TB DOESN'T KNOW THE DIFFERENCE: EXPANDING PUBLIC-SECTOR SERVICES TO FIGHT TUBERCULOSIS THROUGH PRIVATE-SECTOR ENGAGEMENT

SUMMARY

The majority of tuberculosis (TB) patients in India seek initial treatment from private-sector physicians. Earlier interventions focused on identifying and treating patients with drug-sensitive tuberculosis in the private sector; patients with HIV comorbidity or drug-resistant tuberculosis, however, were identified in the private sector but referred to the public sector for treatment, with little or no follow-up. With support from the USAID-funded Challenge TB project, PATH piloted treatment support interventions for HIV coinfected tuberculosis patients and drug-resistant tuberculosis patients in the private health care sector. HIV screening and testing were made available to patients to identify those with HIV coinfection, and support was provided to ensure HIV-positive TB patients enrolled on an appropriate antiretroviral therapy. 8,477 TB patients were screened for HIV with 2.1% testing positive for HIV and 106 individuals started antiretroviral treatment. Out of 4,865 screened with GeneXpert, 346 patients with drug-resistant TB, received counseling and evaluation from their private health care providers and 372 patients were supported to initiate an appropriate treatment regimen in the public sector. Both interventions sought to increase adherence and treatment completion for tuberculosis. We found that stigma against HIV remains high, and many HIV-positive patients are unwilling to disclose their status, even to health care providers. For drug-resistant TB patients, access to support mechanisms, facilitated by a treatment coordinator, increased adherence to treatment completion. These interventions for the screening and treatment of TB co-morbidities and drug-resistance, if scaled up as part of India's comprehensive TB efforts, could serve as models for integration of the public and private health care sectors.

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BACKGROUND

India has the largest tuberculosis (TB) burden in the world in terms of the absolute number of incident cases, with an estimated 2.74 million in 2017. Mortality due to TB is the third-leading cause of years of life lost in the country, with an estimated 410,000 deaths in 2017. Approximately 5 percent of the incident TB cases have HIV comorbidity; this rate varies by region, depending on the HIV prevalence of the population.

India also has the highest burden of drug-resistant tuberculosis (DR-TB), with an estimated 135,000 new cases in 2017. More than 80 percent of people seek health care first in the private sector,[1] where substantial diagnostic delays can occur and diagnosis and treatment are of variable quality. As a result of the high burden of DR-TB and the apparent preference of patients for private-sector health care, programmatic management of DR-TB and private-sector engagement are focus areas in India's National Strategic Plan for Tuberculosis Elimination, 2017–2025.

Mumbai has an estimated 70,000 incident TB cases yearly, including 8,000 to 10,000 multidrug-resistant TB (MDR-TB) cases. However, only around 30,000 cases per year up until 2013 were being notified to India's Revised National Tuberculosis Control Programme (RNTCP) due to the high number of patients seeking care in the private sector where cases were not notified. TB care and prevention in Mumbai is further challenged by the fact that many of the private providers, a significant proportion of whom are informal or unlicensed, work in the urban slums, and are largely unregulated.

In 2014, to address the problem of TB and DR-TB in Mumbai and its slums, the RNTCP, along with the World Health Organization (WHO), development partners, international experts, and donors, designed the Private Provider Interface Agency (PPIA) to integrate the public and private sectors to improve TB outcomes. PATH was selected as the implementing partner for the PPIA in Mumbai. The PPIA was an innovative mechanism that acted as an interface between the government and private sector to facilitate early detection and improve the quality of diagnosis and treatment of TB, in accordance with standards of TB care in India, for persons seeking care in the private sector. The PPIA supported notification of TB cases diagnosed by formal and informal health care providers in the private sector and strengthened treatment adherence to ensure patients completed the full medication regimen. Through the PPIA, TB patients had access to TB testing and treatment using an electronic voucher system, which provided access to the following services:

- Free digital chest X-rays and free GeneXpert® testing.
- Free anti-TB medication for diagnosed patients provided through designated private pharmacies.
- Specialized care provided at a "hub hospital" with an in-house pulmonary physician or internal medicine consultant.

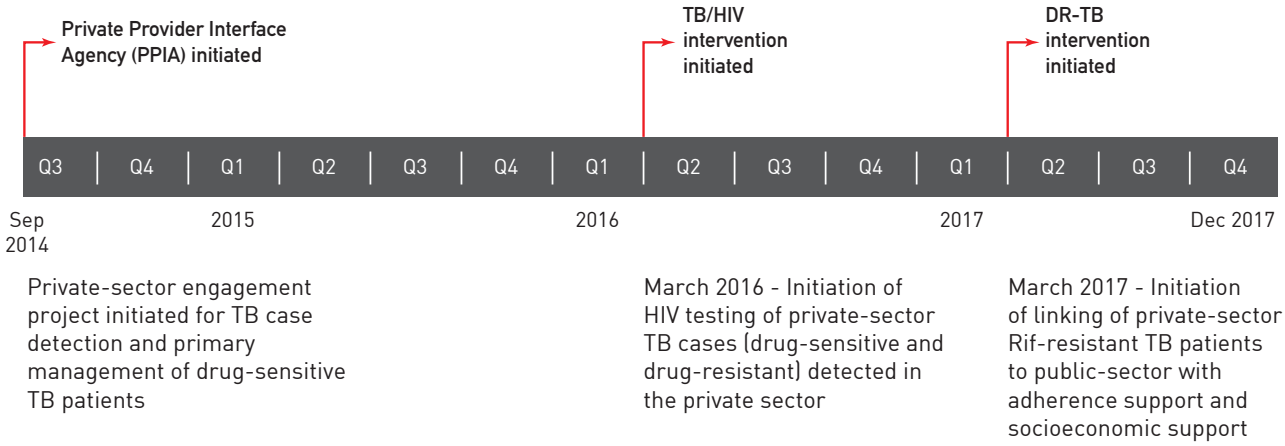
A dedicated patient registration and management software augmented by a call center maintained a centralized database of patient information and managed the voucher system where drug refill schedules were maintained and tracked to ensure treatment adherence; patients received regular reminders

1. Satyanarayana S, Subbaraman R, Shete P, et al. Quality of tuberculosis care in India: a systematic review. International Journal of Tuberculosis and Lung Disease. 2015 Jul; 19(7): 751–763. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4462173/.

through SMS messages and phone calls to promote adherence. Field health workers contracted by the PPIA were alerted by the contact center if signs of non-adherence were detected, which prompted home visits and treatment adherence interventions.

Between September 2014 and December 2017 (see Figure 1), PATH notified 60,361 private-sector TB patients from Mumbai, which constituted a more than 450 percent increase in the local private-sector contribution annually. Beginning in 2016, PATH expanded its PPIA model, with the support of the US Agency for International Development's (USAID's) Challenge TB project, to include TB/HIV testing and DR-TB testing and treatment support for private-sector TB patients. It is these interventions that are documented in this technical brief.

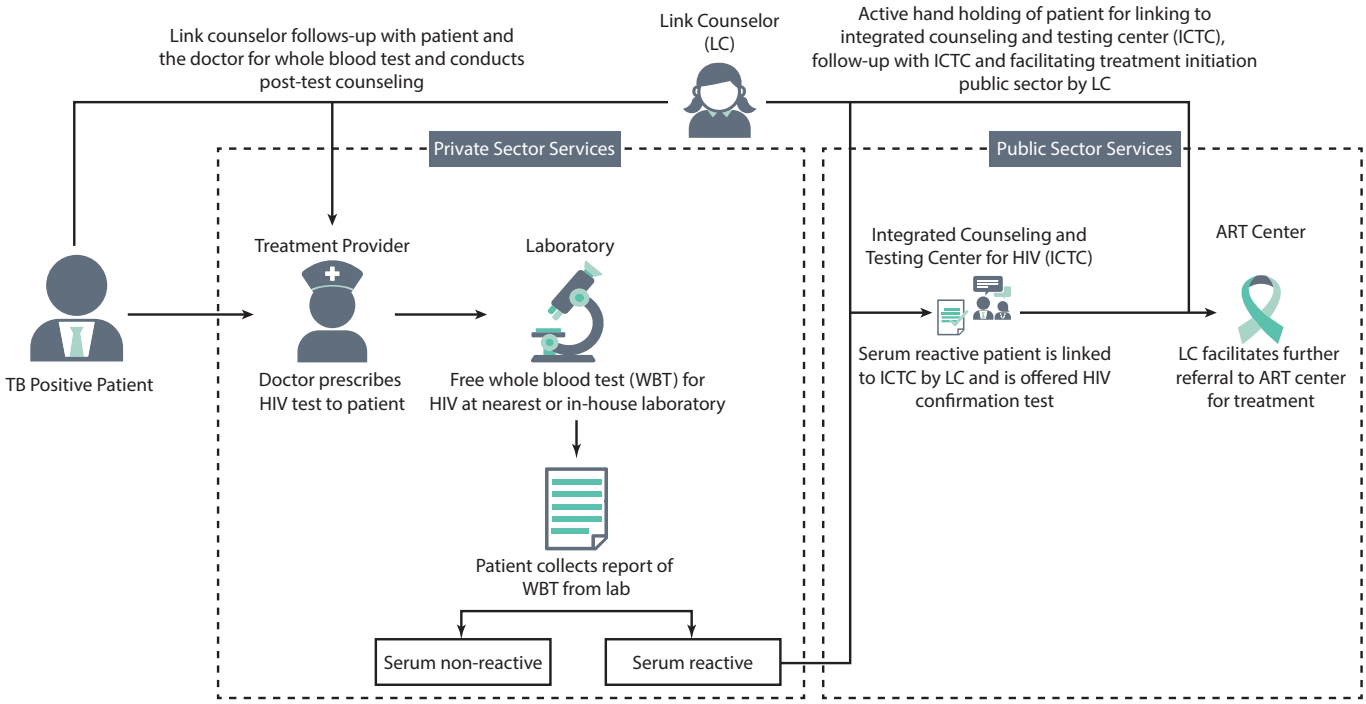
Figure 1. Private-sector provider interventions in Mumbai, India, 2014–2017.



TB/HIV INTERVENTION, MARCH 2016 TO DECEMBER 2017

According to the Revised National Tuberculosis Control Program Annual Status Report (2017), in 2016 one-fifth of the total TB patients were reported from the private health facilities, but for only 13 percent of those was there a reported HIV status in the national TB database, Nikshay. Through the Challenge TB project (and with funding from the President's Emergency Plan for AIDS Relief [PEPFAR]) in Mumbai, PATH sought to increase the number of TB patients aware of their status, and the number of physicians reporting that HIV status, through the PPIA initiative in the private sector. To achieve this objective, PATH offered HIV testing (and linkage to government-run antiretroviral treatment services for those found to be HIV positive) to TB patients notified through the PPIA project in Mumbai from March 2016 and through December 2017 (see Figure 2). High-volume private hospitals, clinics, and laboratories already engaged in the PPIA were prioritized to offer free HIV screening for all TB patients through an expansion of the voucher program with the PPIA-associated labs. TB patients who tested positive for HIV were then linked to integrated counseling and testing centers (ICTCs) under the National AIDS Control Organization (NACO) for diagnostic confirmation and initiation of treatment at antiretroviral treatment centers (ART-Cs).

Figure 2. Schematic model of the TB/HIV intervention in the private health sector, Mumbai, India, 2016–2017.



Prior to offering HIV testing and referrals, PATH collaborated with the Maharashtra State AIDS Control Society (MSACS) (Thane and Pune districts), Mumbai District AIDS Control Society (MDACS) (Mumbai district), and the National Reference Laboratory to build the capacity of the selected private-sector laboratories for rapid HIV testing. PATH supported technical assistance and training for link counselors—field health workers specifically hired and trained for this intervention—through collaborative workshops, as per national guidelines for facility-integrated counseling and testing center (FICTC) training at NACO.

In order to ensure sustainability of this work at the conclusion of the Challenge TB project, PATH used the NACO's public-private mix models for HIV screening in the private sector and integrated those models into the PPIA facilities. With the involvement of MDACS and MSACS in project monitoring from the beginning of implementation, including training of private-sector laboratory technicians and counselors, PATH sought to ease the transition of activities to local government management during the handover phase of the project at the end of 2017. During the transition, PATH continued engagement with the private laboratories, hospitals, and clinics that provided HIV tests using the FICTC Model B (commodity support from government) and Model C (data-sharing model) guidelines (see Table 1).

During this phase (Jan 2019–May 2019), PATH piloted Model B and C among 45 hospitals/laboratories (37 were Model B and 7 were Model C). The pilot ran for four months to demonstrate impact of the intervention to MDACS and support integration into the TB program run by RNTCP in Mumbai; the intervention will be continued under the RNTCP's Public Private Support Agency (PPSA) project as these models are budgeted and approved under the 2019 project implementation plan of the Mumbai City TB office. The overall screening rate in four months was 50 percent in these 45 facilities during transition. Around 1,700 patients were screened, and 22 were screened reactive on the first test during this pilot phase.

Table 1. National AIDS Control Organization public-private mix guideline model schemes.

Model	Guidelines
Model B	• Support of commodities, such as HIV diagnostic test kits from public sector. • Testing point of contact (health worker or lab technician) will be trained under a SACS, as per the national guidelines. • Ongoing technical support through regular technical visits by SACS supervisors. • Demand creation (private-sector engagement) through linkages with local NGOs, community-based organizations, etc. • Linkages for confirmatory HIV testing with SA-ICTC for individuals screened positive by whole blood finger-prick test kits and further with ART center for those tested positive.
Model C	• Patient receives HIV test from preferred private laboratory in network, as per doctor's referral. • Patient pays full amount for the test. • Documentation of HIV status of TB patient will be ensured by the engaged facility.

Building confidence of TB patients/post-test counseling and linkages:
Trained link counselors supported by Challenge TB provided counseling to TB patients who had received care in the private sector through PPIA and had tested positive on their rapid diagnostic test for HIV at the engaged private laboratory. The link counselors also assisted the seroreactive patients with linkages to the public-sector ICTC for confirmation testing. Link counselors were able to schedule appointments at ICTCs and ART-Cs for private-sector patients, which enabled them to be fast-tracked through the lines at the public facilities. As a result of this fast-track model, the patient was provided the HIV test results on the same day. The link counselor further supported the patient to get him or her to the ART-C for registration, pretreatment evaluation (PTE), CD4 testing, and treatment initiation on the same day.[2] The patient's pre-antiretroviral therapy registration was usually completed on the same day of testing at the ICTC, and antiretroviral therapy (ART) was initiated two weeks after TB treatment initiation, which is standard practice.

RESULTS OF HIV TESTING

From March 2016 through December 2017, out of 11,848 TB patients notified from 135 private-sector facilities in Mumbai only, 8,477 (73 percent) individuals opted for HIV testing using rapid diagnostic tests. Of these, 181 (2.1 percent) were TB/HIV coinfected patients; 50 (25 percent) of these coinfected patients were already on ART (link counselors were able to determine that many of the TB patients already on ART deliberately hid their HIV status from the TB doctors for fear of stigma). Out of 127 newly HIV diagnosed patients, 110 (87 percent) were linked to ICTCs, of whom 106 (96 percent of those linked to the ICTCs, or 83 percent of those newly diagnosed) were linked to public ART-Cs. The reasons patients were lost to follow-up varied and included migration, premature deaths, denial of HIV-positive status, and initiation of ART in the private sector instead of at the referred public-sector sites.

2. ART-C and ICTC are both in the public sector. Hence, the link counselor provided linkages at two levels: from the PPIA-related hospitals/clinics to the nearest ICTC, and then from the ICTC to the ART-C. This ensured a higher linkage rate for TB/HIV patients from the private sector to treatment initiation in the public sector.

Table 2. Demographic characteristics of participants who engaged private practitioners for early HIV screening and TB treatment initiation in urban slums of Mumbai, Maharashtra, India, March 2016–December 2017.

Category		Number	Proportion
Total number of TB patients notified in selected facilities		11,848	100.0%
TB patients tested for HIV		8,477	73.0%
Sex disaggregation of HIV testing (n = 8,477)			
	Male	4,031	48.0%
	Female	4,446	52.0%
HIV positivity (of those who tested HIV positive; n = 181)			
	Male	107	2.7%
	Female	74	1.7%
Proportion of HIV positives, by age (n = 181)			
	0 to 14 years	4	2.0%
	15 to 49 years	144	80.0%
	50 years and above	33	18.0%

The link counselor model adhered to the standard operating procedure in NACO's *Operational Guidelines for ART Services*, which mentions that once the patient reaches the ART center, treatment should be initiated within seven days. In PATH's initiative, link counselors supported patients to start treatment within a week's time as per the proposed guidelines through linkage and follow-up with an ART center. Starting from a reactive (screening) HIV test in the private sector, link counselors linked patients to the ICTC on average within 5 days, ART registration at the ART center occurred on average within 7 days, and patients started on ART within an average of 14 days. (Once the patient is screened reactive, the confirmatory test is conducted at a stand-alone ICTC and treatment registration followed by initiation is begun at an ART center within government facilities.)

While time to linkage was as per the proposed guidelines, it is still too long overall, and efforts will need to be made to further reduce time from diagnosis to treatment and start same-day treatment at ART centers.

DRUG-RESISTANT TUBERCULOSIS INTERVENTION, APRIL 2017 TO DECEMBER 2017

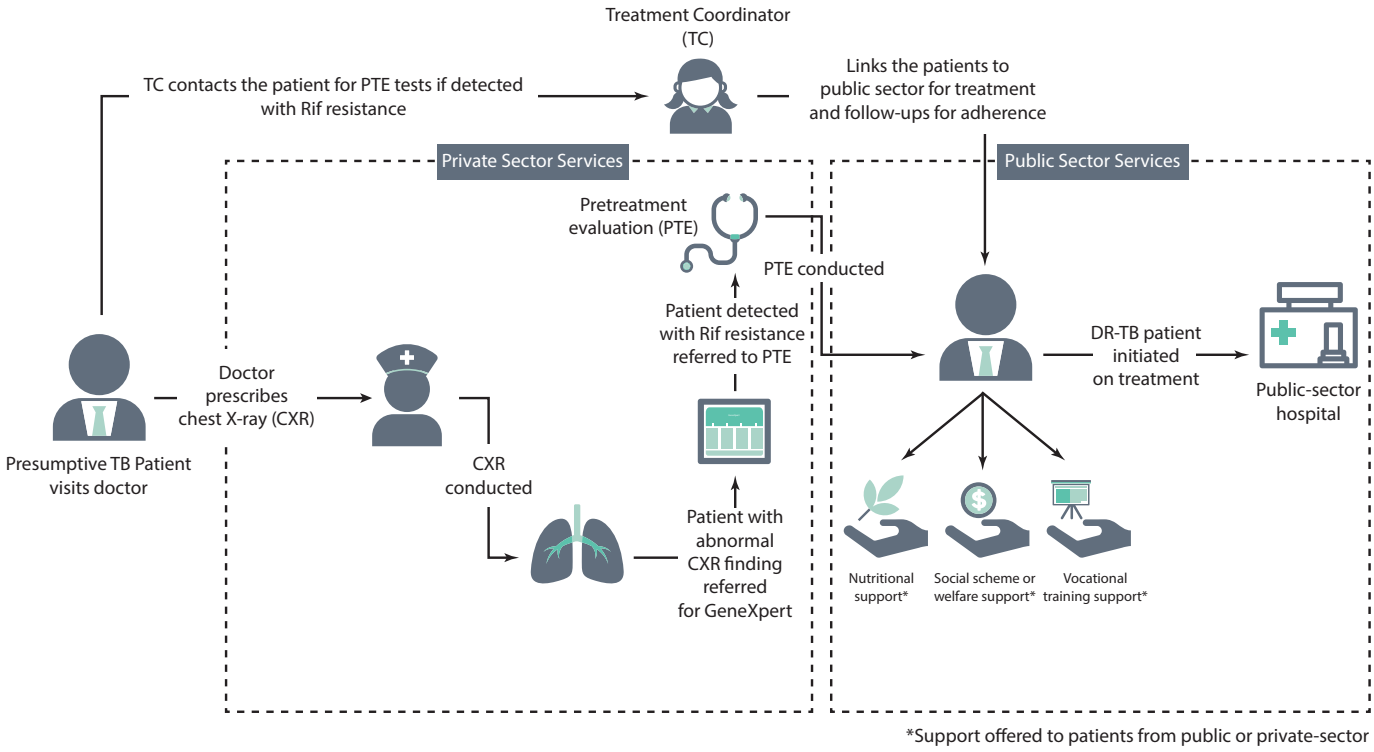
Prior to USAID's support, PATH would refer any rifampicin-resistant case detected by GeneXpert testing to the public sector and counsel patients to seek treatment in a public-sector health facility. Private-sector providers participating in the PPIA program were not and still are not equipped or trained to clinically evaluate or support patients with DR-TB.

Under the Challenge TB project, PATH expanded the scope of services offered by the PPIA to include enhanced DR-TB linkage, referral, and support

activities in 6 out of 24 districts in Mumbai. Early screening and linkage to treatment for DR-TB patients began in January 2017. PATH partnered with local nongovernmental organizations (NGOs) to hire one treatment coordinator per district to provide guidance and support to the patients throughout the care cascade. Conducting pretreatment evaluation tests is the first step before treatment initiation for DR-TB patients. Considering the extensive time taken for pretreatment evaluation in the public sector, as many departments are involved, PATH offered free pretreatment evaluation tests in the private sector under one roof to expedite DR-TB treatment initiation. PATH used the steps outlined in Figure 3 (below) to initiate treatment and follow-up for DR-TB patients.

Over the course of the intervention, PATH worked with the RNTCP and the District TB Office to adapt the patient linkage and support models for adoption by the public sector.

Figure 3. Comprehensive processes involved in the drug-resistant tuberculosis project for the private health sector, Mumbai, India, 2017.



ACTIVITIES FOR TREATMENT INITIATION

The treatment coordinators followed-up on all confirmed rifampicin-resistant patients to ensure that the patients received pretreatment evaluations and linkage to DR-TB treatment in a public-sector facility.

PTE: This comprises complete blood count, blood sugar test, liver function tests, renal function tests (blood urea and serum creatinine), thyroid-stimulating hormone levels, urine examination, chest X-ray, and pregnancy test (for all women of childbearing age). PTE helps to identify patients at increased risk of experiencing adverse effects from DR-TB treatment drugs. These tests were offered free of cost. The tests covered all the necessary evaluations for the patient to receive the appropriate treatment regimen in the public sector.

Patient linkage: After completing the PTE tests in the private sector, treatment coordinators counseled the patients on the nature of the disease, the treatment period, and the financial burden if treatment and drugs were paid out of pocket. They also informed the patient of the opportunity to access high-quality treatment from the public sector free of charge. After successful linkage, the treatment coordinators followed up with patients regularly to monitor adherence to treatment and side effects from the medications. Patients who were not adhering to treatment were counseled and accompanied to doctors to resume treatment.

FOLLOW-UP DURING TREATMENT

To improve treatment adherence and the patient experience, PATH identified social schemes and support programs available to DR-TB patients, including nutritional support, vocational training courses offered by the government of India and private organizations, financial support from charities and private institutions to economically disadvantaged patients, and peer-group support. Support from Challenge TB enabled PATH to support treatment coordinators who would assist DR-TB patients to access these services and host peer support groups. These interventions were informed by the adherence support that TB patients in the private sector receive from the PPIA field staff and expanded to include additional mechanisms.

Importance of Adherence:
To encourage the project's beneficiaries to adhere to their treatment in the public sector and not seek treatment from multiple providers ("provider-hopping"), treatment coordinators conducted the following activities:

- Once the patient initiated their treatment, treatment coordinators conducted meetings with the patient and family members to explain the length of the treatment, possible adverse drug reactions, and most importantly, adherence to treatment.
- Treatment coordinators gave a self-monitoring tool in the form of a card to the patient to update after taking medication. This card served as a daily drug-intake reminder for the patient and was checked by the field staff during home visits.
- Treatment coordinators conducted home visits and calls with the patients at predefined intervals during treatment to monitor adherence and guide the patient to visit their public-sector doctor if they experienced adverse drug reactions.

Socioeconomic Support:
Nutritional Support: Patients received nutritional support (dry-food ration packets) and livelihood opportunities for themselves and family members from other organizations (i.e., local NGOs, corporations, and charitable trusts). PATH, along with the partner NGOs, corporations, charitable trusts, and other NGOs providing nutritional support, approached and facilitated the provision of nutritional support to DR-TB patients.

Social Welfare Schemes: Treatment coordinators linked eligible DR-TB patients to functional government welfare/security schemes and to NGOs offering socioeconomic support. Functional government social security and welfare schemes were mapped through public records and the Right to Information Act.

Patient profiling determined the eligibility for each scheme. Patients were assisted with assembling required documents for filing an application.

Vocational Training: PATH and the partner NGOs facilitated the provision of skill-development courses and transportation assistance under the Pradhan Mantri Kaushal Vikas Yojana (http://pmkvyofficial.org/) to patients who originated from the private sector or to their family members.

Community Engagement: PATH engaged existing structures in the community—such as community-level care providers created under the National Urban Health Mission, women's self-help groups formed under the National Urban Livelihood Mission, and childcare centers (anganwadis) under the Ministry of Women and Child Development—in TB sensitization focused on raising disease awareness, reducing social stigma, and enhancing community awareness. PATH also encouraged them to include TB adherence support in their activities.

To share the experiential learnings from this intervention of DR-TB linkages and socioeconomic support, PATH collaborated with the World Health Organization and Central TB Division to create the *Patient Support System Toolkit*, which describes the step-by-step process to link DR-TB patients to existing programmatic management of DR-TB services in the public sector, as well as to create a patient support system to enhance treatment adherence. The adherence support services documented in the *Patient Support System Toolkit* are available to all DR-TB patients, and patients whom received such support had higher rates of treatment completion.

RESULTS OF DRUG-RESISTANT TUBERCULOSIS INTERVENTION

The private-sector DR-TB referral model demonstrated the feasibility of patient-centric linkages for holistic DR-TB care and management of TB/HIV comorbidities. Out of the total of 4,865 private-sector patients with TB symptoms who were tested with GeneXpert by the PPIA during the period of April to December 2017, 423 DR-TB cases were diagnosed and 372 private-sector patients were successfully linked to public-sector facilities for DR-TB treatment. Of the 51 patients who were not successfully linked, 34 (67 percent) opted for treatment in the private sector, 11 (22 percent) migrated to their hometowns for treatment, 4 (8 percent) could not be traced for treatment initiation, and 2 (4 percent) patients died before treatment could be initiated.

Table 3. Demographic characteristics of participants who engaged private practitioners for early HIV screening and TB treatment initiation in urban slums of Mumbai, Maharashtra, India, March 2016–December 2017.

Activity Description	Achievement
Presumptive cases tested with GeneXpert	4,865
DS-TB case diagnosed by GeneXpert	1,651 (34%)
DR-TB* cases diagnosed by GeneXpert	423 (9%)
DR-TB cases received pretreatment evaluation	346 (82%)
DR-TB patients linked for treatment in the public sector and provided treatment adherence services	372 (88%)
DR-TB patients received socioeconomic support	155 (37%)

*We use rifampicin-resistance, confirmed by GeneXpert testing, as resistance is a surrogate marker for multidrug-resistant TB.

Out of 372 patients who were linked to the public sector between April and December 2017, at least 249 (67 percent) of the DR-TB patients were still on their prescribed treatment regimens six months after initiation. Prior to Challenge TB's intervention, the treatment success rate for DR-TB among notified cases was 46 percent. DR-TB patients received persistent treatment adherence follow-up collectively from the government and project staff through the patient support system model. This model, if adopted and scaled-up to cover all DR-TB patients in the public and the private sectors, could increase treatment completion for DR-TB cases and could potentially avert out-of-pocket expenditures and help meet the RNTCP goal of reducing catastrophic costs to patients who pursue treatment in the private sector.

CONCLUSION AND FUTURE OF PRIVATE-SECTOR INTEGRATION

Comprehensive TB control will not be possible in India without the involvement and engagement of the private health care sector. The PPIA project showed how the public and private sectors could collaborate effectively and how the private sector's contribution to TB care and prevention could be quantified. Support from Challenge TB leveraged an existing model so that the private sector can now successfully refer patients to the public sector for treatment of DR-TB and TB/HIV coinfection.

PATH is transitioning the PPIA program to local management. PATH is using the Patient Support System Toolkit (https://www.path.org/resources/patient-provider-support-agency-india-toolkit/) to provide targeted technical assistance to local governments so that those governments can implement their own DR-TB and TB/HIV patient management models in partnership with the private sector. In Mumbai, the Public Private Support Agency (PPSA) was formed after PPIA transition as part of the City TB Office's activities. The PPSA receives a per patient budget allocation for TB case management, and for 2019 the RNTCP approved additional funding for TB/HIV and DR-TB linkage activities in Mumbai.

The DR-TB and TB/HIV interventions demonstrated that patients seeking treatment for TB in the private sector can be successfully tested and diagnosed for HIV and DR-TB and linked to the public sector for timely treatment initiation, retention, and adherence to treatment through trained counselors who act as the link between the private and public sectors. The Joint Effort for Elimination of Tuberculosis (JEET)—a project of the RNTCTP and the Global Fund—has adopted the TB/HIV intervention model and is scaling it up in several of the JEET-supported cities across India. PATH has provided training to some of the JEET intervention sites to accelerate scale-up and make permanent the system improvements started under Challenge TB.

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