

Defeat Childhood TB:

A Multicountry Assessment of National Policies and Preparedness for Childhood TB Programming





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This project is funded by Unitaid. Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose and treat diseases more quickly, cheaply and effectively, in low- and middle-income countries. Our work includes funding initiatives to address major diseases such as HIV/AIDS, malaria and tuberculosis, as well as HIV co-infections and co-morbidities such as cervical cancer and hepatitis C, and cross-cutting areas, such as fever management.

Unitaid is now applying its expertise to address challenges in advancing new therapies and diagnostics for the COVID-19 pandemic, serving as a key member of the Access to COVID Tools Accelerator. Unitaid is hosted by the World Health Organization.

Acronyms

1HP one month of isoniazid and rifapentine
 3HP three months of isoniazid and rifapentine
 3RH three months of rifampicin and isoniazid

BDQ bedaquiline

CaP TB Catalyzing Pediatric Tuberculosis Innovations

CXR chest X-ray
DLM delamanid

DR-TB drug-resistant tuberculosisDRC Democratic Republic of CongoDS-TB drug-susceptible tuberculosis

DT dispersible tablet

EGPAF Elizabeth Glaser Pediatric AIDS Foundation

EML Essential Medicines List

EPTB extrapulmonary tuberculosis

FDC fixed-dose combination

HCW health care worker

HH household

integrated management for childhood illness

INH isoniazid

IPT isoniazid preventive treatment

LF-LAM lateral flow urinary TB lipoarabinomannan test

M&E monitoring and evaluation

MDR-TB multidrug-resistant tuberculosis

MNCH maternal, newborn, and child health

NRA national regulatory authority

NSP national Strategic PlanNTP national TB programOPD outpatient department

PMTCT prevention of mother-to-child transmission

PTB pulmonary tuberculosis
RH rifampicin and isoniazid

RHZ rifampicin, isoniazid and pyrazinamide

SOP standard operating procedure

TB LAMP TB loop-mediated isothermal amplification technique

TPT TB preventive treatment

TST tuberculin skin test

UNHLM United Nations General Assembly High-Level Meeting

Foreword

The World Health Organization (WHO), Global Tuberculosis Programme welcomes the policy assessment conducted by EGPAF as part of the Unitaid-funded CaP-TB project. It is an important analysis highlighting the status of implementation of programmatic interventions targeting children and young adolescents with tuberculosis (TB), or at risk of TB, in the selected countries. The report also summarises how progress can be accelerated towards the global targets of the United Nations High Level Meeting on the Fight Against TB (UNGA HLM on TB), outlined in WHO's 2018 Roadmap towards ending tuberculosis in children and adolescents.

Estimates included in the WHO Global TB Report 2021 show that 1.1 million children and young adolescents aged below 15 years fall ill with TB each year, and that this age group accounts for 11% of the global burden of TB. However, less than 40% of these children were diagnosed and reported to National TB Programmes in 2020. The case detection gap was estimated at 63% in children aged under 15 years, but 72% in children under five. The COVID-19 pandemic has had a disproportionate impact on the diagnosis and notification of TB in children and young adolescents. For example, the number of TB notifications in this age group dropped by 24% between 2019 and 2020, compared to a drop of 18% for those aged 15 years and above.

This assessment conducted by EGPAF shows that policies on the management of TB in children are more widely available now, when compared to 2018, which is an encouraging finding. However, the report also describes that many persisting gaps remain regarding interventions, policy uptake and funding for the prevention, diagnosis, treatment and care of TB in children and adolescents. This is a concern for all stakeholders involved in TB programming and calls for urgent remedial action.

The WHO Global Tuberculosis Programme will continue to update guidelines based on the latest available evidence and to support countries to rapidly adopt and scale up implementation of WHO recommendations. The findings of EGPAF's policy assessment will inform strategies to optimise the uptake of global policies and guidelines and accelerate progress towards the global targets of the UNGA HLM on TB, which has been too slow to date. Therefore, we encourage countries to use the report to strengthen the implementation of interventions targeting all steps in the TB care cascade for children and adolescents in order to improve outcomes, prevent unnecessary suffering and save lives.

Dr Tereza Kasaeva

Director, Global Tuberculosis Programme World Health Organization

For too long, childhood TB has been neglected by public health interventions. The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is relentlessly working to ensure that childhood TB is a standing priority in the global public health agenda. We have the evidence, tools, and programmatic experience to effectively end the TB epidemic in children. However, the world is far from reaching our internationally agreed-upon TB targets in children. From 2018-2020 only 1.4 million children were treated for TB - a meager 41% of the target to treat 3.5 million children by 2022. Additionally, in 2020, only 40% of the children estimated to fall ill with TB globally were identified and notified, leaving the majority undiagnosed and therefore untreated.

Rapid adoption of innovative tools and policies based on WHO guidelines and recommendations, is a critical first step to ending childhood TB. In recognition of the international commitment, leadership, and support needed to create national policy environments that promote the elimination of childhood TB, EGPAF assessed childhood TB policies and country preparedness in 10 countries in 2018 and 2021 as part of its Unitaid-supported Catalyzing Pediatric Tuberculosis Innovations project (CaP-TB). These assessments evaluated country preparedness for childhood TB programming and national policies on child and adolescent TB. While the comparison among the 2018 and the 2021 assessment shows that progress has been made by national programs in the uptake of best policies and practices, important gaps remain. We call for countries, governments, civil society, patients' groups, technical agencies, and donors act on the remaining gaps identified in this assessment and bring the necessary improvements in the global and national response to pediatric TB.

The clock is ticking. EGPAF is committed to working with partners to advance this agenda together. Implementing these effective policy recommendations to form the best landscape will ensure that children have high-quality services needed to end the TB epidemic. With this assessment readily at our fingertips, TB partners around the world must work urgently if they are to create deep-rooted change for children and adolescents around the globe.

Charles Lyons

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President and Chief Executive Officer, Elizabeth Glaser Pediatric AIDS Foundation

1. Executive Summary

Childhood TB, a preventable and curable infectious disease, continues to negatively affect the lives of millions of children and adolescents every year. In 2020, children (younger than 15) accounted for 11% of the total burden of TB in 2019, but the majority of them remain undiagnosed and untreated.¹ For too long, childhood TB has been poorly addressed by the global public health agenda and often has been neglected by health policymakers and TB control programs. Whereas the international community has recognized the need to put more effort into the fight against childhood TB during the past decade, progress toward the childhood TB global targets remains slow.¹

As part of its Unitaid-supported Catalyzing Pediatric Tuberculosis Innovations project, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) carried out assessments of the national policy landscape and country preparedness for childhood TB in 2018 and 2021 in 10 countries (Cameroon, Côte d'Ivoire, Democratic Republic of Congo, India, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe).

The purpose of the 2021 assessment is to

- evaluate progress made by the countries over a period of three years,
- identify areas that need sustained efforts, and
- propose recommendations to bridge the gaps.

This assessment is intended to be an advocacy tool for countries, governments, civil society, patients' groups, technical agencies, and donors to identify the remaining gaps and act on them.

The findings of the 2021 assessment show an improvement in the childhood TB policy landscape compared to 2018 in the 10 countries assessed. Nonetheless, important gaps remain in ensuring an effective TB response in children.

- There has been increased attention to childhood and adolescent TB in National Strategic Plans between 2018 and 2021. However, adequate financial support and specific budgets for childhood TB activities remain important questions for most countries. Moreover, not all the countries have set specific targets for childhood TB diagnosis and treatment. And even if all countries include plans for capacity building, training material, and guidance for TB in children and adolescents as part of their TB national guidelines, not all are fully updated per the latest internationally recognized recommendations.
- There have been some improvements in all 10 countries assessed in the adoption of the latest policies and recommendations regarding screening and case-finding strategies. This refers, for example, to the inclusion of screening of all household members and close contacts of TB cases, irrespective of age and HIV status, as well as the adoption of new tools for diagnostics. However, efforts are still needed to ensure that TB is fully part of the integrated management for childhood illness guidance and with regard to policies about the use of the lateral flow urinary TB lipoarabinomannan test for pediatric TB diagnosis in children living with HIV.

- Integration of TB services into other health services and adaptation of national policies to include integration of TB diagnosis, treatment, prevention, and follow-up in other health services, based on the most appropriate models of care for the specific setting, should be sped up. Lack of integration of TB care for children and adolescents into other services, such as prevention of mother-to-child transmission of HIV; maternal, newborn, and child health; nutrition; and outpatient department general services, represent a missed opportunity to timely detect children with TB and put them on appropriate treatment, preventing TB and averting the development of the most severe forms of the disease.
- Country policies on treatment regimens for drug-susceptible and drug-resistant TB are in line with best standards of care. Treatment of drug-susceptible TB in children and adolescents is addressed in national guidelines and in line with the best standards of care. In terms of treatment for drug-resistant TB in children and adolescents, it's remarkable that most countries have updated their national guidelines to move to all-oral short and long regimens. However, the lack of recommendations for all oral regimens in few countries is a reason for concern. Similarly, while results show that all countries have started procuring pediatric formulations of second-line drugs, findings on the specific drugs procured show that not all drugs are being procured, and some key ones such as moxifloxacin and BDQ are not yet available in about half of the countries surveyed.
- Providing TB preventive treatment (TPT) to reach global targets by 2022 will require a massive scale-up of efforts and larger investments. The need for early adoption of policies to address TPT in children and adolescents is recognized by all countries. All national guidelines include recommendations about TPT in children and adolescents, and most of the countries have included in their policies three months of isoniazid and rifapentine (3HP) or three months of rifampicin and isoniazid (3RH). However, the assessment found delays in the adoption of policies recommending provision of TPT to all household members and close contacts of TB cases, irrespective of age and HIV status, after ruling out active TB.

Based on the findings and recommendations of the present assessment, the Elizabeth Glaser Pediatric AIDS Foundation calls on national policymakers to do the following:



1. Foster political leadership and financial support for prevention, diagnosis, and treatment of childhood TB. Countries should set and commit to achieving ambitious targets in accordance with international commitments. This must be accompanied by detailed budgets for childhood TB activities that reflect the ambitions of the established targets on prevention, diagnosis, and treatment of childhood TB and the National Strategic Plan. Sustained efforts from domestic and international resourcing remain strongly needed to bridge the financial gaps heavily affecting TB.



2. Rapidly endorse the use of WHO-recommended tools and strategies for screening and active case finding in children and adolescents younger than 15 who are contacts of TB index cases and for children and adolescents living with HIV. This includes the endorsement of a child-adapted screening algorithm including signs and symptoms specific to pediatric TB, especially for younger children (younger than 10), and ensure clear guidance is provided for asymptomatic children to be considered eligible for TPT, especially in high-risk populations.



3. Adopt the most up-to-date guidelines for pediatric TB diagnosis including clinical assessment, radiological assessment, and use of recommended diagnostic assays whenever feasible by endorsing the latest recommendations in terms of use of tools such as lateral flow urinary TB lipoarabinomannan, Xpert Ultra, and use of stool as a sample for Xpert testing.



4. Ensure country availability of child-friendly formulations of TB medicines for all children with TB by quickly moving toward endorsement, approval, and uptake of all child-friendly formulations for treatment and prevention of drug-sensitive TB and DR-TB.



5. Scale up TPT regimens for children at risk by expanding eligibility for provision of TPT and introduction of new and shorter TPT options.



6. Speed up integration of TB services into other health services by ensuring the continuum of care for TB in children and adolescents is included across all services and adapting national policies to include other aspects of integration beyond TB screening, such as diagnosis, treatment, prevention, and follow-up, based on the most appropriate model of care for the specific setting.



7. Improve monitoring and evaluation frameworks and strategies to better inform national programs, identify gaps and challenges, and support the provision of quality care to patients.

Addressing TB in children and adolescents is a human rights imperative that is achievable with leadership and political support—an obligation that the world has committed to undertake with all available means.^{2,3} The clock is ticking. Urgent and more ambitious investments and actions are required to put countries on track to globally reach the United Nations General Assembly High-Level Meeting targets on TB and to end TB in children and adolescents. Political leadership and advocacy at national and international levels is strongly needed to ensure quicker adoption and implementation of these policy recommendations to address the childhood TB crisis.

2. Introduction

Childhood TB is a preventable and curable infectious disease that represents a major contributor to childhood morbidity and mortality. Nonetheless, for too long, childhood TB has remained poorly addressed by the global public health agenda and often has been neglected by health policymakers and TB control programs. The diagnostic and operational challenges to addressing childhood TB as well as the assumption that children with TB are less likely to transmit than adults, and thus represent less of a public health threat to the broader population, have contributed to reduced attention to this vulnerable population.⁴

Data from the WHO 2021 global TB report estimate that children (younger than 15) should have accounted for 11% of the total burden of TB in 2020, equivalent to 1,100,000 cases, but only 430,460 (40%) of the cases were reported to national TB programs (NTPs), leaving the majority of children not diagnosed or not reported. The estimated number of TB deaths in children in 2020 was 226,000. TB coinfection with HIV also continues to represent a great threat to child health. Mortality data show that 10% of the HIV-positive people who died from TB globally in 2020 were children.¹

During the past decade, the international community has recognized the need to put more effort into the fight against childhood TB. The first targeted roadmap, with key steps to scale up the response to childhood TB and end childhood TB deaths, *Roadmap for Childhood Tuberculosis: Towards Zero Deaths*, was launched by WHO and partners in 2013.⁵ A new call to action, *Roadmap Towards Ending TB in Children and Adolescents*,² was launched in 2018, prior to the United Nations General Assembly High-Level Meeting (UNHLM) on TB, setting new recommendations for how to target young people between 10 and 19 years of age and calling for sustained advocacy, strong and clear commitment, funding, and resource mobilization to tackle TB in children and adolescents.

The 2018 UNHLM on TB represented a crucial event in the fight against TB, specifically childhood TB. World leaders committed to reach key concrete targets by 2022, many of them specifically addressing childhood TB.³

Progress toward the childhood TB targets in 2018 and 2020 remained slow:

Only 12,200 children were treated for multidrug-resistant tuberculosis (MDR-TB)/rifampicin-resistant TB, 11% of the five-year target of 115,000.

1.2 million treated from 2018 to 2020, 29% of the five-year target of 4 million.

Similarly, the numbers of household (HH) contacts of children under five provided with TB preventive treatment (TPT) were much smaller than the targets:

1.2 million treated from 2018 to 2020, **29% of the** five-year target of **4 million.**¹

While recent years have seen some progress in terms of screening, diagnosis, treatment, and prevention strategies for TB in this extremely vulnerable population, the current gaps in achieving the UNHLM targets clearly show that more needs to be done. More child-friendly sample collection procedures for use in Xpert MTB/RIF (Xpert) testing as well as a urine-based lateral flow urinary TB lipoarabinomannan test (LF-LAM) assay for diagnosis of TB in children living with HIV have been recommended. Pediatric formulations for the treatment of both drug-susceptible tuberculosis (DS-TB) and drug-resistant tuberculosis (DR-TB) as well as for delivery of preventive treatment have become available, and more attention has been given to integration of childhood TB care into other services, including HIV, maternal and child health, and nutrition services.

Rapid endorsement of the best international policies by national programs, approval of practices at the country level, accountability, and mobilization of adequate financial resources are the first crucial and essential steps toward achieving the UNHLM targets and toward providing quality care for childhood TB.

Advocacy is therefore critical for overcoming access barriers, catalyzing and monitoring political will and country preparedness for improvement of childhood TB services, and taking up key pediatric TB products and models of care.

In line with many other international efforts, as part of its Unitaid-supported Catalyzing Pediatric Tuberculosis Innovations (CaP TB) project, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in 2018 carried out a qualitative assessment of the national policy landscape and country preparedness for childhood TB in 10 countries (Cameroon, Côte d'Ivoire, Democratic Republic of Congo [DRC], India, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe). Findings from the 2018 landscape⁶ showed that while all surveyed countries had the basic elements needed to improve pediatric TB prevention, diagnosis, and treatment, there were important gaps in the regulatory and financial environment as well as delays in introducing and scaling up innovative diagnostics and treatments and in integrating childhood TB activities into other services.

The purpose of the 2021 childhood TB multicountry assessment is to evaluate country preparedness and policies targeting pediatric and adolescent TB and DR-TB. It assesses progress made by national programs during recent years in allocating attention and resources to the rapid uptake of best policies and practices targeting childhood TB and in evaluating remaining gaps.

This assessment does not include the evaluation of practices on the ground and does not represent a picture of the implementation status of childhood TB care at the country level.

3. Methodology

The 2021 childhood TB multicountry policy assessment is a qualitative assessment of national policies and country preparedness for childhood and adolescent TB programming in 10 countries. The target population is children younger than 15.

The assessment focused on the following key areas:



1. Political and financial commitment to and support of childhood TB care, including pediatric and adolescent TB-specific intervention in national plans



2. Screening and case-finding strategies



3. Diagnostic approaches



4. Treatment, including in-country registrations of pediatric formulations and procurement practices



5. Policies and models for provision of TPT



6. Policies supporting integration of childhood TB care into other services



7. Monitoring and evaluation (M&E) framework and tools targeting TB in children and adolescents

The indicators used for the assessment closely follow the key priority areas highlighted in the *Roadmap Towards Ending TB in Children and Adolescents*.² The latest available WHO recommendations, listed in Annex A, in the form of guidelines or rapid communications, were used as reference standards for best policies and practices.

The assessment was performed in the following 10 countries: Cameroon, Côte d'Ivoire, DRC, India, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe.

The assessment was performed by an external reviewer working in close collaboration with the EGPAF CaP TB project team and NTPs.

i. Questionnaire Revision and Indicators

The questionnaire used for the 2021 assessment is the result of a process of revision of the questionnaire used in 2018. The 2018 version is included as Annex B, and the 2021 version is included as Annex C.

As international best policies and practices evolved over the years, the first step was to assess changes in WHO guidance between 2018 and 2021, using the latest published recommendations as reference standards. For most of the indicators, the latest available WHO recommendations, in the form of guidelines or rapid communications, were used as reference standards for best policies and practices. For some of the indicators assessed in the section on political and financial support, recommendations included in *Roadmap Towards Ending TB in Children and Adolescents* were also used.

To allow for comparison between 2018 and 2021, the main structure of the questionnaire and the majority of the indicators remained unchanged, as did the age definition for childhood TB, which included children and adolescents 0 through 14 years old.

The final version of the 2021 questionnaire included 85 indicators, with some subindicators.

The vast majority of questions were closed questions, leading to "yes" or "no" answers. The definition of "partially" was applied in a few cases, and explanations for this categorization are provided in the results. Open questions were answered based on available documentation or on feedback provided by the country teams and NTP managers. Any result that could not be verified by the external reviewer is described in the specific section.

Technical experts within and outside the study team, including representatives of the WHO Global TB Program, reviewed the questionnaire and provided input prior to final validation.

Data Collection

Key national documents such as National Strategic Plans (NSPs), policies, guidelines, official tools as registers, training materials, standard operating procedures (SOPs) as well as national budgets and global fund agreements (when accessible) were collected and compiled. The available documents were shared with the external reviewer between February and April 2021.

Initial results were shared with EGPAF country teams for review and inclusion of missing information. Prefinal filled-in questionnaires were shared with the NTP managers of the respective countries for revisions, collection of pending source documents, and validation of the information collected. The vast majority of the information collected during the review process was verified through review of official national documentation. When information could not be verified, a NTP representative was asked to confirm the accuracy of the information. Results that could not be verified through official documents are specified in each area of the report. Ultimately, policies endorsed by national programs until June 30, 2021, were included.

ii. Analysis and Comparison with Findings from 2018

Results on indicators were compiled into a dashboard. This report presents the 2021 results followed by a comparison with the 2018 assessment.

This report presents the results in the seven above-mentioned areas and a comparison with findings from 2018. Each results section also provides a brief overview of the main gaps identified and specific recommendations to bridge the gaps.

iii. Main Limitations

The main limitations of this assessment include the following:

- Availability of and access to budget resource documents associated with the NSPs were limited. Budget documentation was not available for all countries; thus results were defined as "not available," "not applicable," or "information not verified." Heterogeneity of budgeting tools used was also an important element that could contribute to potential biases in the analysis methodology and the possibility of comparing results among countries.
- Analysis of budgets associated with the NSPs does not represent a financial needs assessment.
- Data on approval by national regulatory authorities (NRAs) were initially provided by the pharmaceutical companies manufacturing the specific drugs and then validated by the

NTPs. In the few cases where discrepancies were identified, information received by the NTPs was retained.

- Data on general procurement of pediatric formulations of second-line drugs were initially extracted from data presented by the Global Drug Facility at the 2020 Union Conference for Tuberculosis and Lung Health, while data on procurement of specific formulation of second-line drugs were provided by NTPs and retained as final results. It was not possible to triangulate and verify this information with international drug procurement agencies.
- Results for new indicators that were added in the 2021 questionnaire but not present in the 2018 questionnaire could not be compared.
- For all indicators, results represent only a snapshot of the situation as of the end of June
 2021 and cannot be used to assess progress after that date.

4. Main Findings and Recommendations



4.1. Political and Financial Support

Strong political commitment and financial support from national governments in the fight against TB and childhood TB are the first essential steps to achieve a reduction in the TB burden in this vulnerable population.

The findings for this section are grouped into 9 main areas:

- A. Inclusion of childhood TB activities in the NSPs for TB
- B. Childhood TB diagnosis and treatment targets established
- C. Call for registration, introduction, and use of pediatric formulations for TB drugs in the NSP
- D. Budget for childhood TB activities included in the NSP and financial support
- **E.** Existence of an active childhood TB working group at the country level
- F. Guidance, SOPs, and stand-alone guidelines for TB in children and adolescents
- G. Plans for capacity building and training materials on TB in children and adolescents
- H. Public outreach campaigns (media/community awareness)
- I. Policies and framework on the role of private providers/private health facilities in the management of TB in children and adolescents

A. Inclusion of childhood TB activities in the NSPs for TB

All (10 out of 10) countries included childhood TB in their NSPs; these good results are in line with findings from 2018, but the 2021 analysis showed an overall improvement in the attention given to childhood TB in the NSPs, articulated by much more detailed and specific interventions across all areas, and particularly in the areas of monitoring and surveillance, operational research, DR-TB treatment, TPT, and technical assistance.

B. Childhood TB diagnosis and treatment targets established

Eight out of 10 countries have established childhood TB diagnosis and treatment targets. One out of 10 has these only in a partial way, with targets established only for case detection and prevention but not for treatment, while 1 out of 10 countries did not include clear targets in any of the verifiable source documents.

It was not possible to compare these results with findings from 2018, as this indicator was not included in the 2018 assessment.

C. Call for registration, introduction, and use of pediatric formulations for TB drugs in the NSP

In order to ensure the comparison between 2018 and 2021, this indicator looked specifically into the fixed-dose combinations (FDCs) of first-line pediatric formulations of TB drugs. Use and approval of other new pediatric formulations such as ethambutol and isoniazid (INH) 100 mg dispersible tablets (DTs) as well as second-line drugs are addressed in section 4.4, regarding treatment.

Results from 2021 show improvements compared to 2018. In fact, 8 out of 10 NSPs from the surveyed countries included a call for registration and/or introduction and use of the first-line pediatric FDC, while for the 2 remaining countries that did not have such specific calls in their NSPs, the policies for introduction and use were already in place from previous years.

In 2018 only six countries had included in their NSPs a specific call for registration, introduction, and use of first-line pediatric formulations of TB drugs.

D. Budget for childhood TB activities included in the NSP and financial support

Only 6 out of 10 countries in 2021 had clear, detailed, and verifiable budgets specifically allocated to childhood TB included in their NSPs; 1 country had a budget for childhood TB activities included as part of a broader budget for key populations, which could be verified but did not allow the analysis of inclusion of funding for specific childhood TB activities; for the remaining 3 countries, it was not possible to analyze this area in detail as national budget documents were not available for revision and thus were not verified. The following information was reported by the country teams and the NTPs:

- One country reported that the budget for childhood TB activities was included in the broader budget for the general population.
- One country reported that the budget had been allocated and secured for the selected activities of training on childhood TB and drug procurement of pediatric formulations, and thus the result was coded as "partially."
- One country reported that all childhood TB activities were included in the proposal submitted for funding to the Global Fund.

The analysis of the 6 out of 10 verifiable country budgets included in the NSP showed that:

- all (6 out of 6) included funding for activities targeting childhood TB in the areas of active case finding and diagnosis, treatment of DS-TB, TPT, and other areas as integration of TB activities in other services and training;
- five out of 6 countries included specific budgets for activities targeting DR-TB in children and adolescents; and
- four out of 6 countries had included specific budgets for activities related to M&E for TB in children and adolescents.

Compared to the 2018 policy assessment, these results show improvements in the financial support allocated by governments toward activities targeting TB in children and adolescents, as shown by the fact that in 2018 only 3 out of 10 countries included in their NSPs specific budgets for active

case finding, DR-TB treatment, and M&E for childhood TB; only 5 out of 10 included budgets for TB diagnosis and TPT in children; and only 4 out of 10 included budgets for treatment of childhood DS-TB.

Unfortunately, as in 2018, 2021 results showed that all budgets for childhood TB have not been fully approved. One country, though, reported that the budget for almost all activities, with the exception of training, had been approved.

E. Existence of an active childhood TB working group at the country level

Seven out of 10 countries, compared to 6 out of 10 in 2018, have active TB working groups focusing on TB in children and adolescents, while in the remaining 3—compared to 2 in 2018—childhood TB represents a work-stream of the general TB working group. All (10 out of 10) countries have a pediatric TB focal point at the national level.

F. Guidance, SOPs, and stand-alone guidelines for TB in children and adolescents

All (10 out of 10) countries had specific guidance and SOPs for TB in children and adolescents as part of their TB national guidelines, compared to only 8 out of 10 in 2018, and 7 out of 10 countries had stand-alone guidelines for the management of TB in children and adolescents. This last result is comparable to the one found in 2018.

G. Plans for capacity building and training material on TB in children and adolescents

A major improvement compared to 2018 was achieved in the area of training and capacity building on childhood TB. All (10 out of 10) countries had plans for capacity building of TB in children and adolescents, and for 9 out of 10, the plans could be verified through the source documents, and the training material was available at the national level. In 2018, only 3 out of 10 countries included defined training and capacity building activities for childhood TB in their national action plans.

H. Public outreach campaigns (media/community awareness)

This indicator investigated whether there had been at least one public outreach campaign during the past year (2020) specifically on TB in children and adolescents, with the aim being to increase community awareness and fight stigma. Results showed that 7 out of 10 countries (compared to 6 out of 10 in 2018) had done at least one public outreach campaign in 2020 specifically on TB in children and adolescents; 1 country had done at least one public outreach campaign on TB, but without inclusion of specific messages about TB in children; and 2 countries reported that such campaigns had not taken place in 2020.

I. Policies and framework on the role of private providers/private health facilities in the management of TB in children and adolescents

Seven out of 10 countries included clear guidance and recommendations in their NSPs or in other key policy documents on the role of the private sector in the management of childhood TB. This represents a relative improvement compared to 2018, when only 5 out of 10 countries had clear guidance on this important area.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: Kenya's and DRC's progress in providing political and financial support to childhood TB services

Several countries showed great improvements in the area of political and financial support for childhood TB; Kenya and DRC are among the best examples.

Kenya's TB NSP for 2019–2023 and DRC's for 2021–2025 visibly prioritize TB in children and adolescents among all areas and include detailed descriptions of the planned key activities focusing on children and adolescents, which address all steps of the TB/DR-TB cascade as well as surveillance, operational research, M&E, and technical assistance needs in the area of childhood TB. The NTPs also establish clear diagnostic and treatment targets for children and develop budgets accordingly, covering almost all of the areas outlined in the NSPs, including training, capacity building, and integration activities across all services. Both countries have developed stand-alone guidelines for management of TB in children and adolescents, which include recommendations for hospitalization and for activities to be implemented at all levels of care, including the community level. Already in 2018, Kenya and DRC had each set up an active childhood TB working group, which has been maintained throughout the years and will hopefully continue to be sustained for the years to come. Kenya also has developed clear policies defining the role of the private sector in childhood TB.

All these aspects show the great progress that these two countries have made since 2018 and are examples of how political commitment can lead to effective change.

Main Challenges and Gaps

From a policy and programmatic perspective, these results show how gaps in the area of financial support still need to be filled and appropriately addressed. It was not possible to evaluate whether the budget proposed for specific activities was adapted to ensure optimal coverage of needs. In addition, the results showed that the budgets for childhood TB activities proposed by the NTPs had not been approved in any of the surveyed countries, with the exception of one that had its budget "almost fully approved." This highlights how childhood TB remains underfunded and how more efforts are needed in this area.

Key Recommendations

- 1. Countries need to include and prioritize in their NSPs for TB all key activities for TB in children and adolescents. Particular efforts are needed in addressing surveillance and M&E activities that remain partially neglected.
- 2. All countries should have clear childhood TB diagnosis and treatment targets included in their NSPs or in other policy documents, as it is an essential step to be able to monitor progress and for countries to be accountable in their commitments.
- **3.** Countries need to include detailed and realistic budgets for childhood TB activities that are aligned with the ambitions of their NSPs and targets on prevention, diagnosis, and treatment of childhood TB that have been established by their ministries of health and NTPs.
- **4.** Further analysis is needed to identify reasons for a lack of full approval of national childhood TB budgets and to act on them to ensure that funding needs are covered.
- 5. National and international advocacy is needed to increase funding support for childhood TB activities. Efforts toward an increase of domestic funding for certain areas, such as procurement of quality-assured first-line drugs, could have a catalytic role and lead to a better use of international funding for more neglected activities and areas such as procurement of newer pediatric formulations as well as implementation of innovative case-finding and prevention activities.
- **6.** Relevant efforts in planning for training and capacity building of health care workers (HCWs) need to be sustained. Improvements seen at the policy and planning levels need to be accompanied by effective implementation of training and capacity building on pediatric TB at all levels of care.
- 7. Countries need to keep prioritizing in their policies the engagement and active role of the private sector. Although not assessed in this analysis, involvement of other care providers such as community-based organizations and civil society organizations remains critical.



4.2. Screening and Case Finding

Case-finding activities are the first critical step of the TB cascade of care; policies and guidance on the best strategies for finding all the missing cases are often neglected. The 2021 analysis looked into country preparedness and adoption of the best standards of care to address this step of the cascade.

The findings for this section are grouped into seven main areas:

- A. Policies and recommendations on screening for and evaluation of active TB of HH and close contacts of TB cases
- B. Tools recommended for screening of child contacts of TB
- C. Policies and recommendations on evaluating for active-TB infants born to mothers with known TB disease (or with known HH TB contact)
- D. Policies and recommendations on TB screening in all children living with HIV and on HIV testing in children with TB
- **E.** Existence of national guidance on integrated management for childhood illness (IMCI) and integration of a screening algorithm for TB in IMCI guidance
- F. Community-based strategies for contact investigation and TB screening
- **G.** Policies and recommendations on periodic, systematic, active case finding and TB screening for pediatric TB in defined settings

A. Policies and recommendations on screening for and evaluation of active TB of HH and close contacts of TB cases

All (10 out of 10) countries clearly recommend screening for active TB of all HH and close contacts, irrespective of age and HIV status, and guidelines include an algorithm for screening of these categories. In 2018, while 10 out of 10 countries were recommending screening and evaluation for active TB of children younger than 5 who were close contacts of TB cases, only 8 out of 10 had recommendations for screening for children between 5 and 15 years of age irrespective of HIV status. The 2018 assessment did not analyze recommendations for all HH contacts older than 15 years old. This represents a very important change as it shows how countries have recognized the importance of quickly adopting the best standards to increase early case detection for all individuals at risk.

B. Tools recommended for screening of child contacts of TB

Deeper analysis of recommendations of tools to be used for screening of active TB (not linked to TPT initiation though) in children younger than 5 and children 5 to 14 years old shows heterogeneity of results, as follows:

 All countries (10 out of 10) recommend the systematic use of WHO TB symptom screening, 9 of them including the adapted pediatric symptom screening for children younger than 5.

- Seven out of 10 countries also recommend, whenever available, the systematic
 use of chest X-ray (CXR) for screening of children younger than 5, in line with latest
 recommendations, while 5 out of 10 recommend the use of CXR, if available, also in
 older children and adolescent contacts of TB cases. In one of these countries, the use of
 CXR is recommended for screening only if Xpert is negative.
- Furthermore, 4 out of 10 and 3 out of 10 countries have updated their guidance to include the use of Xpert, if available, as a screening tool in children younger than 5 and in older children, respectively.

C. Policies and recommendations on evaluating for active-TB infants born to mothers with known TB disease (or with known HH TB contact)

As in 2018, 10 out of 10 countries have clear recommendations on screening of infants born to mothers with TB or with HH contact with active TB.

D. Policies and recommendations on TB screening in all children living with HIV and on HIV testing in children with TB

The analysis confirms the efforts witnessed in 2018, as 10 out of 10 countries have clear recommendations on TB screening among people living with HIV at every encounter with clinical services and on systematic HIV testing in TB cases, irrespective of age.

E. Existence of national guidance on IMCI and integration of a screening algorithm for TB in IMCI guidance

Results from 2021 for these indicators show that 9 out of 10 countries had verifiable IMCI guides in place; 1 country reported having a national IMCI guide that was not shared and could not be verified. However,

- only 5 out of 9 countries have TB screening algorithms included in IMCI, and
- for the remaining 4 out of 9 countries, 1 included a recommendation for TB screening without providing any specific tool, 1 had an algorithm included in the guidelines for management of "the new born" but not in the broader IMCI guidance, and 2 did not have TB screening algorithms included in any IMCI guidance.

While there was improvement compared to 2018 (in 5 out of 10 countries in 2021—compared to 3 out of 10 in 2018—TB screening algorithms were included in IMCI national guidance), efforts are still needed to ensure that TB is fully integrated in IMCI approaches.

F. Community-based strategies for contact investigation and TB screening

Several indicators were assessed to analyze the strategies and recommendations for community-based screening and contact investigation. Results show how countries have fully recognized the importance of a community-based approach for case finding, as 10 out of 10 countries clearly recommend community-based contact investigation that can be performed by community health workers, who also are allowed to perform TB screening at the community level. This represents a slight improvement from 2018, when 9 out of 10 countries had the same recommendations in place.

G. Policies and recommendations on periodic, systematic, active case finding and TB screening for pediatric TB in defined settings

Another important element assessed as part of community-based case-finding strategies was the existence of policies recommending periodic, systematic screening in defined settings such as schools, congregate and refugee settings, detention centers and prisons, and townships and slums. Results show an improvement in the adoption of policies aiming to introduce this important activity, as 7 out of 10 countries, compared to only 3 out of 10 in 2018, had recommendations in place. The most common settings where this was recommended were schools, day care centers, and refugee and congregate settings.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: Cameroon, Côte d'Ivoire, and Malawi showing efforts and progress on screening and case findings policies

Several countries showed sustained efforts leading to major improvements in the area of screening and case finding strategies for childhood TB; Cameroon, Côte d'Ivoire, and Malawi are great examples.

Cameroon has made significant progress in the adoption of best screening and case-finding activities at the facility and community levels. While in 2018, policies for screening of close contacts were focused mainly on children younger than 5 and HIV-infected individuals, the country has now moved toward recommending screening of all HH and close contacts irrespective of age and HIV status. The country also has introduced recommendations on the use of CXR as a screening tool in children younger than 5 who are contacts of active TB cases. IMCI guidelines are in place, and specific recommendations for screening for TB are included in the "new born guidelines." Community-based contact investigation is encouraged, and policies allow community health workers to perform the screening.

Similarly, indicators assessed in 2021 show that **Côte d'Ivoire** has strongly engaged in the area of case finding among children and adolescents, with clear strategies for contact screening and investigation among all categories at risk; a sustained attention to community-based case-finding interventions; allowing community health workers to perform contact investigation and screening at the community level; and periodic, systematic case-finding activities in defined settings such as schools and centers of observation of minors. Although the country has not yet introduced CXR as a systematic screening tool for contacts irrespective of symptoms (only for diagnosis), screening policies include an adapted pediatric symptom-based screening, with specific questions to assess the presence of extrapulmonary tuberculosis (EPTB) signs or symptoms, and the country has started the piloted introduction of Xpert as a screening tool among children younger than 15 who are contacts of TB cases.

Malawi also has clear recommendations and algorithms for TB screening of all HH and close contacts of TB cases, with a special focus on children and adolescents. As HIV prevalence is particularly high in this country, a great deal of attention is given to systematic testing for HIV among children and adolescents with TB and systematic TB screening in HIV-positive children and adolescents. Besides recommendations on the systematic use of TB symptom screening, for children younger than 5 who are contacts of TB cases, the country also recommends as a screening tool the use of CXR and Xpert (if available). The country has national guidance on IMCI, which includes an algorithm for screening for TB in children. Community-based screening and contact investigation activities are recommended and encouraged.

Main Challenges and Gaps

Policies on systematic screening for TB of all HH and close contacts as well as systematic screening for TB in children living with HIV and systematic HIV testing among children with TB are in place across all countries. Despite this, some countries have started introducing more innovative case-finding approaches, such as the use of CXR for screening as recommended by WHO, or Xpert among the most vulnerable people, while other countries lag behind. It is important to note that countries that do have these recommendations in place often include in their guidance the qualifier "if available," showing awareness that access might represent a challenge in many settings. Although it was not the goal of this assessment to evaluate access to care and implementation of policies, we deem it important to highlight this as an area that surely represents an ongoing challenge, even among countries that have the best policies in place. Similarly, global data show that the good results in terms of policies on TB screening in HIV and HIV testing in TB do not always reflect real practices.

In addition, only 5 out of 10 countries have clear recommendations on screening for TB included in their IMCI guidance, and not all countries have policies recommending periodic screening for TB in the most at-risk settings, which is a key and effective activity to ensure early case detection.

Key Recommendations

- 1. Countries need to consider updating their policies to include the use of all effective tools, such as pediatric-adapted symptom screening, CXR, or both of these for screening of all categories at risk, such as children and adolescents who are HH or close contacts of TB cases or children living with HIV who are older than 10.
- More attention is needed to the integration of screening and case detection for TB in IMCI policies and guidance, as IMCI services represent a key entry point for TB case finding among children.
- 3. Countries need to ensure that the existence of policies and recommendations on the best case-finding strategies translate into practice without remaining a luxury accessible to only a limited part of the population



4.3 Diagnosis

The aim of the diagnosis section was to evaluate adoption of internationally recommended guidance on the use of the best diagnostic tools to ensure early detection of TB in children and adolescents. Incorporation of algorithms for pulmonary tuberculosis (PTB) and EPTB, as well as analysis of recommendations on new and existing diagnostic methods such as CXR, Xpert (and Xpert Ultra), alternative molecular methods such as True Nat or TB loop-mediated isothermal amplification techniques (TB-LAMP), and LF-LAM for diagnosis of TB in people living with HIV were the focus of this part of the assessment.

The findings for this section are grouped into eight main areas:

- A. Inclusion of guidance on diagnosis of PTB and EPTB in children and adolescents into national guidelines and provision of indications for hospitalization of children
- B. Inclusion into national guidelines of a diagnostic algorithm for diagnosis of pediatric PTB and EPTB
- C. Policies and recommendations on the use of Xpert MTB/RIF (rather than conventional microscopy and culture) as the initial diagnostic test in children and introduction of Xpert Ultra in the diagnostic algorithm
- D. Type of samples recommended for testing for TB in children and adolescents with Xpert MTB/RIF
- E. Policies and recommendations on additional molecular-based (True Nat or TB-LAMP) diagnostic test as the initial test for TB diagnosis
- F. Policies on the use of LF-LAM for pediatric TB diagnosis in children living with HIV
- G. Recommendations on CXR for TB diagnosis in children with signs or symptoms of TB and availability of SOPs for interpretation of CXR at the national level
- H. Recommendations on tuberculin skin test (TST) and the use of scoring charts/cards for diagnosis of TB in children.

A. Inclusion of guidance on diagnosis of PTB and EPTB in children and adolescents into national guidelines and provision of indications for hospitalization of children

All (10 out of 10) countries already in 2018 had specific guidance on the diagnosis of PTB and EPTB in children and adolescents. These results were confirmed during the 2021 assessment. Eight out of 10 countries, compared to 7 out of 10 in 2018, include clear guidance on criteria to refer children to hospitalization.

B. Inclusion into national guidelines of a diagnostic algorithm for diagnosis of pediatric PTB and EPTB

Nine out of 10 countries in 2021, compared to 8 out of 10 in 2018, had diagnostic algorithms for PTB in children and adolescents included in the guidelines. Only 7 out of 10, compared to 6 out

of 10 in 2018, had algorithms for EPTB. To highlight that, 1 of these countries had a full separate and detailed guideline on diagnosis and management of EPTB. Even if these results show an improvement compared to 2018, the inclusion of specific algorithms for diagnosis in children is a critical element for improvement of diagnosis and a precious help for HCWs across all settings and levels of care. It is thus an area to be further improved.

C. Policies and recommendations on the use of Xpert MTB/RIF (rather than conventional microscopy and culture) as the initial diagnostic test in children and introduction of Xpert Ultra in the diagnostic algorithm

Nine out of 10 countries recommend the use of Xpert as the initial diagnostic test in all children and adolescents with signs/symptoms of TB, while 1 country recommends it only for categories at risk (mainly for people living with HIV and/or at risk of DR-TB). This is an improvement compared to 2018, when only 7 out of 10 countries recommended Xpert as the initial diagnostic test rather than microscopy and culture.

Major improvements are evident in terms of the introduction of Xpert Ultra in the national diagnostic algorithms: 8 out of 10 countries, compared to 1 out of 10 in 2018, have introduced Xpert Ultra as diagnostic test, and all 8 recommend it also for children and adolescents.

D. Type of samples recommended for testing for TB in children and adolescents with Xpert MTB/RIF

The vast majority of countries included recommendations on the use of Xpert on different types of pulmonary and extrapulmonary samples, such as gastric aspirate (10 out of 10), sputum induction (9 out of 10), nasopharyngeal aspirate (10 out of 10), lymph node biopsy/fine needle aspiration (10 out of 10), and cerebrospinal fluid (9 out of 10), representing an overall improvement in all results compared to 2018.

Recommendations on the use of Xpert on stool, more recent and thus not evaluated in 2018, have been adopted already by 3 out of 10 countries. A 4th country will soon pilot use of Xpert on stool through support provided by the United States Agency for International Development.

E. Policies and recommendations on additional molecular-based (True Nat or TB-LAMP) diagnostic test as the initial test for TB diagnosis

Four out of 10 countries have endorsed the use of additional molecular tests, when available, for TB diagnosis in children and adolescents; 3 of them have introduced recommendations on TB-LAMP, and 1 of them on True Nat.

F. Policies on the use of LF-LAM for pediatric TB diagnosis in children living with HIV

It was not possible to assess in detail for all countries whether recommendations applied specifically to children and adolescents. Some countries included recommendations for all people living with HIV, without specifying the criteria for age.

Results show that 9 out of 10 countries have now included clear guidance on the use of LF-LAM for diagnosis of TB in HIV-positive individuals. The analysis of the subgroups for which LF-LAM should be recommended shows the following:

- Nine out of 9 countries adopted a policy on LF-LAM recommending its use for all HIV-positive individuals with advanced HIV or who are severely ill (per WHO's definition) presenting at inpatient department, in line with WHO recommendations.
- Eight out of 9 countries adopted a policy on LF-LAM recommending its use for all individuals with signs or symptoms of TB presenting at outpatient department (OPD), in line with WHO recommendations.
- Only 4 out of 9 countries adopted a policy on LF-LAM recommending its use for all individuals with low CD4 counts (less than 100), irrespective of signs/symptoms of TB, presenting at OPD, as recommended by WHO. Note that 3 of these 4 countries had expanded the recommendations on the use of LF-LAM to include all individuals with CD4 counts less than 200, irrespective of signs or symptoms of TB.

Adoption of policies on the use of LF-LAM were not assessed in 2018, so we report here only the 2021 results.

G. Recommendations on CXR for TB diagnosis in children with signs or symptoms of TB and availability of SOPs for interpretation of CXR at the national level

Ten out of 10 countries, compared to 8 out of 10 in 2018, have introduced recommendations on the use of CXR in the diagnostic algorithms of children and adolescents with signs or symptoms of TB, representing an important improvement in the adoption of best standards of care for TB diagnosis.

Specific SOPs for the interpretation of CXR or detailed explanations about interpretation of CXR in children and adolescents in the national guidelines are available at the national level in 6 out of 10 countries. For 1 of the 6 countries, this information was reported by the CaP TB country teams and NTP, and the content of the SOPs was not verifiable by the external reviewer. This represents an important improvement from 2018, as only 1 out of 10 countries in 2018 had SOPs available to guide HCWs on the interpretation of CXR findings in children and adolescents.

H. Recommendations on TST and the use of scoring charts/cards for diagnosis of TB in children

Recommendations on the use of TST and scoring charts were assessed. These are not recommended anymore as useful tools for diagnosis of active TB disease in children; thus the goal of the assessment was to analyze how many countries had moved away from their use.

Results show that 8 out of 10 countries included TST, if available, in the diagnostic workup of children with signs or symptoms of TB, although most of those countries used TST as a diagnostic aid rather than an initial test.

In terms of recommendations on scoring charts or cards, 2 out of 10 countries still had reference to these tools in their guidelines. Results could not be compared with 2018, as this indicator was not previously assessed.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: Adoption of best standard of care for childhood TB diagnosis—Zimbabwe

Zimbabwe is known for its national capacity to quickly adopt policies and recommendations aiming to provide the best standards of care to fight TB. Results from the 2021 assessment show how this is particularly true in the area of TB diagnosis in children and adolescents, with a special focus on coinfection with HIV. The country's TB guidelines provide clear guidance on diagnosis of TB in children and adolescents, include algorithms for early diagnosis of TB, and although not in the form of an algorithm, give good attention to diagnosis of EPTB. A broad range of SOPs for sample collection and for the use of Xpert on pulmonary and extrapulmonary samples are available at the national level, and Zimbabwe is one of the few countries that has already introduced guidance and SOPs for the use of Xpert on stool. Xpert is the first recommended TB diagnostic test for children and adolescents, and Xpert Ultra was introduced several years ago. Clear recommendations and SOPs are available for use of CXR as a diagnostic tool in those who have a negative Xpert result. Particularly important are the policies regarding the use of LF-LAM in all people living with HIV, as recommendations follow the WHO guidance for use in severely sick adults and children at inpatient department and for those with signs or symptoms of TB at OPD, irrespective of CD4 count; going beyond WHO recommendations, Zimbabwe recommends use of LF-LAM at OPD, irrespective of signs and symptoms, for all patients with CD4 counts less than 200.^a

Main Challenges and Gaps

These results show that during recent years, the countries surveyed have made significant progress toward the introduction of best standards of care for TB diagnosis in children and adolescents. Among the main challenges and gaps in this area, the most important ones are represented by the fact that a few countries have not yet integrated Xpert Ultra into their national algorithms and do not have recommendations and SOPs on the use of Xpert on stool; the lack of clear SOPs for CXR across many countries; and the heterogeneity of recommendations for the use of LF-LAM in children and adolescents, with some countries showing major efforts through the endorsement of internationally recommended policies and beyond and others not yet having moved to its use in symptomatic patients. More efforts are surely needed to adopt policies that increase access to and use of LF-LAM in eligible patients.

a Cameroon and Uganda have adopted the same criteria for TB LF-LAM, which is a great step to increase TB case detection among children living with HIV.

Key Recommendations

- 1. Adopt a comprehensive approach to diagnosing children, including thorough clinical assessment, radiological assessment (if available), and performance of diagnostic assays whenever feasible. Countries cannot rely solely on laboratory-based tests due to the suboptimal sensitivity of commercially available tests for the diagnosis of TB in children.
- 2. Ensure the adoption of all the best recommended tools for early diagnosis of active TB in children and adolescents. Xpert—including Xpert Ultra—CXR, and LF-LAM in children living with HIV, need to be widely recommended and used.
- 3. All countries should introduce the use of Xpert, together with CXR, as an initial diagnostic tool for childhood TB.
- 4. Xpert Ultra needs to be introduced into diagnostic algorithms across all countries, and algorithms need to provide clear guidance on the interpretation of "trace call" results.
- 5. SOPs for all recommended PTB and EPTB tests as well as for the interpretation of CXRs need to be available, and training needs to be provided.
- 6. Policies on the use of Xpert on stool need to be more widely adopted. Once evidence on the performance of different stool-processing methods becomes available, appropriate SOPs should be timely endorsed by national programs.
- 7. Particular attention needs to be given to the diagnosis of TB in children living with HIV, especially the youngest ones—younger than 5—who by definition are living with advanced HIV disease; this is why there is no time to lose in the introduction of LF-LAM for all eligible categories, including children at OPD, with or without symptoms, in line with WHO recommendations.



4.4 TB Treatment in Children and Adolescents

The findings for this section are grouped into three categories:

- A. Policies and recommendations on the treatment of DS-TB
- B. Policies and recommendations on the treatment of DR-TB
- C. Drug procurement and approval aspects

A. Policies and recommendations on the treatment of DS-TB

The following results for 2021 apply to all (10 out of 10) countries:

- Treatment of TB in children and adolescents is addressed in national guidelines.
- Treatment regimens for DS-TB in HIV-positive and in HIV-negative individuals and for PTB and EPTB were in line with the best standards of care, consisting of daily 2RHZE/4RH^b for PTB and other forms of EPTB with the exception of TB meningitis and osteoarticular TB, which are treated with 2RHZE/10RH.^c This represents an improvement compared to 2018, as the previous assessment had shown that 9 out of 10 countries had adapted the recommendations for EPTB to be in line with internationally recommended regimens.
- Monitoring and management of adverse events in children and adolescents is well addressed in all national guidelines, compared to the guidelines of 8 out of 10 countries in 2018.
- National guidelines specifically recommend the use of pediatric oral dispersible first-line FDCs for treatment in children weighing less than 25 kg, in line with the 2018 findings.

New indicators assessed in 2021 include recommendations on ethambutol 100 mg DTs and on recommendations on the use of dolutegravir in children living with HIV and in need of starting TB treatment. Results show the following:

- Six out of 10 countries have adopted recommendations on the use of ethambutol 100 mg DT for treatment of DS-TB in children.
- Ten out of 10 countries recommend dolutegravir-based antiretroviral therapy in TB-HIV-coinfected children, 10 out of 10 for children weighing more than 30 kg, and 8 out of 10 for children in the 20 to 30 kg weight band.

B. Policies and Recommendations on the Treatment of DR-TB

Many of the indicators assessed in 2021 are not comparable to findings from 2018. The 2021 assessment looked into the adoption of new policies on oral regimens for DR-TB and the use of new drugs, bedaquiline (BDQ) and delamanid (DLM), in children and adolescents. The only

b 2-month intensive phase of rifampin (R), isoniazid (H), pyrazinamide (Z), and ethambutol (E), followed by a 4-month continuation phase of rifampin and isoniazid

c 2-month intensive phase of rifampin (R), isoniazid (H), pyrazinamide (Z), and ethambutol (E), followed by a 10-month continuation phase of rifampin and isoniazid

comparison versus 2018 is the procurement of a second-line pediatric formulation.

Results about recommendations on all-oral regimens and the use of new drugs for DR-TB in children show the following:

- Nine out of 10 countries have adopted policies on all-oral regimens for DR-TB treatment. A deeper analysis showed that 7 out of 9 countries have specific DR-TB treatment recommendations for children and adolescents; 1 out of 9 countries have recently introduced oral regimens through a circular that does not specify age, but information received by the NTP is that the new recommendations also apply to children and adolescents. One country out of the 9 has national guidelines recommending the all-oral treatment regimen for patients eligible for the long regimen but an injectablebased regimen for patients eligible for the short regimen; the use of the new oral short regimen is recommended only under operational research. For this specific country, information received by the NTP is that although guidelines have not been fully updated. all children are systematically started on either the long or the short all-oral regimen, depending on eligibility criteria; the injectable-based short-course regimen is not used anymore in children. In 1 country, the recently released guidelines for the management of DR-TB exclude children younger than 5 from eligibility for the short all-oral regimen. This exclusion may be attributed to limited access to new drugs and to the fact that at the time of this assessment, BDQ was not yet recommended for use in children younger than 6, but alternative treatment regimen options, without necessarily using BDQ or DLM, should be considered. This is a solution that has been endorsed by other countries.
- The analysis of policies about the use of new drugs in children and adolescents show that all (10 out of 10) countries have recommendations on the use of BDQ in children and adolescents. Nine out of 10 countries have recommendations on the use of DLM in the same category of patients. The remaining 1 country did not have official recommendations at the time of the closure of data collection, but information received from the NTP was that DLM was already in use for treatment of DR-TB in children and adolescents and that new official policies were expected soon in 2021.
- With regard to the age groups eligible for BDQ, 9 out of 10 countries recommend BDQ in adolescents older than 12, whereas for 1 country the information was not available.
 Eight out of 10 countries also recommend the use of BDQ in children older than 6; for 1 country there are no recommendations on the use of BDQ in this age group, and for the other 1 country, the official policy is not in place but is expected soon.
- With regard to the age groups eligible for DLM, 9 out of 10 countries recommend DLM for children older than 6, while for 1 country, the official policy is not in place but is expected soon. Eight out of 10 countries also recommend the use of DLM in children older than 3, whereas for 1 country the use of DLM in this age group has to be approved by a national committee and for the other 1 country, the official policy is not in place but is expected soon.

C. Drug Procurement and Approval Aspects

Results from an analysis of the procurement of pediatric formulations (FDC of rifampicin, isoniazid and pyrazinamide (RHZ), FDC of rifampicin and isoniazid (RH), and ethambutol 100 mg), approval from NRAs, and inclusion of the formulations in the national Essential Medicines Lists (EMLs) can be summarized as follows:

- All 10 out of 10 countries procure the pediatric dispersible FDC RHZ and RH. Nine out of 10 procure through the Global Drug Facility.
- In 9 out of 10 countries, the FDCs have received approval from the NRAs. The remaining country does not have an NRA but follows the NRA of a neighboring country; thus it is not included in this analysis, although the use of FDC is clearly recommended by the NTP.
- In 6 out of 10 countries, the pediatric FDCs are included in the national EMLs, this
 indicator representing a great improvement compared to 2018 when this was true of
 only 2 out of 10 countries.
- In 5 out of 10 countries, ethambutol 100 mg DT is approved by the NRAs. This indicator was not assessed in 2018.
- In only 2 out of 10 countries, ethambutol 100 mg DT is already included in the EML. This
 indicator was not assessed in 2018.
- In 4 out of 10 countries, procurement of first-line FDCs is supported by domestic funding, while in 6 out of 10, it is supported by international donors (Global Fund). These results are comparable to the ones from 2018.

Analysis of procurement of pediatric formulations of second-line drugs shows that 10 out of 10 countries are procuring these important child-friendly treatment tools, which is a major improvement compared to 2018, when only 1 country of the 10 had initiated the process. Based on information received by the NTPs,

- seven out of 10 countries are now procuring levofloxacin and cycloserine,
- five out of 10 are also procuring pyrazinamide and BDQ, and
- four out of 10 countries are procuring moxifloxacin and ethionamide.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: The determination of Uganda and Lesotho in adopting the best treatment policies for DS-TB and DR-TB

Uganda represents a great example of early adoption of the best policies for treatment of DS-TB and DR-TB in children and adolescents. Besides the national policies and guidelines that provide clear and up-to-date recommendations for treatment of DS-TB and DR-TB, including for the management of adverse events, the country is one of the first to endorse the new recommendations on all-oral regimens for DR-TB in children, for both the long and the short oral regimen. For children eligible for the short regimen, the recommended treatment at the country level follows WHO guidance with the use of BDQ in children older than 6. In children younger than 6, BDQ is replaced by DLM. Although BDQ has not yet been procured, its procurement is planned. Based on information received by the NTP, a policy update on the use of ethambutol 100 mg DT is planned for this year, together with appropriate training. For children with TB coinfected with HIV, for all children weighing more than 20 kg, the use of dolutegravir is recommended.

Lesotho is another exemplary model when it comes to treatment strategies for DR-TB. The country, in fact, was one of the first to move toward recommending all-oral regimens for DR-TB in children and adolescents and one of the first to push for the use of treatment regimens for childhood DR-TB including new drugs. The third edition of the national guidelines for management of DR-TB, released in 2019—thus ahead of the latest WHO recommendations—specifically addresses all aspects of management of DR-TB in children and adolescents, providing clear guidance on the use of all oral regimens for all categories of patients and recommending new and repurposed drugs in children, even the youngest ones.

Main Challenges and Gaps

The following are the main gaps in the area of treatment: 3 out of 10 countries do not yet have national recommendations on the use of ethambutol 100 mg, and findings on its registration by national regulatory agencies as well as inclusion in the EMLs remain poor.

In terms of treatment for DR-TB in children and adolescents, it's remarkable that most countries have updated their national guidelines to move from injectable-based to all-oral short and long regimens for DR-TB, but the fact that there are still a few countries that have not fully endorsed all-oral regimens in children is a reason for concern. Similarly, while results show that all countries have started procuring second-line formulations, findings on the specific drugs procured show that not all drugs are being procured, and some key ones such as moxifloxacin and BDQ are not yet accessible.

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Key Recommendations

- 1. All countries need to update their guidance to include the child-friendly ethambutol 100 mg DT formulation as the preferred option for treatment of the youngest children.
- 2. Approval by the NRAs and registration of WHO quality-approved ethambutol 100 mg DT is strongly and urgently encouraged, as is its inclusion in the national EMLs.
- 3. Countries should update their policies on all-oral regimens for DR-TB in children. Evidence about the toxicity and lack of efficacy of most of the injectable agents previously used for DR-TB is massive, and use of these agents is not justifiable anymore in any patients except those with extremely complex resistance profiles and with drug susceptibility testing results showing susceptibility to the injectable agents. This applies even more to children and adolescents for whom exposure to such toxic agents can have a detrimental effect.
- 4. Procurement of all second-line pediatric formulations for DR-TB treatment is urgently needed. Also urgently needed are, for countries that do not yet have them, recommendations on the use of new drugs (BDQ and DLM) adapted to age groups.
- **5.** It is essential to ensure that policies are translated into practice and access. Any further delay in provision of the best available treatments for DS-TB and DR-TB to children and adolescents is not defensible anymore.



The findings for this section are grouped into seven categories:

- A. Policies and guidance on TPT for children and adolescents, including algorithms and criteria for eligibility for TPT
- B. Recommendations for TPT for HIV-exposed or -positive infants younger than 12 months with TB contact history and for HIV-positive children older than 12 months who are considered unlikely to have TB disease (regardless of TB contact history)
- C. Recommendations for TPT for children who are HH or close contacts of people with TB and who are found not to have active TB
- D. Regimens recommended by national guidelines for preventive treatment in children
- E. INH 100 mg DTs: Recommendations, approval, and inclusion in national EMLs
- F. Policies on TPT for selected high-risk HH contacts of patients with MDR-TB
- G. Policies on community-based initiation of preventive treatment

A. Policies and guidance on TPT for children and adolescents, including algorithms and criteria for eligibility for TPT

Adoption of policies to address TPT for children and adolescents is well recognized by all countries. Results show that all (10 out of 10) countries, as reported in 2018, have clear guidance on TPT for children and adolescents and that all countries also outline criteria for eligibility for TPT for children and adolescents.^d

B. Recommendations for TPT for HIV-exposed or -positive infants younger than 12 months with TB contact history and for HIV-positive children older than 12 months who are considered unlikely to have TB disease (regardless of TB contact history)

Ten out of 10 countries in 2021 clearly recommend offering TPT to these two categories of children at high risk; this represents a minor but important improvement compared to 2018, when only 9 out of 10 countries had such recommendations.

C. Recommendations for TPT for children who are HH or close contacts of people with TB and who are found not to have active TB

The assessment of 2018 showed that all 10 countries would target all children younger than 5 but not older children who were not living with HIV. This was in line with international recommendations at the time, which had not yet expanded criteria to all contacts.

d A minor discordancy is reported in terms of the existence of algorithms to identify children eligible for TPT between the 2018 and 2021 analyses. In 2021 only 9 out of 10 countries, compared to 10 out of 10 in 2018, had criteria included in the form of algorithms, while the remaining country had only the criteria outlined as narrative text in the guidelines. This discordant result is likely due to the limitation of having different reviewers perform the analyses in 2018 and 2021.

In 2021, only 5 out of 10 countries had updated policies on the provision of TPT, after ruling out active TB, to all children and adolescents who are HH or close contacts of TB cases, irrespective of age and HIV status. The remaining 5 countries recommend TPT to all children younger than 5, irrespective of HIV status and found not to have active TB, while TPT is offered to older children and adolescents only if they are living with HIV.

D. Regimens recommended by national guidelines for preventive treatment in children.

As new TPT options are now available and recommended internationally, the 2021 analysis looked into updates of country policies with regard to the new options. Results show that the majority of countries include more than one option for TPT, as follows:

- As in 2018, 10 out of 10 countries still include INH preventive treatment (IPT)—6 months
 of INH—as one of the TPT options, although 1 country is in the process of phasing out
 IPT.
- Seven out of 10 countries recommend three months of RH (3RH) as an additional TPT option, clearly an improvement compared to 2018, when only 1 country had adopted 3RH.
- Seven out of 10 countries have updated their recommendations to include the new TPT regimen of three months of HP (3HP). This result cannot be compared to 2018 as 3HP was not yet recommended at the time.
- Three out of 10 countries now recommend one month of HP (1HP) as a TPT option for children older than 13, showing efforts toward the early adoption of the latest recommendations. As with 3HP, these results cannot be compared to 2018.

E. INH 100 mg DTs: Recommendations, approval, and inclusion in national EMLs

It was deemed important to assess the status of policies and approval with regard to the new pediatric formulation of INH 100 mg DT, which is much more child friendly and adapted to the needs of the youngest children. These indicators were not assessed in 2018, as INH 100 mg DT was not available at the time.

- Four out of 10 countries included in their national policies and guidelines recommendations on the use of INH 100 mg DT.
- Two out of 10 countries had already received approval from their NRAs for the use of INH 100 mg DT.
- Two out of 10 countries had already included INH 100 mg DT in their national EMLs.

These results show that while it is encouraging that some countries have already adopted policies, requested approval and registration, and updated their EMLs, there is still a lot for the remaining countries to do to make sure that this new child-friendly formulation becomes accessible as soon as possible.

F. Policies on TPT for selected high-risk HH contacts of patients with MDR-TB

Three out of 10 countries had updated their national policies to include recommendations on provision of TPT to selected high-risk HH contacts of patients with MDR-TB.

G. Policies on community-based initiation of preventive treatment

Only one country had a policy recommending community-based initiation of TPT.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – <u>HERE</u>



Spotlight: Tanzania—a great example of early adoption of new policies and recommendations for TPT

Tanzania has shown great commitment to the early adoption of best standards of care for TB prevention among children and adolescents. Eligibility criteria for TPT for children and adolescents, together with comprehensive guidance on the recommended treatment options, are well defined in the guidelines, which were recently revised and released. Eligibility includes all HH and close contacts, irrespective of age and HIV status, found not to have active TB, as recommended by WHO. All the internationally recommended treatment options (IPT, 3RH, 3HP, and 1HP) are detailed in the guidelines with specific criteria for provision, such as age or HIV status. Although Tanzania has not yet included it on the EML, the country has included guidance on the use of the new dispersible pediatric formulation of INH 100 mg, which is preferred for young children. Tanzania is also one of the few surveyed countries that includes guidance and recommendations on provision of TPT to contacts of DR-TB cases, after exclusion of active TB/DR-TB, in line with the latest best standards of care. Sustained efforts to ensure that policies translate to effective implementation are essential.

Main Challenges and Gaps

Policies on the provision of TPT to children younger than 5 who are contacts of TB cases have been adopted by all countries. However, results show that many countries lag behind in adopting policies on the provision of TPT for all at-risk children and adolescents irrespective of age, including contacts of DR-TB cases, even though international recommendations on the provision of TPT to all HH and close contacts, irrespective of age and HIV status, were released a long time ago.

In addition, some countries have not yet endorsed policies on the provision of shorter TPT regimens such as 3RH—which is available in a dispersible, fixed-dose, child-friendly formulation—or the newer rifapentine-based options, which are now available as FDC in the case of 3HP. As IPT remains one of the most often recommended options, these results clearly show that more effort is needed to approve, recommend, and use the new DTs of INH 100 mg.

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Key Recommendations

- Countries need to rapidly endorse new policies on the provision of TPT and offer TPT to all children and adolescents, irrespective of age and HIV status, who are HH or close contacts of TB cases, after ruling out active TB.
- 2. Recommendations need to include provision of TPT to HH and close contacts of DR-TB cases, after exclusion of active TB/DR-TB, with a TPT regimen based on the resistance pattern of the source case.
- 3. All countries need to include in their guidance shorter TPT regimens, such as 3RH or 3HP, and rapidly approve and recommend the use of INH 100 mg DT, which is an important child-friendly option particularly for the youngest children.



4.6 Integration

In this section, policies and recommendations providing guidance toward integration of childhood TB activities in different services are explored.

The findings for this section are grouped into four categories:

- A. Integration of TB services for children and adolescents into prevention of mother-to-child transmission (PMTCT) clinics
- B. Integration of TB services for children and adolescents into maternal, newborn, and child health (MNCH) services
- C. Integration of TB services for children and adolescents into nutrition services
- D. Integration of TB services for children and adolescents into general OPDs

A. Integration of TB services for children and adolescents into PMTCT clinics

All (10 out of 10) countries had guidance and recommendations on the integration of TB services into PMTCT services, but not all countries addressed all the aspects of integration. Results show that 10 out of 10 countries recommended integration of TB screening, compared to 6 out of 10 in 2018; 6 out of 10 recommended integration of TB diagnosis, compared to 4 out of 10 in 2018; 3 out of 10 recommended integration of TB treatment initiation, compared to 3 out of 10 in 2018; 4 out of 10 recommended integration of TB treatment follow-up, compared to 3 out of 10 in 2018; and 6 out of 10 recommended integration of reporting to the NTP, compared to 3 out of 10 in 2018.

These results show a definite improvement in this area compared to 2018.

B. Integration of TB services for children and adolescents into MNCH services

All (10 out of 10) countries had guidance and recommendations on the integration of TB services into MNCH services, but not all countries addressed all the aspects of integration. Results show that 10 out of 10 countries recommended integration of TB screening, compared to 5 out of 10 in 2018; 8 out of 10 recommended integration of TB diagnosis, compared to 5 out of 10 in 2018; 6 out of 10 recommended integration of TB treatment initiation, compared to 3 out of 10 in 2018; 6 out of 10 recommended integration of TB treatment follow-up, compared to 1 out of 10 in 2018; and 7 out of 10 recommended integration of reporting to the NTP, compared to 1 out of 10 in 2018.

These results show a good improvement in this area compared to 2018, especially in the area of TB screening and diagnosis.

C. Integration of TB services for children and adolescents into nutrition services

All (10 out of 10) countries had guidance and recommendations on the integration of TB services into nutrition services, but not all countries addressed all the aspects of integration. Results show that 10 out of 10 countries recommended integration of TB screening, compared to 5 out of 10 in 2018; 4 out of 10 recommended integration of TB diagnosis, compared to 2 out of 10 in 2018; 2 out of 10 recommended integration of TB treatment initiation, compared to 1 out of 10 in 2018; 1 out of

10 recommended integration of TB treatment follow-up, compared to 1 out of 10 in 2018; and 3 out of 10 recommended integration of reporting to the NTP, compared to 1 out of 10 in 2018.

These results show a definite improvement in the integration of TB screening and diagnosis but more to do in the other aspects of integration.

D. Integration of TB services for children and adolescents into general OPDs

All (10 out of 10) countries had guidance and recommendations on the integration of TB services into general OPD services, but not all countries addressed all the aspects of integration. Results show that 10 out of 10 countries recommended integration of TB screening, compared to 5 out of 10 in 2018; 7 out of 10 recommended integration of TB diagnosis, compared to 4 out of 10 in 2018; 3 out of 10 recommended integration of TB treatment initiation, compared to 1 out of 10 in 2018; 3 out of 10 recommended integration of TB treatment follow-up, compared to 1 out of 10 in 2018; and 6 out of 10 recommended integration of reporting to the NTP, compared to 1 out of 10 in 2018.

These results show a definite improvement in this area compared to 2018 across all aspects of integration.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: India's commitment to integrating childhood TB activities into other services

India is the country with the highest burden of TB and DR-TB. India has set an ambitious goal of eliminating TB by 2025, and to do this, it had to address the challenges of integrating TB services into the primary health system to reduce delays in diagnosis, treatment, and prevention of TB. From a policy perspective, India has developed several guidelines and recommendations to boost integration of childhood TB care at the HIV/PMTCT, MNCH, nutrition, and OPD/primary health care levels. Across all services, integration of TB screening, diagnosis, and reporting activities is recommended. In addition, at the MNCH level, treatment initiation and follow-up on TB cases are also recommended. Among the relevant guidance documents that the country developed in 2020, Operational Guidelines for TB Services at Ayushman Bharat Health and Wellness Centres7—primary health care level—was released, describing, among other elements, the service delivery framework, human resources roles and responsibilities, training, M&E requirements, and financial support to integrate TB care at PHC. Other important policy documents are the Collaborative Framework for Management of Tuberculosis in Pregnant Women8 and National TB Guidelines,9 highlighting key aspects of integration of childhood TB care into MNCH and nutrition services.

Main Challenges and Gaps

Results show that major improvements in policies and guidance on the integration of childhood TB into other services have been achieved during recent years. Despite this, gaps remain. While screening for TB in children is a common recommendation from all countries, and across most of the services that have been assessed, other areas, such as diagnosis, treatment initiation, provision of TPT, and reporting, are not fully addressed by a relevant number of guidelines. Integration of all the steps of the cascade is not mandatory in all services, as a lot depends on the model of care that is the most appropriate for the specific setting. Nonetheless, integration of activities such as diagnosis and provision of TPT, especially into PMTCT or nutrition services, would be an important step as a "one-stop" approach can contribute to improved linkage to care and can reduce loss to follow-up while promoting adherence. Integration, though, should go beyond simple policies. It should include mentoring and capacity building on the provision of TB services among all HCWs, which were not assessed in this exercise.

Another limitation of this assessment is that we did not analyze recommendations on referral and linkage to TB services, which represents a key aspect in countries where TB activities for children and adolescents are not fully integrated into other services.

Key Recommendations

- Countries need to ensure that policies on the integration of TB screening across PMTCT, MNCH, nutrition, and OPD services are fully implemented.
- More effort is needed to integrate other aspects of the TB cascade across all services, taking into consideration the most appropriate model of care and the benefits of a one-stop service for children and adolescents accessing care.
- 3. Nutrition services are a critical entry point for TB diagnosis, as the prevalence of TB among malnourished children is known to be very high.10 Particular effort is needed in this area, especially in considering integration of TB diagnosis into screening.
- **4.** Clear guidance on referral from other services to TB services and linkage to care need to be looked at.



4.7 Monitoring and Evaluation

The area of M&E shows one of the biggest improvements between 2018 and 2021. The assessment includes analysis of several indicators, including the existence of guidance on M&E reporting systems, registers, and other M&E tools to keep track of all the key activities and most important data to monitor all aspects of the TB cascade (screening, diagnosis, treatment, and prevention).

Key findings for this section are grouped into three main areas:

- A. M&E of TB in children and adolescents in national guidelines
- B. Reporting of data and availability of tools
- **C.** Reporting from the private sector

A. M&E of TB in children and adolescents in national guidelines

Ten out of 10 countries, compared to 6 out of 10 in 2018, clearly address M&E in children and adolescents in their national guidelines and policy documents, showing the increased attention given to M&E for childhood TB.

B. Reporting of data and availability of tools

Ten out of 10 countries recommend the collection of, and have a reporting system for, all the key data (type of TB, bacteriological confirmation, treatment follow-up and outcomes, and TPT). Six out of 10 countries also include data related to adverse events in their reporting tools.

Ten out of 10 countries have registers and other M&E tools to record and report contact screening and investigation, as well as initiation, follow-up, and outcomes of TPT, and keep track of the age of contacts.

All data for children and adolescents are reported in age bands: 4 out of 10 countries have moved to reporting into four age bands (0–4, 5–9, 10–14, and 15–19 years); 3 out of 10 countries report into two age bands (0–4 and 5–14 years); and 3 out of 10 countries have electronic reporting systems that can extract data into both categories of age band reporting (e.g., two age bands reporting or four age bands reporting). In 2018, 8 out of 10 countries were reporting into two age bands, while results for the other 2 countries showed that no reporting system seemed to be in place.

C. Reporting from the private sector

Nine out of 10 countries have policies recommending that the private sector report TB cases in children and adolescents to the NTP; the remaining country does not have a mandatory notification policy but strongly encourages this activity. Similar results were observed in 2018.

2021 dashboard— HERE

2018 – 2021 comparative dashboard – HERE



Spotlight: The importance of M&E recognized by all countries

All countries showed a great commitment to the improvement of recording and reporting key data on childhood TB. While indicators for Kenya, Tanzania, Uganda, and Zimbabwe were extremely good already in 2018, some gaps were identified in the remaining countries. This is not the case anymore, as the 2021 assessment shows that Cameroon, DRC, Côte d'Ivoire, India, Lesotho, and Malawi have adopted more comprehensive M&E policies and tools and meritoriously increased their attention on surveillance, recording, and reporting of all childhood TB activities. It is critical to keep putting strong effort into ensuring rapid implementation of these policies and tools.

Main Challenges and Gaps

No major challenges can be reported in the field of M&E from a policy and preparedness perspective, as shown by the encouraging results of this section. Among the minor ones, it is worth mentioning that four countries did not provide recommendations or adopt tools for recording and reporting adverse events in children and adolescents.

Acknowledging these excellent results, it is important to highlight how systematic and periodic training is needed to ensure appropriate M&E of TB in children and adolescents and how the existence of policies and availability of tools at the national level does not always translate into availability of tools at all levels of care.

Key Recommendations

- 1. All countries need to ensure sustained focus on all M&E activities for childhood TB and, as new international guidance appears, adapt their policies and guidelines accordingly.
- 2. Attention is needed to recording and reporting of adverse events in children and adolescents and to availability of related tools.
- **3.** All countries should provide systematic and periodic training to HCWs on M&E and ensure the availability and use of M&E tools and the data collected at all levels of care.

5. Call to Action

Childhood TB is a preventable and curable infectious disease. But for too long it has remained poorly addressed by the global public health agenda and often has been neglected by health policymakers and TB control programs.

Global and national leaders should never forget that addressing TB in children and adolescents is a human rights imperative and is achievable with leadership and political support.

This assessment shows an overall improvement in the childhood TB policy landscape from 2018 in the 10 countries assessed. But important gaps remain in ensuring an effective TB response in children and in achieving the global targets.

Political leadership and advocacy will remain critical to ensuring specific budget lines and the inclusion of targets for childhood TB within countries' national plans. Whereas this assessment found improvements from 2018 in the adoption of the latest policies for case finding, diagnostics, and treatment policies, there remains a need to ensure that more effective tools, programmatic innovations, and models of care are included in the national policy landscape. Furthermore, there is a long way to go in terms of policies and recommendations promoting integration of childhood TB care into other services, especially nutrition services.

Based on the findings and recommendations of this assessment, EGPAF calls on national policymakers and TB advocates to do the following:



- **1.** Foster political leadership and accountability. This is the primary requirement to achieve an effective and fully funded TB response for children and to achieve the targets of the United Nations political declaration on TB and the end TB strategy. To achieve this, countries must
 - address in a comprehensive way in their NSPs for TB the problem of childhood TB, including a description of the burden and challenges and actions needed to prevent, diagnose, treat, and record and report TB and DR-TB in children and adolescents;
 - establish clear and achievable national targets for childhood TB case detection, treatment, and prevention;
 - engage in regular community awareness and public communication outreach campaigns and promote knowledge of childhood TB among the population to fight stigma and discrimination;
 - ensure training and capacity building of HCWs at all levels to ensure appropriate interventions for childhood TB;
 - advocate for detailed and realistic budgets for childhood TB activities that reflect the ambitions of the NSPs and the established targets on prevention, diagnosis, and treatment of childhood TB;
 - advocate for increased domestic and international resources to implement childhood TB policies, address inequities faced by children regarding access to TB services, and move toward the global goal of universal health coverage; and

 support advocacy and stakeholder engagement to increase awareness and accountability among global and national leaders, the private sector, health policymakers, service providers, and communities about the specific needs of children and adolescents with TB and to adopt the best policies and standards of care.



- 2. Scale up systematic TB screening at relevant child health entry points and appropriate active case-finding strategies among children and adolescents at risk. An active case-finding strategy is the cornerstone of the TB cascade of care and the only way to ensure early diagnosis and treatment. To achieve this, countries must
 - recommend the use of child-adapted, symptom-based screening tools, including signs and symptoms that are characteristics of pediatric TB, and whenever feasible, ensure the inclusion of CXR to support the identification of children with presumptive TB;
 - ensure that IMCI policies and guidance are up to date and include TB screening algorithms for the appropriate recognition and management of TB in the context of child health; and
 - commit to translating policies and recommendations on active case finding into practice.



- 3. Adopt a comprehensive approach for pediatric TB diagnosis including clinical assessment, radiological assessment (if available), and use of WHO-recommended diagnostic assays whenever feasible. Huge gaps remain in TB diagnosis among children and adolescents, and there is no treatment without diagnosis. To achieve this, countries must
 - quickly adopt policies and recommendations on the use of WHO recommended diagnostic tools for TB diagnosis in children and adolescents;
 - prioritize the use of Xpert as the first tool for diagnosis of childhood TB, rapidly introduce Xpert Ultra, and improve the access to quality CXR;
 - ensure that SOPs for recommended PTB and EPTB sample collection and for interpretation of CXR are available and that related training is provided;
 - endorse policies promoting the use of Xpert on stool as an additional and childfriendly strategy for TB diagnosis in the youngest children; and
 - update policies on the use of LF-LAM for all eligible categories of children living with HIV, including those accessing care at OPD, with or without symptoms.



- 4. Ensure the availability of child-friendly formulations of TB medicines for all children with TB. Delay in the initiation of effective treatment can have detrimental effects on the mental and physical health of this population. Deferral of endorsement of the best standards of TB/DR-TB treatment care is not defensible anymore. To achieve this, countries must
 - move rapidly toward the endorsement and provision of child-friendly formulations for the treatment of DS-TB and DR-TB, with a special focus on approval, procurement, and introduction of ethambutol 100 mg DT and all second-line pediatric drugs for DR-TB;
 - ensure that children and adolescents affected by DR-TB are treated with all-oral regimens, thus translating policy into practice, and for the few countries that have not yet fully endorsed all-oral regimens for children irrespective of age, do so without any further delay; and
 - prioritize early adoption of the new international policies on the treatment of TB/ DR-TB in children and adolescents, about which an update is expected from WHO before the end of 2021.



- 5. Scale up TPT regimens for children at risk. Offering TPT to all people at risk not only is an essential component of the end TB strategy but also is a very effective action that can contribute to the reduction of morbidity and mortality among children and adolescents. It is not an "maybe" but rather a "must." This is why strong advocacy is needed to promote the scale-up of TPT to all eligible individuals. To achieve this, countries must
 - rapidly endorse new policies on the provision of TPT and offer TPT to all children and adolescents, irrespective of age and HIV status, who are HH or close contacts of TB cases, after ruling out active TB, including contacts of DR-TB cases;
 - adapt their guidance to include shorter and newer TPT regimens, such as 3RH, 3HP, and 1HP, taking into consideration the availability of child-friendly formulations^e; and
 - approve and recommend the use of INH 100 mg DT as an important child-friendly option for the youngest children.

e Child-friendly formulations are currently available only for RH. There is no dispersible formulation for rifapentin. Currently, HP is recommended only for children older than 2; for children younger than 2, only 3RH is currently recommended as a shorter TPT regimen.



- 6. Speed up the integration of TB services into other health services. Lack of integration of TB services for children and adolescents into other services, such as PMTCT, MNCH, nutrition, and OPD general services, is a missed opportunity to timely detect children with TB and put them on appropriate treatment, preventing TB and averting the development of the most severe forms of disease. To achieve this, countries must
 - ensure the continuum of care for TB in children and adolescents across all services;
 - adapt national policies to include other aspects of integration beyond TB screening, such as diagnosis, treatment, prevention, and follow-up, based on the most appropriate model of care for the specific setting; and
 - ensure particular attention to case detection and prevention of TB in nutrition services.



- 7. Improve M&E frameworks and strategies to better inform national programs as they move toward their goals, to identify gaps and challenges, and to support the provision of quality care to patients. To achieve this, countries must
 - sustain their efforts in the field of M&E of childhood TB activities and ensure that the
 adoption of policies is accompanied by appropriate capacity building of all HCWs
 and the availability of tools at all levels of care.

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References

- World Health Organization (WHO). Global tuberculosis report 2021. https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2021 Published October 2021. Accessed October 2021.
- 2. WHO. Roadmap towards ending TB in children and adolescents. https://www.who.int/tb/
 publications/2018/tb-childhoodroadmap/en/. Published 2018. Accessed April 2021.
- United Nations General Assembly. Resolution 73/3: Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3. Published 2018. Accessed April 2021.
- 4. Marais BJ, Schaaf HS. Childhood tuberculosis: an emerging and previously neglected problem. *Infect Dis Clin North Am.* 2010;24(3):727–749. doi: 10.1016/j.idc.2010.04.004.
- 5. WHO. Roadmap for childhood tuberculosis: towards zero deaths. http://apps.who.int/ http://apps.who.int/ http://apps.who.iris/bitstream/handle/10665/89506/9789241506137_eng.pdf?sequence=1. http://apps.who.iris/bitstream/handle/10665/89506/9789241506137_eng.pdf?sequence=1. <a href="mailto:iris/bitstream/handle/1
- National Policy Assessment. Creating an Enabling Environment for Effective and Innovative Pediatric Tuberculosis Diagnostic and Treatment Interventions. EGPAF. https://www.pedaids.org/wp-content/uploads/2019/02/CaPTB_PolicyAssessmentBrief-2.pdf. Published 2018. Accessed April 2021.
- 7. Central TB Division, Ministry of Health & Family Welfare, Government of India. Operational guidelines for TB services at Ayushman Bharat Health and Wellness Centres. https://tbcindia.gov.in/showfile.php?lid=3575. Published December 2020]. Accessed April 2021.
- 8. Ministry of Health and Family Welfare, Government of India. Collaborative framework for management of tuberculosis in pregnant women. https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteReadData/
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 https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteReadData/
 https://www.tbcindia.gov.in/WriteRead
- Government of India. National TB guidelines. https://tbcindia.gov.in/index1.
 php?lang=1&level=2&sublinkid=4573&lid=3177. Published 2016. Accessed April 2021.
- 10. Patel, LN, Detjen, AK. Integration of childhood TB into guidelines for the management of acute malnutrition in high burden countries. *Public Health Action*. 2017;7(2). https://www.who.int/emergencies/kits/patel-2017-tb-in-sam-guidelines.pdf.

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