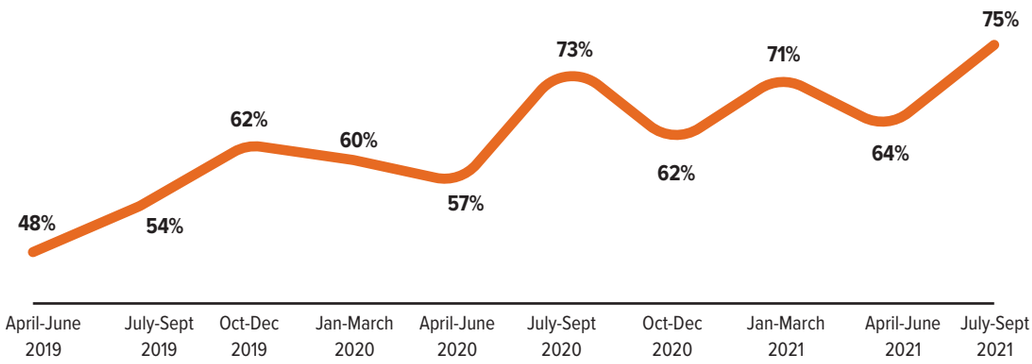


FIGURE 6: proportion of children presumed tested with Xpert MTB/RIF over time

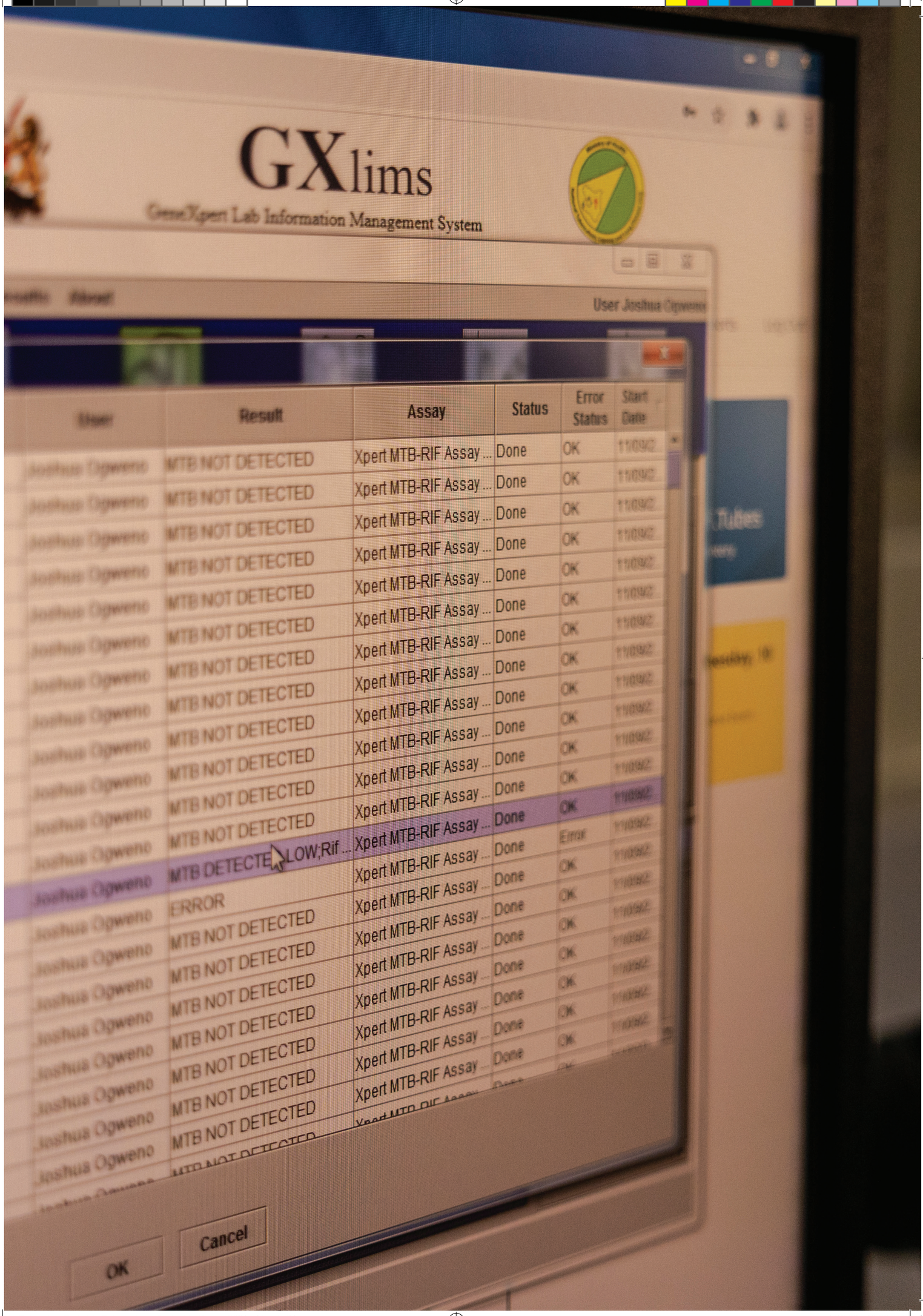
The project also began to procure and supply items needed to make advanced sample collection procedures (gastric aspiration, sputum induction, and nasopharyngeal aspiration) available at the supported sites. HWCs were offered on-site mentorship for supply usage.

TABLE 1: sample collection methods for children under five years old (Apr. 2019 – Sept. 2021)

Presumptive TB	5,417	
Sputum expectoration	460	8%
Induced sputum	11	0%
Nasopharyngeal aspirate	49	1%
Gastric aspirate	537	10%

The project procured a GeneXpert machine in Turkana County. It was placed at Lopiding subcounty Hospital, where it networked samples to sites without machines. A power backup system was installed to ensure uninterrupted operation even during power outages. Turkana also received buffer stock to cover MTB/RIF cartridge shortages and facilitate effective forecasting. Two laboratory officers were trained by Turkana's (certified) advanced GeneXpert user, while the hospital's biomedical engineer helped with preventive maintenance and calibration.

With help from Timiza90 in Homa Bay and USAID partners (the academic model providing access to healthcare and the African Medical and Research Foundation) in Turkana, the project strengthened and supported laboratory specimen referral networks by engaging motorcyclists. An additional rider was engaged in the Lokichoggio area (Turkana) with the goal of reducing the turnaround time from 10 days to 24 hours so clinicians could make timely decisions.


GXlims
GeneXpert Lab Information Management System
User Joshua Ogweno
Result
Assay
Status
Error Status
Start Date
MTB NOT DETECTED
Xpert MTB-RIF Assay ...
Done
OK
MTB DETECTED LOW;Rif ...
ERROR
Error
Cancel
OK

At the national level, a revised algorithm for TB diagnosis in children was developed to incorporate the role of Xpert in relation to the other tests (e.g., chest X-ray) – per the recommendation of 2016 Kenya prevalence survey. The project trained 154 HCWs (clinical officers, nurses, pharmaceutical technologists, and laboratory officers) in the following areas: (1) clinical management and diagnosis of pediatric TB, (2) sputum collection strategies for children, (3) the role of chest X-rays in TB diagnosis, and (4) interpreting results to achieve timely and accurate TB diagnosis. The 76 cough monitors engaged by the project received training for TB screening and the use of CaP TB tools.

Quality chest X-rays have the greatest potential to detect TB in children and enhance clinical diagnosis. The project established an X-ray referral system in which patients who have TB symptoms and need an X-ray for diagnosis are linked to digital X-ray hubs. This has facilitated patient referral from spokes to hubs. To aid clinical decision-making, radiographers and clinicians in two facilities were trained to document and interpret X-rays taken from children or transmit them to the existing teleradiology platform for virtual interpretation. X-ray payment vouchers were availed to supported sites to cover the costs of children between 5 and 14 years old whose caregivers were unable to afford the service.

FIGURE 7: TB diagnostic methods used (Apr. 2019 – Sept. 2021)

Clinical diagnosis was improved in the following ways: (1) strengthening HCWs' capacity to make clinical diagnoses, (2) availing and using the clinical diagnostic algorithm for TB in children, (3) the SOPs for clinical diagnosis, and (4) developing of a follow-up strategy for children who are suspected to have TB despite negative lab results. These changes made HCWs feel more confident in their ability to perform clinical diagnosis on children.

The CaP TB team partnered with the MoH to provide facility support supervision and mentorship for cough monitors and HCWs. These efforts served to integrate TB screening services into pediatric service entry / delivery points (including the MNCH, nutrition, OPD, and IPD departments) and used a structured site monitoring checklist. Moreover, the team developed a standard screening tool that is used at various entry points where children

seek and receive routine services. Known as the pediatric TB intensified case finding screening form, the tool guides clinicians as they take further action for children suspected to have TB. The form is used in conjunction with the existing presumptive TB register. Moreover, EGPAF-Kenya developed a framework for adolescent health that incorporated TB care into the Adolescent Package of Care.

The NTP upgraded the GeneXpert machines to allow for the use of the Ultra cartridges once these are procured (when the current stock is depleted). Consequently, HCWs were trained to forecast and quantify these commodities, then familiarized with relevant tools to reduce health facility stock outs via improved reporting and stocking. The Cap TB project procured cartridges as buffer stock to prevent further stockouts, as seen in 2018. Additional measures included facilitating chest X-ray access (supporting patients' transport and test costs) to improve diagnosis for better access to pediatric TB treatment and consultations from expert digital X-ray readers.

The CaP TB project also conducted targeted TB screening and health education events at schools, to support prevention and control, diagnose active TB, and initiate preventive therapy for eligible children. Two community liaison officers worked on TB screening and contact tracing at the facility and community levels, with help from cough monitors and CHVs. Reverse contact tracing was conducted for children who were index cases, regardless of clinical or bacterial diagnosis. As a result of these efforts, 818 TB cases were identified over the project period.

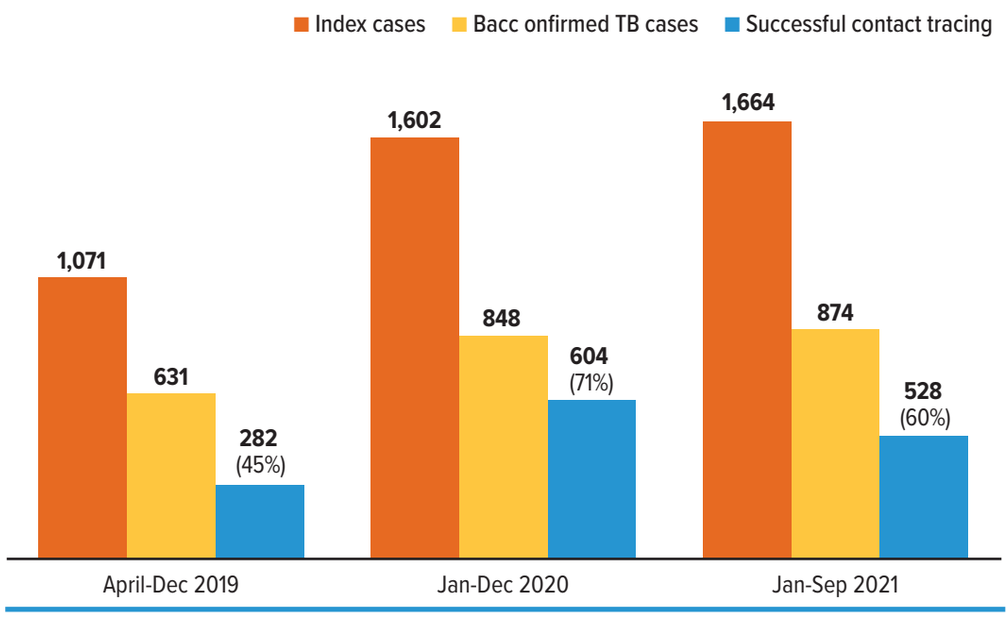


FIGURE 8: contact tracing cascade

TABLE 2: achievements versus overall programmatic targets (Apr. 2019 – Sept. 2021)

Output 2 programmatic results	Overall target	Achieved	%
O2.1 Number of children screened for TB	561,538	332,328	59%
O2.2 Number and proportion of pediatric (0-14 years) presumptive TB cases tested with Xpert	3,273	3,083	94%
	47%	63%	63%
O2.3 Number of pediatric cases diagnosed with active TB	1,037	818	79%
O2.4 Number and proportion of TB index cases for whom contact tracing was successfully completed	2,541	1,402	55%
	39%	34%	32%
O2.5 Number and proportion of MNCH, peds inpatient, pediatric outpatient, HIV, nutrition entry points where TB screening is provided	74	125	
	100%	100%	

OUTPUT 3:

ensuring rapid uptake of – and access to – improved pediatric treatments for active and latent TB by implementing innovative models of care

These are some of the innovative models that were implemented: (1) improving contact management register use, (2) introducing shorter-course TPT, (3) printing and providing the dosage wheel chart, (5) facility-based training to help HCWs administer and monitor TB and TPT treatment. Kenya is currently using the improved, floured, dispersible medication (2RHZ/4RH) to treat childhood TB. There is adequate stock at the country level, but three health facilities in Turkana and three in Homa Bay experienced a monthlong RHZ/RH stockout from July to August, 2018. The expected supply from the Kenya Medical Supplies Authority was delayed by an issue with a manufacturer. The CaP TB team worked with the county pharmacist and TB coordinator to organize the redistribution of TB drugs, so patients' medication supply could continue uninterrupted.

The project enjoyed significant benefit from efforts to mentor HCWs in the areas of pediatric DS TB treatment (TX) and documentation. Indeed, in pilot sites, where a baseline assessment was conducted, DS TB initiation rose from 87% to 99%.

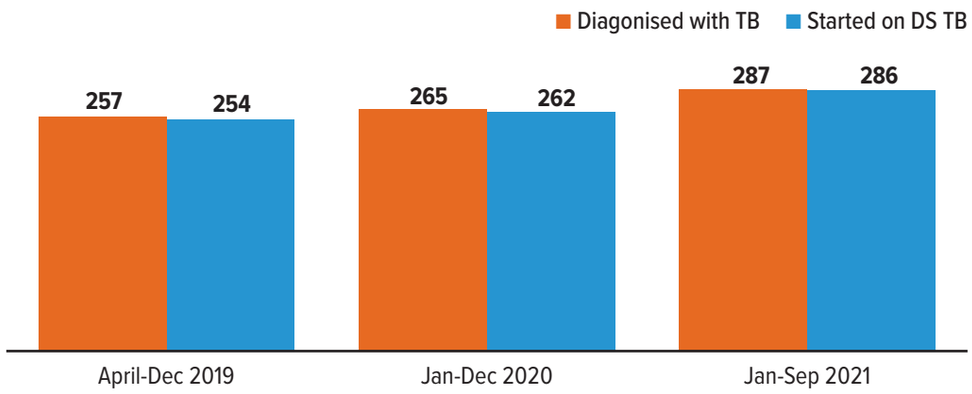


FIGURE 9: initiation on DS TB treatment

The project mentored facility staff and subcounty TB coordinators to enhance TB patient follow-up and ensure that treatment and documentation were completed to foster appropriate action.

To improve retention and treatment success rates, PSSG groups were formed at facilities. This move helped bring patient education to caregivers, and raised TB treatment success from 68% at baseline to 87% during project implementation.

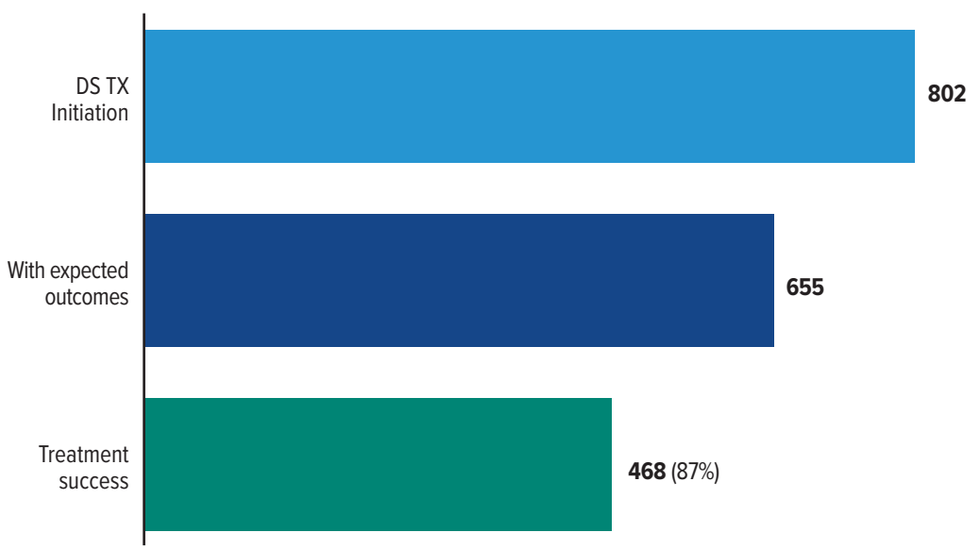


FIGURE 10: DS TB treatment outcomes

The project focused on TPT for children below age five who were contacts of bacteriologically-confirmed TB cases, and children living with HIV. In October 2019, CaP TB piloted the use of 3RH for the former in three project-supported facilities. This was expanded to 34 facilities once Kenya adopted and rolled out 3RH, and phased out 6INH. The portion of patients who completed TPT rose dramatically, from 64% at baseline to 95% during the first year of project implementation in the 15 pilot sites.

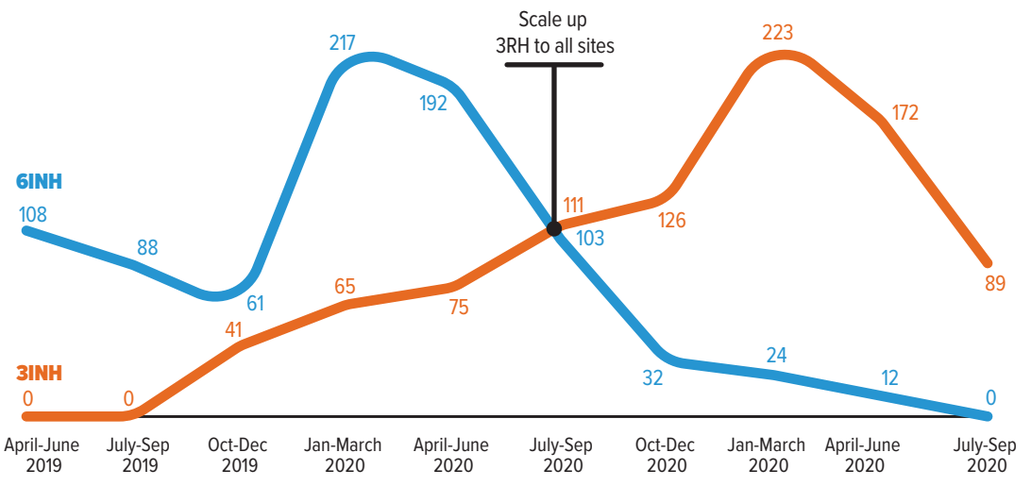


FIGURE 11: transition from 6INH to 3RH over the implementation period

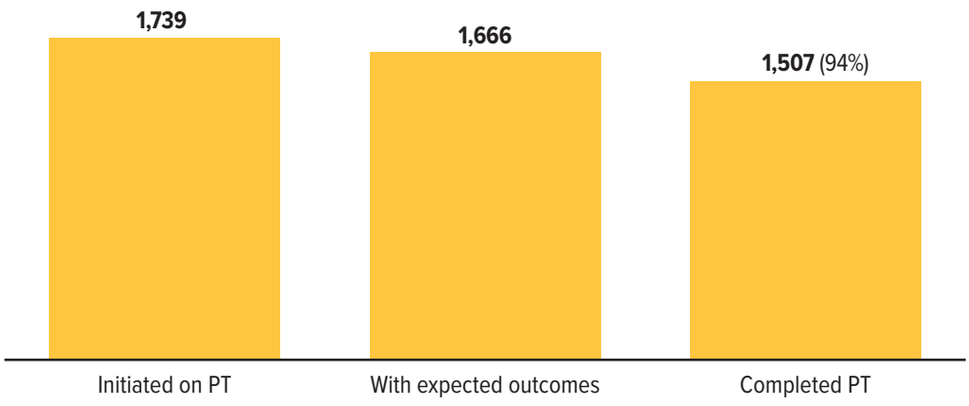


FIGURE 12: key TPT outcomes

The CaP TB project supported the achievement of TPT targets by hosting pediatric TWG meetings. Implementing partners used these gatherings to reinforced TB work and share lessons that could be scaled up. The team also provided technical input to aid the realization of TPT targets.

HCWs were sensitized to adverse drug reactions occurring in children on TB and LTBI treatment—more specifically, how to the identify and report them. The project provided SOPs for pediatric TB and LTBI, along with dosing wheels and 330 doses of 3RH that were procured for this purpose. To better monitor TB and LTBI treatment adherence, facility directories were used to follow up on clients who transfer out, and to orchestrate CHV home visits, which improve treatment outcomes.

As a standard of care, EGPAF and Timiza90 developed facility rubber stamps with the cardinal symptoms of TB for use in all patients pass books to prompt clinicians to perform TB screening. Timiza90 was a U.S. Centers for Disease Control and Prevention (CDC)-funded project (2016-2021) that supported the implementation and expansion of high-quality, sustainable, and comprehensive HIV prevention, care, and treatment programs in Homa Bay. The use of rubber stamps bolstered active case finding among children in non-CaP TB sites and will be expanded to all facilities.

TABLE 3: programmatic achievements (Apr. 2019 – Sept. 2021)

Output 3 programmatic results	Overall target	Achieved results	%
O3.1 Number and proportion of pediatric TB cases started on DS TB treatment	1,028	811	79%
	100%	99%	
O3.2 Number and proportion of successfully treated pediatric TB cases	891	706	79%
O3.3 Number and proportion of eligible pediatric contact patients started on TPT	2,215	1,818	87%
	95%	158%	82%
O3.4 Number and proportion of pediatric patients who completed TPT	1,924	1,555	81%
	80%	87%	
O3.5 Number and proportion of EGPAF-supported health facilities with at least one healthcare professional trained in pediatric TB diagnosis and treatment	38	37	100%
	100%	100%	

OUTPUT 4: generate novel evidence and cost-effectiveness data to inform policy guidelines and further scale-up in new countries, through additional donors, and implementers

EGPAF-Kenya developed the TIPPI protocol, which was subsequently approved by the WHO, and the Kenya and Advarra IRBs. The country implementation plans for the TIPPI study, and its M&E SOPs, were developed and approved for data collection. This served to generate the requisite data to inform project achievements, innovations to expand, and to develop an abstract and manuscript.

The team also participated in the INPUT study. The protocol was developed and submitted to the WHO ERC and the Advarra and Kenya IRBs for approval. Kenya developed an M&E training module, which was used for HCW training and facility-based training at all implementation sites. The results of the INPUT are being finalized and will be shared in another report.

The project identified gaps in the existing data collection tools and adopted an additional tool, the CaP TB monthly summary. It served to collect missing data in service of project implementation. Routine data collection (i.e., country-level indicators) continued at the agreed-upon implementation sites as part of the baseline assessment. The data were used to make programmatic improvements. With the approved M&E protocol, they will ultimately be shared via published manuscripts.

OUTPUT 5: effective and sustainable transition to national programs

From the outset, the CaP TB team planned for implementation work to be sustained beyond project completion. This prompted high-level engagements with various partners to ensure that children were permanently represented in the national TB response. The team also worked closely with the NTP to identify specific sustainability issues to be addressed at the national and county levels.

The project was actively engaged in the national pediatric TB TWG. This gathering brings together the NTP, GTAFM, WHO, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), civil society, and other implementing partners to discuss the country's TB response. This platform ensured that pediatric TB was integrated into development plans. The resultant human resource and budgetary allocations, even at the county level, will facilitate sustainability. The TB TWGs will continue to be responsible for joint planning, supportive supervision, and implementation oversight at the county and national levels. This will guarantee that a robust, skilled, and capacitated team will continue implementation activities now that the project has ended.

The project convened biannual TAG review meetings, in which discussions were held about CaP TB results and the financial and technical support needed to sustain and expand access to pediatric TB care. These projected future needs were addressed with key stakeholders, and the CaP TB team advocated for their support towards sustained care for pediatric TB post-closeout.

Kenya transitioned to the use of flavored fixed-dose combination drugs (FDCs) for pediatric TB treatment, as these are better for children, before implementation of CaP TB. This shift

was discussed with the national TAG and county pediatric TWGs. The country revised its national guidelines to include the new FDCs, ensuring their availability to all children with TB. Sufficient quantities were procured from the manufacturer, but a few facilities experience stockouts due to delivery delays. Training key staff to forecast and quantify these drugs can significantly reduce these challenges.

EGPAF will continue to use lessons learned from the CaP TB project to advocate for the integration of pediatric TB into domestic budgets, donor funding proposals (e.g., PEPFAR Country Operational Plans, CDC continuation applications, and GTAFM proposals), and reprogrammed budgets for existing GTAFM grants. Through the existing TWGs, EGPAF will continue to work with the MoH and/or other partners to support and sustain pediatric TB care.

MILESTONE 1:

facilitate widespread availability of new pediatric TB medicines and diagnostics

CaP TB worked closely with the STOP TB Partnership to advocate for widespread availability of new pediatric TB medicines and diagnostics. As a technical partner, EGPAF provided technical leadership, while the Stop TB acted as an advocacy partner. Together, they held a sensitization meeting regarding the uptake of the 3RH, which was attended by the NTP's national and county forecasting and quantifications team. This advocacy initiative focused on increasing the age cap on the TPT eligibility (from 5 to 15 years) to reduce the number of children who fall ill with TB. This strategy been added to the integrated TB guidelines 2021 and the country will procure enough TPT drugs.

The NTP was urged to develop an algorithm for Xpert stool testing for childhood TB. This advocacy effort proved successful: a stool testing policy was adopted and will soon be rolled out to high burden counties. The stop TB partnership also drafted a circular and petition letter to the cabinet secretary to advocate for a waiver on X-ray costs for children below age 15 in high TB burden counties. Waiving the costs of X-rays would improve children's diagnostics by providing much-needed access, and it would support the sustainability of CaP TB interventions.

Stop TB also engaged the Parliamentary Health Committee to raise awareness about pediatric TB and encourage pediatric TB medicines to be prioritized in the national health budget. Despite limited opportunities for interaction due to the COVID-19 pandemic, these messages were shared and elected officials at the county level noted the importance of providing these resources –pledging to do so in the next budget cycle.

Because raising awareness is a central component of effective advocacy, the project engaged members of the media through sensitization sessions. This helped them understand key issues in childhood TB so they could improve the quality of their reporting and better advocate for the cause. This work was done in partnership with Media for Environment, Science, Health and Agriculture – an association of specialized journalists and communicators. This media advocacy work resulted in the publication of multiple stories over the project's duration. These pieces highlighted the challenges and successes in the diagnosis and treatment of pediatric TB. A few examples are listed below.

- Family TV – https://familymedia.tv/family-tv-live/
- Radio France International – https://www.rfi.fr/sw/e-a-c/20210324-covid-19-inavyorudisha-nyuma-jitihada-za-kupambana-na-kifua-kikuu
- TV47 – https://youtu.be/U-wo2xYAV-w
- Switch TV – https://youtu.be/MsLTP5IokQM
- MESHA – https://nation.africa/kenya/healthy-nation/how-i-beat-tb-despite-two-years-of-misdiagnosis-3332590

The Stop TB partnership also worked through its social media channels to advocate for childhood TB and support an expanded service reach.

MILESTONE 2:

community engagement to increase demand for child-friendly TB services for improved pediatric TB outcomes

Lean on Me, a local CSO, was responsible for implementing this milestone. The organization provided pediatric TB training to 78 CHVs, with a special focus on TPT and contact tracing for children in the Kisumu and Siaya counties. The CHVs were taken through the TPT guidelines to support their implementation at the grassroots level. Post-training, they received the necessary support to perform home visits to raise awareness and conduct contact tracing. They reached 177 children below age 15, who were referred for various TB services during the implementation period.

MILESTONE 3:

increase the age of children eligible for shorter regimen (3HP and 3RH) from 5 to 15 years old

The Stop TB partnership advocated with the NTP to extend the age limit for children eligible for the shorter regimen (3HP and 3RH) from > 5 years old to > 15 years old. The NTP committed to changing the age limit once there were enough doses of the drugs available to do so. Since then, TB guidelines have incorporated the age extension, though implementation is pending until there are sufficient doses for the target population.

The rolled out of use of 3HP done I 10 Counties since October, 2021 and will scale up in the remaining 37 Counties from Jan, 2021

LESSONS LEARNED

The CaP TB project saw successful implementation and executed its objectives. Key factors that fostered the project's success included the engagement, buy-in, and commitment of the national and county governments. It also proved extremely helpful to align the project's objectives with those of the government's strategic plan, as this ensured institutional support. Other noteworthy lessons are listed below:

- To increase TB screening, it is critical to use dedicated cadres (cough monitors) and **LAY WORKERS** to support and integrate this service into child service entry points
- **CONTACT INVESTIGATION**, including monitoring and supervising contact investigation cascades of care, is a key pediatric TB management intervention, and a vehicle for both case detection and TB prevention
- The **CHILD CONTACT MANAGEMENT REGISTER** critically supports the identification of children eligible for TPT and prompt linkage for diagnostic TB workup
- Home visits for TB contact tracing and TPT provision for children are feasible and increase TB service uptake
- TB case finding increases when TB screening is **INTEGRATED** into all departments and the **ICF SCREENING** tool is used
- Timely **TRACKING OF PRESUMPTIVE TB** clients is paramount, as these clients will transition into active TB, or infect others, if overlooked
- Use of the **CLINICAL DIAGNOSIS ALGORITHM** and **CHEST X-RAY** improves TB case identification
- It is more feasible to provide **FACILITY-BASED** pediatric TB management training that reaches the majority of HCWs than it is to do so through classroom training sessions
- **ALTERNATIVE SPUTUM COLLECTION** methods like Gastric aspiration increase access to MTB/RIF testing for children
- Community engagement and CSO partnership is a critical component of successful advocacy

REMAINING GAPS

The project has demonstrated the value of X-ray subsidies (transport reimbursement for caregivers unable to meet the cost, vouchers for the x- ray costs of children aged 6-14, and payment of radiology experts who interpret X-rays). However, these interventions remain under-resourced as the project comes to an end. While access to X-ray services will continue, parents or caregivers will need to take on the cost.

There remains work to be done to transition cough monitors to lay workers, as part of the effort to facilitate enhanced TB screening (CaP TB model) through HCWs.

CONCLUSION

Integrated pediatric TB diagnosis, treatment, and prevention remains a key agenda for TB control and prevention. This outcome requires the sustainable adoption and scaling of effective, innovative strategies of care.

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