# Consolidated report of country success stories in mitigating the impact of the COVID-19 pandemic on TB services



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## Impact of the COVID-19 pandemic on the TB response

The response to the COVID-19 pandemic continues to adversely affect essential tuberculosis (TB) services in many countries. Data reported to WHO by Member States show a sharp, unprecedented fall in the global number of TB case notifications between 2019 and 2020 (from 7.1 million to 5.8 million), with the largest reductions in the South-East Asia and the Western Pacific regions (1). Globally, deaths from TB increased from 1.4 million to 1.5 million in 2020. Other impacts include a downturn in the number of people initiated on TB preventive treatment (from 3.6 million to 2.8 million), a reduction in spending on TB services (from US\$ 5.8 billion to US\$ 5.3 billion), a 15% decrease in the number of people provided with treatment for drug-resistant TB and a reduction in coverage of the bacille Calmette-Guérin vaccine (5% or more in 31 countries). Provisional data show a sustained reduction in global TB notifications through 2021 when compared with 2019 levels in many countries (2).

WHO has undertaken model projections to forecast the further impact of the pandemic on TB services (1). Modelling of TB incidence and mortality in 16 countries with high TB burdens between 2021 and 2025 indicated a further increase in TB mortality in 2021 and an increase in TB incidence in 2022, consistent with earlier projections (3–6). Socioeconomic shocks and widening inequity as a result of the pandemic are also anticipated to drive the determinants of TB, such as poverty and undernutrition, resulting in further disease incidence among infected individuals.

## WHO's response to improve TB prevention and care during the pandemic

WHO is working across all three levels of the Organization with partners and countries to mitigate the pandemic's impact on TB services. These include by

- monitoring the impact of the COVID-19 response on TB notification monthly in over 100 countries to provide country-specific guidance and technical assistance;
- issuing guidance on maintaining TB services in the context of the COVID-19 pandemic. The advice on this guidance includes maximizing remote care and support for people with TB through digital technologies; improving the use of WHO-recommended all-oral TB treatment regimens and community-based care to reduce health care facility visits; and providing simultaneous testing for TB and COVID-19 for individuals when indicated; and
- sharing case studies of programmatic innovations to address emerging challenges in TB prevention and care in the context of the pandemic.

Other sources of information about the impact of the COVID-19 pandemic on TB include a review of data published between January 2020 and March 2021 (7), a study of changes in TB services provided in 19 countries between 2019 and 2020 (8) and a compendium of research studies related to TB and COVID-19 (9). Content related to TB is also included in WHO guidance on maintaining essential health services and the role of community-based care during the COVID-19 pandemic (10, 11). An evidence review of the impact of COVID-19 on TB is under way (12), and WHO is promoting a standardized collection of data on dual testing for TB and SARS-CoV-2 ("bidirectional screening")(13).

WHO urges countries to try to restore access to and provision of essential TB services such that levels of TB case detection recover to at least pre-pandemic levels.

## **Country interventions to restore TB services**

National TB programmes, with support from partners, have been innovating to rebound from temporary setbacks due to the pandemic. WHO has been compiling case studies of innovative responses that have succeeded in mitigating or reversing negative impacts of the pandemic to provide examples for affected countries. A first report comprising 23 case studies from all six WHO regions was published in May 2021(9). The report was disseminated widely with countries and partners, and a request to compile additional best practices was made by National TB Programmes from high-TB burden countries as well as funders. WHO subsequently issued a second call for case studies to collect additional lessons in August 2021–February 2022 (14). This report summarizes the findings from both calls for case studies in order to disseminate best practices that have been successful in overcoming disruptions to TB service. The audience of this report are national TB programmes, partners, funders, civil society organizations, as well as the private sector engaged in TB response at country level.

### Methods

In response to the two open calls for case studies between November 2020 and February 2022, 42 submissions from 21 countries were received. A panel of at least two experts reviewed each case study. The main criteria for selection were relevance to the topic of the call, interventions to address challenges to TB services due to the COVID-19 pandemic; evidence that the intervention has had a measurable impact on service provision and health outcomes or is projected to yield results soon; and evidence that the intervention could be duplicated in other geographical contexts or other population groups. According to these criteria, 29 case studies (70% of submissions) from 20 countries in the six regions of WHO were selected; 23 were published in the first report (9), and six are included in the present report. The implementers of the interventions worked in all sectors, from nongovernmental organizations (50%) to public agencies (39%) and universities (11%).

All the studies were reported directly by countries or institutions. For the present report, relevant national health authorities were invited to comment on the submissions. WHO was not involved in the design, financing or implementation of the initiatives, nor did it undertake independent validation of the reported findings. The studies are presented below in alphabetical order by country name; the person responsible for each case study is identified by name.

### **Findings**

Six new case studies collected between August 2021 and February 2022 are included in this report (Annex). The scope of the new case studies is narrower than that of the first reports and focused more on operationalization of dual testing for TB and SARS-CoV-2 ("bidirectional screening") or using COVID-19 vaccination programmes to screen for TB, sustaining real-time surveillance to improve TB detection and digital interventions to support treatment adherence and reduce health facility visits.

All the case studies in the current and the previous report are summarized in Table 1. Together, they demonstrate diverse interventions to address country-specific challenges, with some common themes. For example, half of the studies involve application of digital technology to

facilitate health-care provision; others report real-time surveillance to monitor and respond rapidly to the impacts of the pandemic (17%); and some address socioeconomic determinants or the consequences of TB (14%).

In the context of the cascade of care, more than half of the case studies reported on finding people with TB and improving treatment initiation and adherence. At least three studies showed that dual testing for TB and SARS-CoV-2 was feasible, with varying yields, depending on the target population, site and screening strategy. The prioritization of screening and diagnostic testing is not surprising, as many countries are experiencing significant decreases in the numbers of people with newly diagnosed with TB and reported, as a result of disruptions to TB services. Application of successful, feasible strategies to improve detection, initiation of care and reporting of cases of TB is imperative to reverse this impact.

Country	Digital health	Prevention	Screening and	Treatment	Socio- economic	Monitoring and	Training of health-care	Other
			diagnosis		support	evaluation	staff	
Brazil (1)	Х			Х				
Brazil (2)	Х			Х				
Colombia							Х	
Dominican Republic	х					х		
Ethiopia	Х		Х	Х				
Guatemala	Х							
India (1)	Х		Х	Х				
India (2)	Х		Х	Х	Х			Х
India (3)		Х	Х					
India (4)	Х	Х	Х	Х		Х		Х
Kenya, Malawi, Zimbabwe			x	x		x		
Mozambique	Х	Х	Х					
Myanmar					Х			
Nigeria			Х	Х				
Pakistan	Х	Х	Х	Х		Х		
Paraguay							Х	
Philippines (1)	х			х				
Philippines (2)			х					
Philippines (3)			x					

#### Table 1. Consolidated list of case studies organized by theme

Philippines (4)			х					
Russian Federation		х	х	х				
South Africa		Х		Х	Х			
Uganda (1)	Х			Х				
Uganda (2)	Х	Х		Х	Х			Х
Ukraine							Х	Х
Uruguay (1)	Х			Х				
Uruguay (2)	Х						Х	
Zambia						Х		

## **Conclusions**

The case studies reported below and those published in 2021 show that, faced with a crisis, countries have adopted innovative interventions to maintain and improve TB service provision. The studies further demonstrate the significant power of digital innovations, community engagement, public–private partnerships and intersectoral approaches to enhance health-care delivery in a crisis. Countries and partners should continue to conduct research in TB care delivery and document and publish what works and what does not work to optimize and scale up impactful innovations. Beyond TB, lessons learnt in finding innovative interventions to reach vulnerable populations can support efforts to achieve universal health coverage and the Sustainable Development Goals.

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## Annex. Case studies submitted between August 2021 and February 2022

Impact of COVID-19 on TB services: a real-time public health surveillance project in three African countries (Kenya, Malawi, Zimbabwe)

#### 1.1 Contact person

Anthony David Harries

#### 1.2 Thematic areas

Treatment Screening and diagnosis Monitoring and evaluation

#### 1.3 Background of the project

This is a follow-up to a case report previously provided to WHO. The aim was to determine whether the impact of COVID-19 on TB case detection and TB treatment outcomes could be mitigated by strengthening real-time monthly surveillance in selected health facilities in Nairobi (Kenya), Lilongwe (Malawi) and Harare (Zimbabwe). The specific objective was to collect aggregate monthly data on cases of presumptive pulmonary TB, registered TB (all types) and TB treatment outcomes during the COVID-19 period (March 2020 to February 2021) and compare them with aggregate monthly data on the same parameters collected during the pre-COVID-19 period (March 2019 to February 2020).

#### 1.4 Intervention and methods

We selected 18 health facilities in Nairobi (Kenya), 8 in Lilongwe and 10 in Harare. We worked with the national TB programmes to collect and validate data for the previous month from the selected health facilities each month with an EpiCollect5 application. The TB treatment outcomes of monthly cohorts of patients enrolled on treatment 8 months previously were used. At the time of collection of prospective monthly data, the same procedures were used to collect retrospective data for the pre-COVID-19 period. Monthly reports, including a narrative explaining changes and observed interventions, were prepared and shared each month with the national authorities.

#### 1.5 Results

The overall numbers of people presenting with presumptive pulmonary TB decreased, ranging from 31% decrease in Kenya to 46% decrease in Malawi. registered for TB in each country showed parallel decreases. After the initial lockdown, which lasted several months, measures to improve TB case detection were implemented. As a result, the decreases in TB case detection were far less in Kenya and Malawi in the second 6 months of the COVID-19 period (September 2020–

February 2021) than in the first months (March 2020–August 2020). Zimbabwe, however, continued to see reductions in TB case finding, largely due to widespread health sector industrial action and stock-outs of TB diagnostic reagents. In all three countries, TB treatment success was less severely affected with Kenya seeing a slight improvement in the COVID-19 period compared with the pre-COVID-19 period. The key determinant impacting on TB treatment success was the category "not evaluated" and this was potentially correctable.

#### 1.6 Timeline and funding source

Start date: 1 May 2020

End date: 31 March 2021

Funding source: The research was funded by Bloomberg Philanthropies through a grant with Vital Strategies and the Resolve to Save Lives Initiative, New York City (NY), USA

#### **1.7 Additional Information**

Explanations of the study observations and of the interventions used in the two countries to counteract the negative impact of COVID-19 are provided in published papers in *Tropical Medicine and Infectious Disease (15–17)*. Key actions to improve case detection included active case finding and contact tracing, and actions to improve treatment success included minimizing the category "not evaluated". Data collection was led and monitored by national coordinators engaged for the study, who worked with a central monitoring and evaluation coordinator at the International Union Against Tuberculosis and Lung Disease in preparing monthly reports. In brief, 2 weeks after the end of each month, data on TB case finding and treatment outcomes were collated, validated and presented in a monthly report as a series of figures, tables and narratives. These were sent to the TB programme directors, usually within 1 week of collating the data, and shared with the study sites as well as the other stakeholders involved in the project. The TB programme directors reviewed the monthly surveillance reports, which they received within 4 weeks of the end of the month, and used the data to make decisions. Cause and effect are difficult to distinguish from a study such as this; however, it is likely that timely access to data helped the programmes to maintain services during this challenging time.

### Dual testing for TB and SARS-CoV-2 in Manila (Philippines)

#### 2.1 Contact person

Mary Rosary Santiago

#### 2.2 Thematic area

Screening and diagnosis

#### 2.3 Background of the project

COVID-19 has greatly affected the provision of TB services, including screening and testing. In this initiative, screening and testing for TB disease were conducted in three COVID-19 facilities

in Manila (COVID-19 swabbing and isolation areas of Delpan Evacuation Center and Santa Ana Hospital and the COVID-19 isolation wards of the Manila COVID-19 Field Hospital) to improve efficient, safe specimen referral transport, thus increasing TB testing and notification and ensuring prompt treatment initiation for people with bacteriologically confirmed TB.

### 2.4 Intervention and methods

In the swabbing areas, people being tested for COVID-19 are initially screened for the presence of respiratory symptoms (cough, fever, dyspnoea), regardless of duration. If no respiratory symptoms are present, chest radiography is offered in a mobile van equipped with computer-aided detection software to identify abnormalities associated with TB. Sputum was collected for TB testing from people with respiratory symptoms and/or chest radiography findings suggestive of TB. In the isolation wards, individuals with confirmed COVID-19 are offered screening for TB with Xpert MTB/RIF testing, regardless of signs and symptoms. Data are recorded in the project-specific database with real-time daily updating. Key indicators are monitored regularly (Table A1).

#### 2.5 Results

Screening was offered when it was medically feasible and with consent. The main reason people gave for refusing screening was fear of exposure to SARS-CoV-2 and perception of low risk for TB. Preliminary data from 25 August–30 September 2021 showed a total of 1510 people screened for TB (1106 in swabbing areas and 404 in isolation wards) among 5818 people served in the three COVID-19 health facilities. Among these, 647 sputum samples were collected and tested with Xpert MTB/RIF, and bacteriologically confirmed TB was diagnosed in 16 people (12 males, 4 females), five of whom were from the isolation areas. Rifampicin-resistant TB was not found. The number of people to be screened in order to find one bacteriologically confirmed TB case was 94 (yield of 1.1% among those consenting to screening). The final analysis of results is scheduled in 6 months.

#### 2.6 Timeline and funding source

Start date: 25 August 2021

End date: 31 March 2022

Funding source: United States Agency for International Development (USAID) through the TB Innovations and Health Systems Strengthening project managed by FHI360

### 2.7 Additional information

Regular on-site and remote joint monitoring are being conducted within the USAID TB Innovations and Health Systems Strengthening Project, Manila Health Department, National TB Programme and other stakeholders. TB notification is managed through the National TB Programme's Integrated TB Information System.

Table A1. Indicators used for monitoring systematic TB screening in swabbing facilities and isolation centres

Swabbing facilities					
Indicator	No. of people				
No. of people served in the swabbing area	4865				
No of people who consented to screening	1106				
No. of people screened with any respiratory signs or symptoms (cough, fever, dyspnoea), regardless of duration	1106				
No pf people screened by chest X-ray with computer-aided detection	977				
No. of people with presumptive TB	251				
<ul> <li>Presence of any respiratory sign or symptom</li> </ul>	206				
<ul> <li>By chest-X-ray with computer-aided detection</li> </ul>	45				
No. of people who submitted sputum specimen for TB testing	244				
No. of people tested by Xpert MTB/RIF	244				
No. of people with bacteriologically confirmed TB	11				

Isolation facilities						
Indicator	No. of people					
No. of people with confirmed COVID-19 admitted to the health facility	953					
No. of people who consented to Xpert MTB/RIF testing	404					
No. of people who submitted a sputum specimen for TB testing	403					
No. of people tested by Xpert MTB/RIF	403					
No. of people with bacteriologically confirmed TB	5					

## Integration of TB screening into COVID-19 vaccination activities (Philippines)

## 3.1 Contact person

Christine Joy Candari

### 3.2 Thematic area

Screening and diagnosis

#### 3.3 Background of the project

The COVID-19 pandemic has disrupted the provision and demand of TB services in the Philippines. The country's case notification rate decreased from 70% of estimated cases in 2019 to 45% in 2020. Three large regions that account for 40% of all TB cases (regions 3, 4A and National Capital Region) reported 127 113 TB cases, representing 49% of all estimated cases. To improve the number of people with TB diagnosed and reported, USAID's TB Platforms for Sustainable Detection, Care and Treatment Project supported 16 sites in resuming TB case-finding during the pandemic, by integrating TB screening into COVID-19 vaccination activities in the three regions. TB screening activities were undertaken in tandem with COVID-19 vaccination events between May and September 2021.

#### 3.4 Intervention and methods

Guidance from the Department of Health National Adaptive Plan on TB case-finding strategies during the pandemic was used. In compliance with national guidelines, symptom-based screening and chest radiography were offered on an optional basis to priority groups receiving COVID-19 vaccination. These groups included health-care workers, the elderly, people with comorbid conditions, indigenous populations and front-line personnel in essential sectors. TB screening was offered after vaccination. Sputum was collected from people presumed to have TB, and those diagnosed with TB were enrolled on treatment. The impact was assessed by descriptive analysis of the care cascade, including a comparative analysis of the present integrated model with TB-focused case-finding.

#### 3.5 Results

In total, 21 304 vaccinees were screened for TB by symptoms and chest radiography, of whom 1365 (6%) were presumed to have TB. A total of 915 (67%) vaccinees with presumptive TB were tested with Xpert MTB/RIF®, of whom 259 were diagnosed with TB and enrolled on treatment; the remaining 450 people refused consent to give a sputum sample. To find one person with TB (including bacteriologically confirmed and clinically diagnosed), 82 people had to be screened. The yield from this integrated activity in this population was comparable to that from TB-focused active case-finding and is considered a viable option, especially by local governments keen on efficient use of resources. This activity provided evidence for the development of local guidelines for adaptive TB case-finding during COVID-19 vaccination.

### 3.6 Timeline and funding source

Start date: May 2021

End date: September 2021

Funding source: USAID's TB Platforms for Sustainable Detection, Care and Treatment Project

### **3.7 Additional Information**

The proportion of vaccinated people who were screened for TB varied widely between urban and rural regions (20% in the urban National Capital Region vs 70–90% in rural regions 3 and

4A). Despite the disparity, more vaccinated people in urban areas were screened than in rural areas, given the better availability of vaccines in the National Capital Region. The lower uptake of TB screening in the National Capital Region could be due to poor health-seeking behaviour. For instance, many urban dwellers were only interested in being vaccinated and did not want to linger for fear of exposure to SARS-CoV-2. Many thought that chest radiography was hazardous. There was still stigmatization of TB, and many people were concerned about being associated with the disease. A large proportion of urban dwellers working in the formal sector had employment-related chest radiography before returning to work, adding to the low uptake of this service at vaccination sites.

Compliance with TB screening tended to be low, given that it was optional and provision of other services was not conditional on being screened. Accordingly, USAID's TB Platforms recommends intensive social preparation, both before and during the activity, to address these challenges. The collective testing rate of 67% was due mainly to the ready availability of Xpert MTB/RIF in the National Capital Region. The testing rates were lower in regions 3 and 4A, where the availability of Xpert MTB/RIF remains limited. Ensuring that people with presumptive TB were linked to the necessary services was human resource-intensive. A "one-stop shop" model is ideal, with all TB services, from screening to testing, diagnosis and treatment, are available on site, which reduces patient loss along the care cascade.

## Integration of TB screening with COVID-19 swabbing activities (Philippines)

#### 4.1 Contact person

Christine Joy Candari

#### 4.2 Thematic area

Screening and diagnosis

#### 4.3 Background of the project

The COVID-19 pandemic has severely affected the number of people diagnosed with TB in the Philippines. Notification of estimated TB cases dropped from 70% in 2019 to 45% in 2020. To improve TB case-finding, USAID's TB Platforms for Sustainable Detection, Care and Treatment Project supported three cities in the National Capital Region to resume TB case-finding by integrating TB screening into swabbing activities for COVID-19. TB screening activities were undertaken in tandem with COVID-19 swabbing events October and December 2020.

#### 4.4 Intervention and methods

We were guided by the Department of Health National Adaptive Plan, which provided guidelines on case-finding during the pandemic. All patients presenting for SARS-CoV-2 testing were also offered TB screening. Populations at risk for COVID-19, including public transport operators, factory workers, vendors, government workers and senior citizens, were swabbed and assessed for TB by symptom surveillance and chest radiography. Sputum from individuals presumed to have TB were collected and tested by GeneXpert, and those with a positive diagnosis were enrolled in treatment. The impact was assessed by comparative analysis with TB-focused casefinding (active case finding).

#### 4.5 Results

A total of 2495 individuals were tested for SARS-CoV-2 and TB. Of these, 401 were presumed to have TB. All were tested with GeneXpert, of whom 88 (4%) tested positive for TB. TB case-finding during COVID-19 screening yielded a higher rate of case-finding (1 person diagnosed for every 28 people screened bacteriologically or clinically) than active TB case finding (1 person diagnosed for every 59 people screened).

#### 4.6 Timeline and funding source

Start date: 1 October 2020

End date: 30 December 2020

Funding source: USAID TB Platforms for Sustainable Detection, Care and Treatment Project

### 4.7 Additional information

The success of this intervention can be attributed to the availability of TB services at sites, such as a facility for sputum collection and a medical technologist. When a sputum collection service was not available, trained community health workers visited people presumed to have TB at home to collect samples. The availability of chest X-ray wet film-reading at most sites ensured rapid identification of people with presumptive TB. In terms of challenges, we had less community participation than envisaged. Intensive social preparation activities before and during the activity, with messages to address community members' concerns, such as fear of contracting COVID-19 from health workers, might improve their engagement. The availability of swabbing kits was limited during the activity, thus limiting the number of people who could be screened for both COVID-19 and TB. Engagement of other sectors such as the private sector, nongovernmental organization and civil society will be necessary to mobilize resources and leverage the opportunities offered by COVID-19-related activities to increase TB detection.

## Supervision of TB treatment during the COVID-19 pandemic: Role of 99DOTS (Uganda)

#### 5.1 Contact person

Alex Kityamuwesi

#### 5.2 Thematic areas

Treatment Digital health

#### 5.3 Background of the project

99DOTS is a low-cost digital technology for adherence that could improve adherence to and completion of TB treatment. It involves inserting a TB medication blister pack into a customized envelope with hidden toll-free numbers. Patients receive daily dosing reminders by text message and are instructed to call the number revealed when the pills are pushed out of the blister pack. The calls are logged as consumed medication on the 99DOTS server, and providers can view the adherence histories for individual patients with a smartphone application. In a stepped-wedge randomized trial completed before the COVID-19 pandemic in which 52% of patients were enrolled on 99DOTS, their treatment outcomes improved (*18*). Another study, however, showed that patients found difficulty in maintaining engagement with 99DOTS records to identify nonadherence(*19*). We describe a project to scale up use of 99DOTS at 30 health facilities in Uganda during the COVID-19 pandemic and specific interventions to increase patient and health worker engagement with the technology.

### 5.4 Intervention and methods

During the COVID-19 pandemic, we trained 227 health workers in 17 districts of Uganda to counsel, register and monitor TB patients in use of 99DOTS. The intervention was refined by providing low-cost phones to patients without access, simplifying lists of daily tasks and shifting adherence monitoring and patient follow-up to community health workers. The total patient volume between July 2020 and February 2021 was derived from TB treatment registers, and data on medication adherence by all patients enrolled on 99DOTS was extracted from the 99DOTS system.

#### 5.5 Results

Of the 3075 adults with pulmonary TB who initiated first-line treatment at the study sites, 2618 (85%) were enrolled on 99DOTS. Altogether, 96% of the expected daily doses of anti-TB medications were confirmed as taken (70% via patient phone calls to the 99DOTS platform and 26% via follow-up phone calls or home visits by community health workers when patients did not make calls). Community health workers made 6747 phones calls to 1466 (56%) patients (median, three per patient) and 1394 home visits to 680 patients (median, one per patient). 99DOTS was well received by both patients and providers.

#### 5.6 Timeline and funding source

Start date: 1 April 2020 End date: 31 December 2021 Funding source: TB REACH and Stop TB Partnership

### **5.7 Additional Information**

We used people-centred methods to adapt 99DOTS to better meet the needs of providers and patients. The adapted 99DOTS platform included a re-designed envelope that concealed pills (with patient choice of image on the front to reduce stigmatization), space to write the health worker's name and contact on the inside cover to facilitate connection, simplified pictorial instructions for taking pills and motivational–educational images on the inside cover. In addition, we used a series of rotating educational–motivational audio messages that patients heard when they called the toll-free number to report dosing. As part of the scale-up, we have also lent low-cost phones to patients who did not have one and made an automated task list in the smartphone app that flags patients who do not call for 3 or more days to facilitate follow-up by community health workers. With these additions, enrolment on 99DOTS has increased to 85% (with 52% in the earlier study), and the proportion of doses confirmed by patient phone calls has increased to 70% (from 56%).

Use of digital adherence technology and other strategies for delivering TB preventive treatment to people with HIV during the COVID-19 pandemic (Uganda)

#### 6.1 Contact person

Jillian Kadota

#### 6.2 Thematic areas

- Prevention
- Treatment
- Digital health
- Socioeconomic support
- Managing co-morbidities

#### 6.3 Background of the project

The study on delivering a 3-month regimen of weekly rifapentine and isoniazid for TB prevention (3HP Options Trial) study is a three-arm, open-label, parallel randomized trial. This type-3 hybrid effectiveness—implementation trial is being conducted with people living with HIV who are receiving care at the Mulago Immune Suppression Syndrome clinic in Kampala, Uganda. The overall objective is to identify a patient-centred delivery strategy that will facilitate acceptance and completion of the 3-month weekly regimen of isoniazid and rifapentine for the treatment of TB infection among people living with HIV under routine HIV/AIDS care. The primary outcome is acceptance and completion of treatment.

#### 6.4 Intervention and method

Participants are randomized to receive treatment with in-person observation or selfadministered therapy or an informed choice of one of these two options. All patients receive streamlined, reimbursed clinic visits and are registered on a digital adherence technology platform for monitoring treatment. Patients on self-administered therapy receive interactive voice reminders and adverse-event check-ins and can make toll-free calls to confirm dosing, while those receiving treatment in-person receive interactive appointment reminders to visit the clinic weekly. Participants who complete 11 or more doses within 16 weeks meet the criteria for the primary outcome. Sputum is collected from all participants 15–16 months after enrolment for TB culture to determine TB incidence.

#### 6.5 Results

The project is under way. So far, we have learnt that our adapted, patient-centred digital adherence technology has resulted in fewer clinic visits by remote monitoring of treatment adherence, presenting an important strategy for reducing clinic congestion during the pandemic. Travel restrictions to prevent SARS-CoV-2 transmission increased the cost of attending HIV clinic visits. As a result, patients appreciated the possibility of remote confirmation of medication intake and the possibility of raising concerns with their health-care providers at no cost. The majority of the enrolled patients found the weekly interactive dosing and appointment reminders important for adhering to care. Most patients appreciated the ease of engagement with the

interactive reminders, as they were recorded in the most widely spoken local language (Luganda) and were easy to understand. Future adaptations might include coordinating such reminders into routine HIV care.

#### 6.6 Timeline and funding source

Start date: 13 July 2020 End date: 2023 Funding source: NIH/NHLBI R01HL144406

### 6.7 Additional Information

Interim results show satisfaction among both patients and providers in use of this technology and indicate that digital adherence technology and other patient-centred strategies may be effective for delivering TB preventive therapy to people living with HIV in high-burden settings. Moreover, in a situation in which crowding should be minimized, use of remote treatment monitoring technologies and other design features such as streamlined clinic visits has the threefold benefit of reducing the cost of travel to a clinic, reducing congestion at clinics and at the same time effectively delivering and monitoring TB preventive therapy among vulnerable populations. Other adjustments to the study design to improve patient access to the clinic during the COVID-19 pandemic include a 33% increase in the transport reimbursement to account for the increase in fares resulting from the reduced capacity of public transport vehicles. Other popular features included built-in motivational audio messages after dosing confirmation and phone calls to encourage patients to complete treatment.



