



CHILDREN AND TUBERCULOSIS

FROM NEGLECT TO ACTION

RECOMMENDATIONS ▶

A lack of political will, inadequate funding of programs and research, and failure to include children in many National Tuberculosis Programs (NTPs) are significant barriers to saving lives from childhood tuberculosis (TB). Though preventable and treatable, TB still takes the lives of 1.4 million people every year — and children remain largely unreached and uncoun- ted. The first steps to removing these barriers include prioritizing the use of available tools; integrating TB services with other health programs; and, the development of child-friendly diagnostics, drugs, and vaccines. These initial steps to achieve progress on childhood TB require:

DONOR COUNTRIES	HIGH-BURDEN COUNTRIES
<ul style="list-style-type: none"> Donor governments must address TB as part of child survival initiatives and increase funding for programs that address childhood TB, including the Global Fund to Fight AIDS, Tuberculosis and Malaria; UNITAID; and bilateral aid channels. 	<ul style="list-style-type: none"> NTPs must collect and report childhood TB data to guide the development of evidence-based policy, planning, and management.
<ul style="list-style-type: none"> Additional resources must be urgently invested to ensure the development of child-friendly diagnostics, drugs, and vaccines. 	<ul style="list-style-type: none"> Governments must increase direct funding for TB programs; train and support health workers to address childhood TB; and, integrate TB services with primary care, maternal and child health programs, and HIV services.
<ul style="list-style-type: none"> Drug developers, regulatory authorities, domestic TB programs, and donors must work together to clarify the development pathway for childhood TB drugs, address information gaps, and prioritize resources so that new treatments— and better formulations of existing treatments — can reach children as quickly as possible. 	<ul style="list-style-type: none"> Countries must address TB as part of wider poverty and child survival agendas. Increased access to proper housing, education, good nutrition, psychosocial support, and health services are necessary to combating TB and improving child survival.

Over the last few years, childhood TB has received increased attention from global health experts, yet the disease remains a major cause of illness and death for children worldwide. Children’s immune systems are not fully developed, which makes them prime targets for contracting TB. Despite the disease being preventable and treatable, the World Health Organization (WHO) estimates 490,000 children get sick with TB each year and up to 64,000 die as a result.¹ However, most experts agree these are gross underestimates. TB preys on the most vulnerable children — the poor, the malnourished, those living with HIV — and it causes an unimaginable burden to children and their families.

How big is the problem of TB among children?
Surprisingly, there is little data to answer this question. According to the WHO, approximately 8.8 million people become sick with TB each year. However, most experts estimate 10 to 15 percent of these cases occur in children — much higher than the number actually reported.^{4,5} Because children are difficult to diagnose using the standard microscope method, which is the only test available in many high-burden countries, the vast majority of childhood TB cases go unreported — making it very difficult to determine the true burden of childhood TB that exists in the world.⁶

There is currently no point-of-care diagnostic to detect TB in children or adults. Without accurate disease estimates for children, it is difficult to develop evidence-based policy, planning, and management.⁷ The WHO has called for children to be included in TB prevalence surveys, yet despite the call for more accurate reporting, few high-burden countries are tracking TB in children. While it remains difficult to get accurate reporting without a point-of-care diagnostic, it is critical that NTPs make better use of currently available tools and report all childhood cases broken down by age.

A RESEARCHER’S PERSPECTIVE ON CHILDHOOD TB: STORIES FROM ROMANIA

“TB patients frequently told me that their greatest fear is infecting their children. One man, a now deceased multi-drug resistant TB (MDR-TB) patient told me that he was ‘tormented by guilt’ because he passed the disease to his son. Parents face serious challenges in Romania because there are no resources available to help them care for their children while they are receiving treatment in the hospital or at home. Benefits like providing free preschool or kindergarten would increase treatment success rates for patients with children. Another major issue is TB disease and treatment’s interference with a child’s schooling. Because of the side-effects of TB treatment, especially for M/XDR-TB patients, children may miss significant amounts of school because the nausea, weakness, and other side-effects make it impossible for them to attend school. In one recent case, a stock-out of [anti-TB medication] in the south of the country prevented one 14 year old boy from leaving the Bucharest hospital so he could take his high school exams.”

Jonathan Stillo
PHD CANDIDATE FOR MEDICAL ANTHROPOLOGY, CITY UNIVERSITY OF NEW YORK GRADUATE CENTER

TB IS A DISEASE OF FAMILIES
Providing family-centric TB services is an opportunity to find and treat more cases of TB. When one family member gets TB, the disease can easily pass to the rest of the family, as TB germs spread from person to person through the air. Many children sleep in the same room as their parents — often in close proximity — leading many family members to become sick. Even when parents aren’t sick, they often take time off work to care for their children, resulting in loss of family income. Similarly, when parents are too sick to work their children often leave school to earn money for the family. In 2009, there were 10 million children orphaned by TB.² The high cost of health care can also force families to sell their belongings to pay for doctor’s visits, leading them into poverty. Children with TB fall behind in their education, harming their mental wellbeing along with their ability to earn good wages in the future. In many countries, women with TB are heavily stigmatized and sometimes abandoned by their families, who fear becoming infected themselves.³



SARA LIZA BAUMANN



REBECCA SULLIVAN

CHILDHOOD TB REMAINS A HIDDEN EPIDEMIC

Since September 2011 when ACTION first highlighted the issue of Childhood TB in *Children and Tuberculosis: Exposing a Hidden Epidemic*, there has been increasing discussion and awareness about this neglected killer of children, particularly at the global level. However, a lack of awareness remains a persistent and significant barrier to diagnosing children with TB. Because children on average are less contagious than adults, they've been overlooked by many NTPs. Many health care providers believe TB to be an 'adult' disease and rarely consider it as a cause of childhood illness. Additionally, because its symptoms mimic other childhood diseases such as pneumonia, TB is often overlooked or misdiagnosed.⁸ More training, supervision, and referral feedback is needed to correctly diagnose and treat these children. For example, research from Bangladesh showed that integrating childhood TB training into NTPs can improve the number of children who are properly diagnosed and treated for TB.⁹

WHILE MUCH HAS IMPROVED, MANY CHALLENGES REMAIN FOR DIAGNOSING AND TREATING CHILDHOOD TB

New technology and improved tools help detect childhood TB

The most commonly used TB diagnostic test is over 130 years old and fails to detect TB in most children, due to difficulty in coughing up sputum needed for the test. While some health centers use safe and effective methods to induce sputum samples from children, which can identify nearly a quarter more cases than using symptom screening alone,¹⁰ diagnosing children with TB can still be a challenge. Children produce fewer bacteria in their cough samples, making it much harder to detect under a microscope.

The newest TB diagnostic, GeneXpert¹¹, uses sophisticated DNA technology and delivers results in two hours instead of weeks with the old method of slides and microscopes. It can also identify possible cases of drug-resistant TB — enabling treatment to be tailored to fight TB properly, rather than making it worse or even drug-resistant. Though the test still requires a sputum sample and is not a point-of-care test, research shows GeneXpert can detect twice as many childhood TB cases than the microscope method and is recommended to diagnose TB in children living with HIV or who have possible

drug-resistance.¹² UNITAID, an international organization aimed at increasing access to TB, HIV, and malaria treatment, together with the Stop TB Partnership's TB REACH initiative, The Bill & Melinda Gates Foundation, and United States Agency for International Development (USAID), have committed \$40 million to roll-out GeneXpert in developing countries at a reduced cost.¹³ It is critical this test be used for children.

Despite this progress, most health centers still lack access to the latest technology. In these circumstances, it's best to diagnose a child based on symptoms and whether they have been in contact with an infected adult. Until recently, there was no standard guidance for diagnosing children with TB based on their symptoms. In 2011, the U.S. National Institutes of Health convened a group of experts to develop guidelines for diagnosing TB in children based on their symptoms, such as coughing or fever.¹⁴ However, many health providers are either unaware of these guidelines or lack even the most basic tools necessary to make a diagnosis. More effort should be placed on increasing access to basic diagnostics and incorporating the most recent diagnostic guidelines into NTPs.

NEW CHILD-FRIENDLY TREATMENT OPTIONS ARE URGENTLY NEEDED



GARY HAMPTON

Hampering effective treatment of children is the lack of appropriate, quality-assured pediatric TB drug formulations. Drug companies perceive pediatric TB to be a small market with little profit. As a result, children are routinely excluded from drug treatment clinical trials and few child-friendly TB drugs exist, such as liquids or chewable tablets. Children with TB are often treated using complicated mixtures of children's formulations and crushed adult tablets with estimated appropriate doses, which is difficult for caregivers to administer and runs the risk of over- or under-dosing a child.¹⁵ The medicines, especially those used to treat MDR-TB, often have terrible

side effects ranging from severe nausea to loss of hearing.¹⁶ The WHO has proposed a better way to treat children with TB using one tablet containing all medicines — a Fixed Dose Combination (FDC).¹⁷ Development of child-friendly FDCs that meet WHO guidelines is a top priority requiring urgent attention.

Other barriers, such as lack of clarity about the regulatory process for earlier testing of new drugs in children and unavailability of data about treatment practices at the country level, further complicate drug development and discourage potential manufacturers. Furthermore, little has been invested in

the development of pediatric treatments by international donors. Drug developers, regulatory authorities, country TB programs, and donors need to work together to clarify the development pathway, address information gaps, and prioritize resources so that new treatments — and better formulations of existing treatments — can reach children as quickly as possible.

More lives can be saved with currently available treatment

While eagerly awaiting the development of new treatments for childhood TB, hundreds of thousands of children's lives can be saved with the medicines we currently have. With the support of USAID, Cambodia has made great progress treating children and expanding access to childhood TB services in 17 districts.¹⁸ Children tend to respond well to treatment, including treatment of MDR-TB. Due to uncertainties about diagnosis and the concern of toxic effects of treatment, many health care providers are reluctant to treat children with MDR-TB. However, studies show that when children are treated the outcomes are at least as good as for adults, especially when delivered through community-based programs.^{19,20} The Global Fund to Fight AIDS, Tuberculosis and Malaria, together with UNITAID, are supporting access to child-friendly TB medicine.²¹ It is essential that donor governments continue to support these institutions and NTPs implement the latest WHO childhood treatment guidelines to ensure children with TB are properly treated.

THE PIPELINE ► CHILDHOOD TB DIAGNOSTICS

Challenge No point-of-care TB test currently exists and current diagnostics require sputum samples, which are difficult for children to produce.

Opportunity It is essential to invest in research to develop a TB test that is simple, accurate, uses a non-sputum sample such as blood or urine, and produces results on the spot.

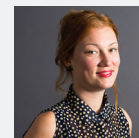
“Finding and treating children who are exposed to or infected with tuberculosis is both cost-effective and morally necessary.”



Jeffrey R. Starke, M.D.

PROFESSOR OF PEDIATRICS — BAYLOR COLLEGE OF MEDICINE,
DIRECTOR OF INFECTION CONTROL — TEXAS CHILDREN'S HOSPITAL,
DIRECTOR OF THE TUBERCULOSIS INITIATIVE OF THE TEXAS
CHILDREN'S CENTER FOR GLOBAL HEALTH

“In the European Union and worldwide we need tuberculosis treatment options specifically for children. Investing in new tools for childhood TB must become a global health R&D priority for European decision-makers in order to eliminate TB as one of the top ten killers of children worldwide.”



Fanny Voitzwinkler

GLOBAL HEALTH ADVOCATES
FRANCE AND TB EUROPE COALITION,
ACTION PARTNER

THE PIPELINE ► CHILDHOOD TB DRUGS

Challenge No child-specific TB drugs meet WHO's specified guidelines for a childhood FDC.

Opportunity Drug developers, regulatory authorities, and donors must work together to clarify the development pathway, address information gaps, and prioritize resources for new child-friendly TB treatments.

DRUG-RESISTANT TB IN CHILDREN: A STORY FROM INDIA

Akash and Praveen* are siblings from a small village in Northern India. Their parents, Meenu and Gyanchnad, own a vegetable store. One day they noticed their children had a cough that would not go away. Worried, Meenu and Gyanchnad took their children to the neighborhood doctor, who was unable to figure out what was wrong. Throughout the following year they visited multiple health clinics before bringing their children to a hospital in Delhi where they were finally diagnosed with extensively drug-resistant TB (XDR-TB), a form of TB that is resistant to most anti-TB medicine.

The family faced multiple hurdles getting their children properly diagnosed and treated. Most health facilities lack the necessary tools to diagnose XDR-TB. Moreover, treatment was extremely expensive and required hospitalization. While the National TB Program provides most medicine for free, medicine to treat XDR-TB is not always covered. Global Health Advocates India, an ACTION partner, took up the matter with the government to provide access to free medicines through the government. Although the cost of medicine was eventually covered, Meenu and Gyanchnad were forced to mortgage their home to pay for their children's hospital stay. In addition to the economic burden, the family faced intense stigma, which caused Akash and Praveen to be expelled from school. Meenu and Gyanchnad were afraid to tell their family and friends about the situation for fear that the stigma of XDR-TB would affect Akash and Praveen's future opportunities.

Today, Akash and Praveen are on the road to recovery. However, the family wishes the children were diagnosed and treated earlier. They believe the National TB Program needs to prioritize childhood TB, including drug-resistant TB, in order to increase access to diagnosis and treatment.

*ALL NAMES HAVE CHANGED
TO MAINTAIN CONFIDENTIALITY



REBECCA SULLIVAN

PREVENTING TB IN CHILDREN

A new vaccine is critical to combating childhood TB

The only TB vaccine that exists, called the Bacille Calmette-Guérin (BCG) vaccine, was invented in 1921. In most of the world, BCG vaccine is given at birth to help protect young children against the most severe forms of TB, including TB meningitis. However, BCG fails to protect children and adults against the most common form of the disease, TB of the lungs. WHO recommends that all children who live in countries with high TB rates receive the immunization, and saving even a small percentage of children with this vaccine is an unmitigated success. Unfortunately, as children grow older the effect of the vaccine wears off. Furthermore, children with HIV

are unable to receive BCG vaccine because it can make them sick.²²

Scientists are working on developing a new vaccine that addresses these shortcomings. A dozen vaccine candidates are currently undergoing clinical trials. The most advanced candidates are in proof-of-concept clinical trials. Results from the first proof-of-concept study of a preventable TB vaccine, which enrolled nearly 3,000 infants in South Africa, are expected in early 2013.²³ If proven effective, the vaccines will advance to the final trial stage, which is estimated to cost \$100-\$150 million.²⁴ Collaboration among the public and private sectors is urgently necessary to ensure adequate investment to develop and roll out a new TB vaccine.

THE PIPELINE ▶ CHILDHOOD TB VACCINES

Challenge Currently, there is no safe, effective vaccine to protect children from all forms of TB.

Opportunity Advanced vaccine candidates are currently in clinical trials for proof-of concept. Additional funding is needed to advance the vaccines to the final trial stage.

Prevention: The Three I's

It is more cost effective to prevent disease than it is to treat it. The most effective way to prevent childhood TB is to stop the disease from spreading. This is achieved by what is commonly referred to as the *Three I's* — intensified case finding, isoniazid preventive therapy, and infection control.

▶ **Intensified case finding:** Finding and treating adults with TB is not enough to help children. When an adult is diagnosed with TB, all close contacts and family members — including children — should be screened and, if symptomatic, provided appropriate diagnosis and treatment. Additionally, children at high risk of TB, including those living with HIV, should be routinely screened. A large proportion of childhood TB cases could be prevented by treating infected children discovered during case finding.

▶ **Isoniazid preventive therapy (IPT):** All asymptomatic children exposed to an adult with TB should be provided IPT, which prevents infection from developing into active disease. IPT is especially important for children diagnosed with HIV. Together with antiretroviral medication (ART), providing IPT makes children living with HIV 90 percent less likely to develop active TB.²⁵

▶ **Infection control:** It is likely that TB is spread within many health care facilities in high-burden areas. Therefore, it is extremely important that health facilities, homes, schools, and other community settings need to be made safe from TB. Simple measures such as separating patients who are coughing, providing masks, and opening windows and doors to establish natural ventilation can prevent the spread of disease.²⁶

These methods are very effective at reducing childhood TB and are endorsed by the WHO. A recent study from Zambia and South Africa found children living in communities that engaged in intensified case finding were 50 percent less likely to become infected with TB.²⁷ Unfortunately, many countries with constrained resources don't follow these methods. Increased resources, training, and health care workers are needed to make TB prevention a reality. Donor governments should continue to invest in TB treatment and prevention programs through bilateral TB programs; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and UNITAID. High-burden countries must also increase national TB budgets and consider alternate funding revenues to fund TB services, such as a national tobacco tax or other taxes.

THE FOURTH I: INTEGRATION

Integration of TB services — often referred to as the *'fourth I'* — is central to tackling HIV and improving maternal and child health. HIV weakens the immune system, making a person vulnerable to TB. Nearly half of new childhood TB cases occur in children with HIV; TB remains the third leading killer of children with AIDS.²⁸ Historically, TB prevention, treatment, and diagnosis have not been included with other child health services. To ensure more children receive TB services, the following must be implemented:

▶ Health care workers must be trained and supported to address childhood TB and TB services must be incorporated into the Integrated Management of Childhood Illnesses (IMCI), a broad child health strategy that includes multiple interventions at health facilities and in communities.

▶ TB services should be incorporated with maternal health care and the prevention of mother-to-child transmission of HIV (PMTCT). The WHO and the President's Emergency Plan for AIDS Relief (PEPFAR) recommend screening all pregnant women with HIV for TB, as pregnant women with TB are 2.5 times more likely to pass on HIV to their unborn child.^{29,30,31}

▶ Because children with HIV are at high risk of developing TB — up to 20 times more likely than children with healthy immune systems³² — it is imperative that all children with HIV are screened for TB at every health care visit, and that all children with TB are screened for HIV.

▶ Once diagnosed, children living with HIV should be placed on ART immediately. Early initiation of ART is the single most important intervention for reducing overall mortality and the risk of TB among HIV-infected infants, reducing the chances of getting TB by 70 percent.^{33,34}

▶ When children are diagnosed with TB and HIV at the same time, the WHO recommends they be given both TB and HIV medication.³⁵

“The Ministry of Health needs to increase contact tracing for adults with TB. It's the best way to find children who have been exposed — and it's not happening enough.”



Evaline Kibuchi

KENYA NATIONAL AIDS NGOs
CONSORTIUM (KANCO),
ACTION PARTNER

A MOTHER’S STRUGGLE TO SAVE HER SON:
A STORY FROM SWAZILAND

When Sipho* was eighteen months old, he began coughing and his feet began to swell. His mother, Masia, brought Sipho to a clinic where he was given a chest X-ray. The health workers did not find any signs of TB and sent him home with medicine for a common cold. When Sipho did not get better, Masia traveled to a hospital in Mbabane. This time, Sipho’s X-ray indicated that he had TB. He began treatment at the hospital in Mbabane, where he stayed for two months before being transferred to a hospital closer to home.

Despite completing six months of treatment, Sipho remained ill. Worried, Masia went back to the local hospital where Sipho was diagnosed with MDR-TB after doctors tested a sputum sample. He began treatment, which included a combination of daily injections and pills that were crushed and put in water. Every day for six months Masia traveled with Sipho six kilometers over hills and on dirt roads so he could receive the injections. “The main challenge was paying for transport,” said Masia. “The bus was too far from the clinic so we had to take a kombi [taxi], which was more expensive.”

Masia did not have a job, and the family had difficulty finding enough food for Sipho to take with the medicine. “It’s hard to make a living when you have to spend more than a year and a half in the hospital,” she explained. Masia believes food should be included with TB treatment, as well as support for families to generate income.

*ALL NAMES HAVE CHANGED
TO MAINTAIN CONFIDENTIALITY

IN ORDER TO END
CHILDHOOD TB, WE MUST
ADDRESS POVERTY

Health is intricately related to the cycle of poverty. Poverty is a main risk factor for TB, and TB is a major driver of poverty. Children living in poverty are more likely to be malnourished, lack access to medical care, and live in overcrowded homes with little ventilation — all of which place them at higher risk of acquiring TB.³⁶ People living in impoverished conditions often cook indoors, exposing themselves and their children to smoke, which weakens the lungs and makes children more vulnerable to TB.³⁷

Education, nutritional support, and transportation are important tools for fighting both poverty and TB. A study in Bangladesh found that children who completed primary school were three times less likely to develop TB.³⁸ Children living in poverty lack access to adequate or timely health care due to geographic isolation, lack of transportation, and the cost of seeking care. These barriers prevent children and families from accessing life-saving health services. Children with TB need more calories and nutrition in their diet,³⁹ however children living in poverty suffer from malnutrition, not only leaving them vulnerable to TB, but also making treatment and care more difficult. Insufficient nutrition makes it painful and difficult for children to take their medicines and can cause them



MANDY SLUTSKER

to forgo treatment.⁴⁰ Food support and transportation should be made an integral part of TB care in children and not just seen as an optional “enabler” or “incentive.”

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“Childhood TB is all about money —
who doesn’t have it, who wants it,
and who is unable to provide it.”



Jennifer Furin, MD, PhD
ASSISTANT PROFESSOR, TB RESEARCH UNIT,
CASE WESTERN RESERVE UNIVERSITY.



RESULTS CANADA
OTTAWA, CANADA
RESULTS Canada is a nonprofit grassroots advocacy organization, committed to creating the political will to end the worst aspects of poverty through education, public events, media coverage, educational trips, and research.

RESULTS EDUCATIONAL FUND
WASHINGTON, DC
RESULTS Educational Fund creates long-term solutions to poverty by supporting programs that address its root causes — lack of access to medical care, education, or opportunity to move up the economic ladder.

AIDES
PARIS, FRANCE
Established in 1984, AIDES is the leading HIV/AIDS organization in France with 1,200 activists.

RESULTS UK
LONDON, UNITED KINGDOM
RESULTS UK is a nonprofit grassroots advocacy organization, committed to creating the political will to end the worst aspects of poverty through education, public events, media coverage, educational trips, and research.

GLOBAL HEALTH ADVOCATES FRANCE
FRANCE
Established in September 2001 in Switzerland (and officially registered in France since 2008), Global Health Advocates functions as a network of professionals from the NGO community focusing its activities in the areas of global health advocacy and partnership building in France and also at European Union level in Brussels.

GLOBAL HEALTH ADVOCATES INDIA
INDIA
Established in September 2001, Global Health Advocates functions as a network of professionals from the private sector and NGO community focusing its activities in the areas of global advocacy and partnership building.

KANCO
NAIROBI, KENYA
The Kenya AIDS NGOs Consortium (KANCO) is a national membership network of NGOs, CBOs, and FBOs, Private Sector actors and Research and Learning Institutions involved in or that have interest in HIV & AIDS and TB activities in Kenya.

CITAM+
LUSAKA, ZAMBIA
Community Initiative for Tuberculosis, HIV/AIDS and Malaria plus related diseases (CITAM+) is a local Zambian NGO.

RESULTS JAPAN
TOKYO, JAPAN
RESULTS Japan is a nonprofit grassroots advocacy organization, committed to creating the political will to end the worst aspects of poverty through education, public events, media coverage, educational trips, and research.

RESULTS AUSTRALIA
COLLAROY PLATEAU, AUSTRALIA
RESULTS Australia is a nonprofit grassroots advocacy organization, committed to creating the political will to end the worst aspects of poverty through education, public events, media coverage, educational trips, and research.

ACKNOWLEDGEMENTS

The lead author of this brief was Mandy Slutsker. This work would not have been possible without the insight and experience of ACTION partners in Australia, Canada, the E.U., France, India, Japan, Kenya, U.S., U.K., and Zambia. Particular thanks to Kate Finch, David Bryden, Fanny Voitzwinkler, Shibu Vijayan, Niya Chari, Evaline Kibuchi, Jessica Kuehne, Aparna Barua, and Yuko Niizato. Additional gratitude to Kirby Tyrrell, Laura Martin, Victoria Treland, and Blair Hinderliter, ACTION; Heather Ignatius, TB Alliance; Jennifer Woolley, Aeras; Erica Lessem, Treatment ACTION Group; Grania Brigden, Médecins Sans Frontières; Dr. Jeffrey Starke, Texas Children’s Hospital; Dr. Jennifer Furin, Case Western Reserve University; Christine Lubinski, Infectious Diseases Society of America; Dr. Sharon Nachman, Stony Brook University Medical Center; Ellen Mitchell, KNCV; Jonathan Stillo, PhD Candidate, CUNY Graduate Center; Dr Katherine Floyd, Stop TB Department, World Health Organization; Dr. Malgosia Grzemska, Stop TB Department, World Health Organization; Dr. Ben Marais, Sydney Medical School; Michael Odey Odo, FHI Nigeria; and, Dr. Steve Graham, Royal Children’s Hospital Melbourne, for their expertise, commitment, and partnership.

We continue the fight against TB together. // Kolleen Bouchane, ACTION Director



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