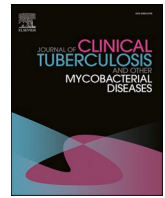




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# Journal of Clinical Tuberculosis and Other Mycobacterial Diseases

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## Partnering with the private laboratories to strengthen TB diagnostics in Nigeria

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### ABSTRACT

Despite being curable and preventable, tuberculosis (TB) affected 10 million people worldwide in 2020. In the seven highest TB burden countries, private providers account for more than two-thirds of initial care seeking. Closing gaps and finding the “missing people” with TB requires engagement of the private sector for better diagnostics and treatment.

This review explores the efforts of a public–private partnership to enhance TB diagnostics in Nigeria, covering logistics and the distribution of GeneXpert machines and other diagnostic tools. Over three years, the Nigerian “hub and spoke” model led to a 28-fold increase in referrals of people with presumed TB in private diagnostic facilities. Various stakeholders’ perspectives are also included, providing insight into opportunities and challenges of working with the private sector in this effort.

As countries tackle the setbacks brought by COVID-19 and move towards reaching the End TB targets, partnerships such as these can strengthen the foundations of health systems.

### 1. Background

“Access to quality tests and laboratory services is like having a good radar system that gets you where you need to go. Without it, you’re flying blind”, Dr Tedros, Director General, World Health Organization (WHO).

The WHO End TB Strategy has, as one of its components, early diagnosis of tuberculosis using universal drug-susceptibility testing and screening of contacts and high-risk groups. [1] This is partly because the underdiagnosis of TB has remained a recurring problem particularly for low- and middle-income countries. This has contributed to the missing millions of TB cases yearly and has hampered development efforts. WHO recommends using bacteriological diagnostic tools (rapid molecular tests or culture) to enable correct diagnosis and ensures effective treatment for susceptible and resistant forms of TB. [2].

Efforts to increase TB notifications is particularly challenging in several high-burden TB countries that have large private health sector, including India, Indonesia, and Nigeria. In these countries, a majority of people with TB seek care first in the private sector [3]. Yet, most private providers do not use recent WHO-endorsed diagnostic tests, including

microbiological tests such as liquid cultures, line probe assays, and GeneXpert Mycobacterium tuberculosis (MTB)/rifampicin (RIF) [4–7].

Globally, there are different models for engaging private laboratories. In one model, manufacturers and distributors are engaged with private laboratories, for instance, the Initiative for Promoting Affordable and Quality TB Tests (IPAQT) Program [8] in India and the Private Sector Diagnostics Consortium in the Philippines [9]. In another model, private facilities are provided publicly procured devices and commodities under certain contracts or terms, for example, the “hub and spoke” model in Nigeria which is captured in this article.

In this paper, we reviewed the program data and interviewed key stakeholders to outline how the private laboratories in Nigeria are engaged in the efforts to end TB. The data presented here were collected by the authors and their team as part of their routine program monitoring efforts.

### 2. Engaging private providers in Nigeria for tuberculosis care

Nigeria accounts for 4% of the global incidence of TB [10] and 11%

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of the global missing people (notification gap between the estimated number of persons with TB and the actual number notified annually) [11]. This notification gap is due to the underdiagnosis and under-reporting of people with TB [11]. According to the 2012 national TB prevalence survey [12], 75% of the people who were detected with smear-positive pulmonary TB had symptoms that met national screening criteria but had remained undiagnosed resulting in a large pool of persons with infectious TB. This demonstrated the need to ensure universal coverage of TB services in Nigeria with special focus on improving access to quality-assured, person-centered screening, diagnostic, and treatment services.

According to WHO, Nigeria has the lowest treatment coverage rate amongst high-burden countries, at just 27% of estimated incidence in 2019 [11]. An estimated 60% of Nigeria's population of over 200 million inhabitants seeks healthcare first in the private sector [3] due to accessibility, convenience, confidentiality, or the perception that the private sector provides higher quality of care [13]. Private provider engagement has remained suboptimal and where some engagement exists, a significant proportion of these providers have low awareness and knowledge of TB and often do not adhere to national guidelines [13].

The Institute of Human Virology, Nigeria (IHVN), under the leadership of the National Tuberculosis and Leprosy Control Programme (NTBLCP), and with funding from The Global Fund (GF), is coordinating the engagement of the private sector in TB service expansion. As of December 2021, the Nigerian national TB laboratory network includes one supra-national, two national, seven zonal, and state TB reference laboratories, in addition to over 3000 Acid-Fast Bacillus (AFB) microscopy and 420 GeneXpert sites (see Table 1). The number of tests conducted in two of these private labs is shown in Table 2. As the overall number of Gene Xpert tests increased, there was decreased reliance on traditional approaches like smear microscopy and cultures. Prior to private sector engagement in this national TB laboratory network, over 90% laboratories were in the public sector. Currently, 13% of the total GeneXpert labs, 10% of the line probe assay (LPA) and culture labs, and at least 60% of AFB microscopy labs in Nigeria are in the private sector [14]. The overall approach, coordinated by IHVN, involves the public sector using donor funds (GF) for central procurement of instruments and cartridges which are then distributed to private labs at no charge in exchange for data, along with an agreed-upon incentive package for administering the tests. IHVN is responsible for procuring the diagnostic machines and cartridges, while NTBLCP procures medicines (first- and second-line drugs for DS-TB) and Personal Protective Equipment (PPE).

### 3. The IHVN “Hub and Spoke” model

Currently, the IHVN is working in 21 of Nigeria's 36 states in both

**Table 1**  
Distribution of GeneXpert and AFB microscopy in the public and private sectors.

	Q2 2021	Q4 2021
GeneXpert Machines		
Public sector	356	420
Private Sector	49	49
• Private Stand-alone	6	6
• Faithbased organization (FBO)	43	43
• Private for Profit	–	–
Total no. of GeneXpert machines	405	420
AFB Microscopy		
Public sector	2576	2576
Private Sector	424	424
• Private Stand-alone	381	375
• FBO	43	43
• Private For profit	NA	NA
Total AFB Microscopy sites	3000	3000
Total Linkage Coordinators*	425	433

\*Personnel who coordinate referrals between the PPM facilities and laboratories

**Table 2**  
Contribution from Private Labs.

Tests conducted in private labs*	2018	2019	2020	Q2 2021
Culture	4536	2900	2190	1460
DST	959	1098	878	595
GeneXpert	1381	5782	9208	10,944
Sputum smear microscopy	2267	1455	1095	737

\* These data are from Zankli and El-Lab alone which are 2 of the biggest stand-alone private laboratories

formal and informal settings (approximately 60% coverage of the Nigerian population). It follows a “hub and spoke” model, where the hubs are facilities where the complete cascade of care (screening, diagnosis, treatment) is available (Fig. 1). The spokes, on the other hand, are facilities that do not have capacity for TB diagnosis and treatment but offer other services such as screening for symptoms of TB and referring to hubs for further treatment. The majority of private laboratories are spokes providing only screening and follow-up monitoring, whereas only a few fit into the “hub” category.

Within this model, IHVN engages private laboratories (both stand-alone laboratories and those within hospital settings, also including faith-based organizations (FBOs), and private-for-profit (PFPs)) that have capacity for diagnosis and GeneXpert machines as hubs. Other entities such as community pharmacists, patent medicine vendors, traditional birth attendants (or healers), and standalone laboratories (i. e., private diagnostic labs not embedded within a health facility) are engaged as spokes.

### 4. Current approach to private laboratory engagement

Firstly, state and local governments engage with umbrella bodies, associations, and sub-recipients (SRs) to create a list of existing private facilities. After visiting and assessing these facilities for their viability, infrastructure, and willingness to collaborate, some facilities are selected based on set criteria for signing a memorandum of understanding (MoU). This tripartite MoU is signed between the private facility, IHVN, and the NTBLCP to cover the terms of engagement vis-à-vis the responsibilities of each party. Next, GeneXpert machines, cartridges, microscopes, reagents, and recording and reporting tools – all procured by the NTBLCP using Global Fund funding – are deployed to the private facility. Thus, the facility is automatically integrated into the national commodity distribution network and all engagements are done in conjunction with the local government TB supervisor and state TB program team (Fig. 2). Following this, under GF funding, SRs (overseen by IHVN) conduct training of the facility staff through hands-on support and supervision. National TB Program training modules that are used to train employees in the public sector are also used for these sessions. These formal didactic training sessions help educate, inform, and train the staff about the National Program guidelines and international standards of TB care.

In addition to training of the staff, capital for infrastructure and electricity (e.g., solar power) is crucial. Once operational, the private laboratories conduct diagnostic tests and document the results in the NTBLCP recording and reporting (R&R) tools. GeneXpert machines are equipped with GxAlert, a connectivity software that can greatly improve the TB test reporting times and information sharing. Thus, GxAlert is monitored weekly to track utilization of machines. Since these private laboratories are paid incentives by IHVN from GF funding, they are not expected to charge the patient any fee for tests conducted. Tests are incentivized at an agreed fee based on the volume of tests conducted, for instance, \$2.50 per test for the GeneXpert MTB/RIF assay and \$1.00 per follow-up AFB microscopy test. This fee was based on an SR-conducted survey of the amount charged per test by laboratories within communities. Only the laboratories that send referrals receive reagents and consumables from IHVN under GF funding.

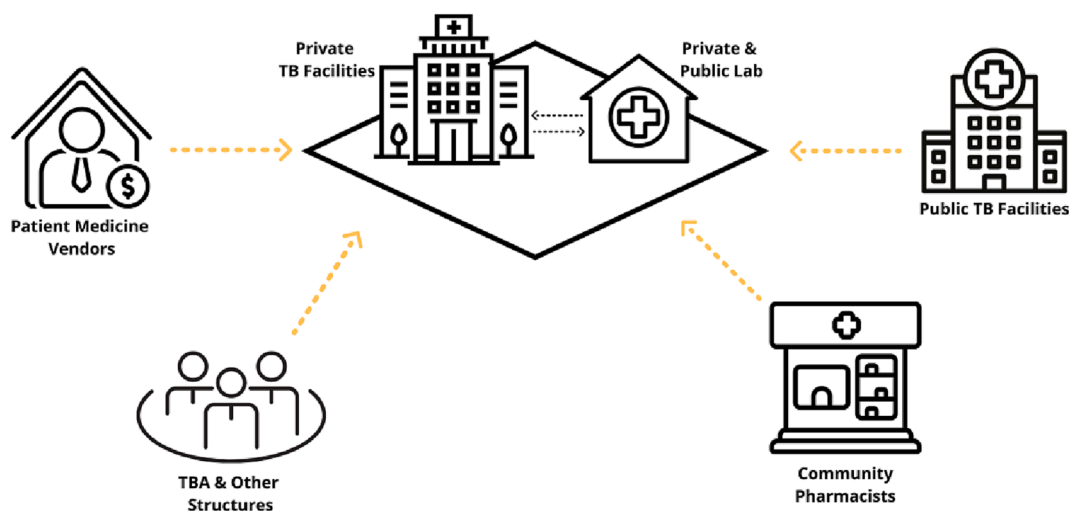


Fig. 1. Laboratory Engagement Model under the PPM grant in Nigeria.

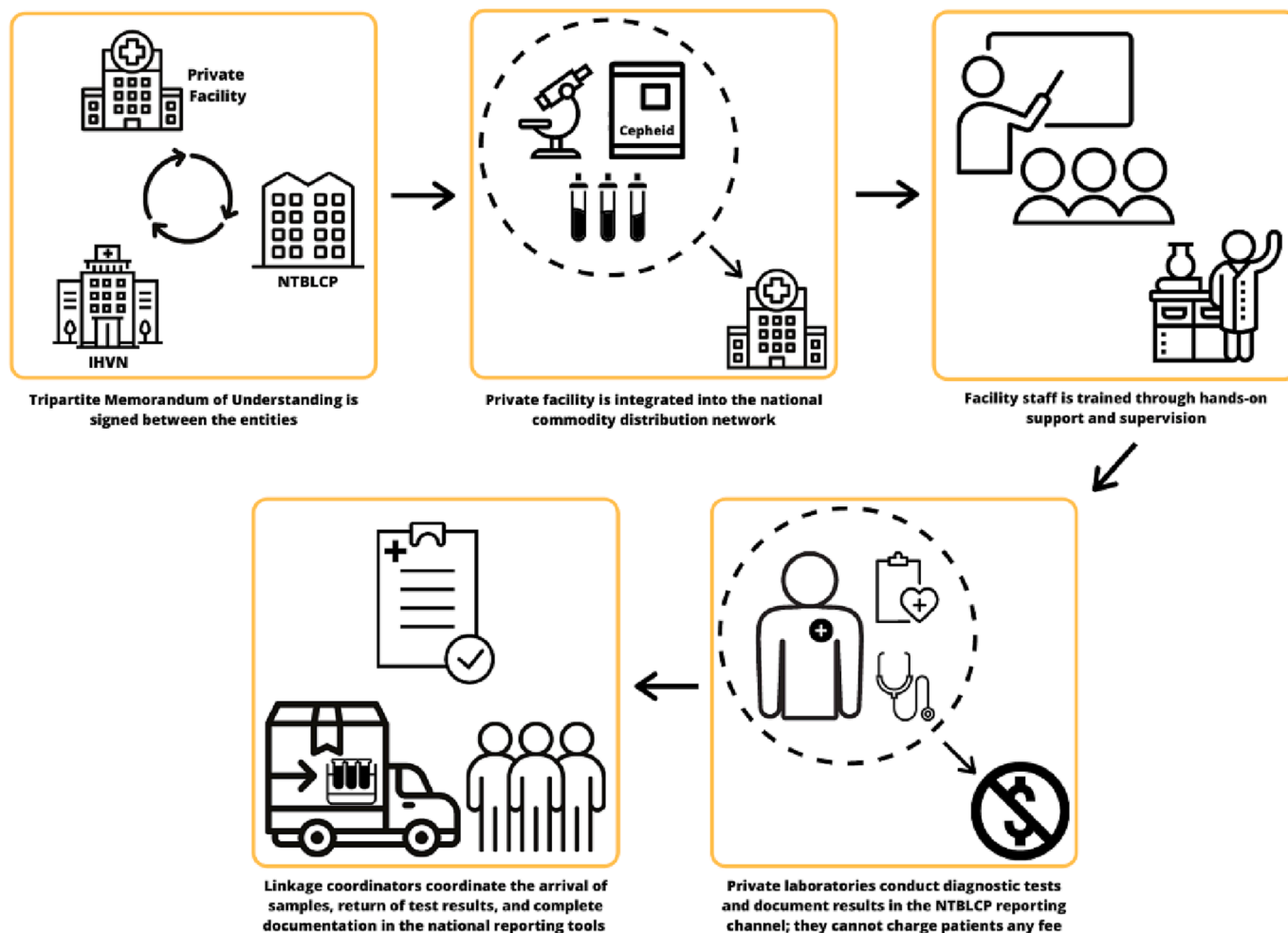


Fig. 2. Current Approach to Private Laboratory Engagement in Nigeria.

Ad hoc staff called linkage coordinators are paid from the Global Fund grant and assigned by IHVN to these laboratories. These linkage coordinators are field workers and community volunteers –some with previous experience working in the health system – engaged by SRs from communities where this engagement model is implemented. They are compensated financially to coordinate the arrival of samples at the

diagnostic site, return test results to the facility, and complete documentation in the national reporting tools. Linkage coordinators move samples from the point of generation to the lab using carrier bags with sputum coolers. These coolers can store sputum samples up to 2–3 days. Each linkage coordinator is responsible for 3–5 hubs, and each hub has multiple spokes (approximately 10 each). To ensure the judicious use of

resources, samples are not transported every day, but every 2–4 days, when linkage coordinators move stored samples collected from the spokes to the labs (hubs). Given that GeneXpert MTB/Rif is considered the preferred first line of TB diagnosis in Nigeria, where a laboratory does not have a GeneXpert machine on site, their samples are sent to a hub with a GeneXpert. In addition, all new presumptive cases seen at referral sites/spokes have their samples sent exclusively to labs with GeneXpert systems on site.

For follow-up monitoring, the system leverages the existing installed capacity of laboratories that already offer AFB microscopy even before being engaged. These microscopes are looped into the national supply chain mechanism, and the lab receives free reagents and other consumables for AFB microscopy. Since the start of the COVID-19 pandemic, PPE has also been made available to engaged private facilities.

### 5. Impact of the initiative

From 2017 to 2020, this effort to engage private laboratories in TB diagnostics has yielded an increase from 96 (in 2017) to 397 (in 2020) standalone private laboratories in Nigeria. During this same period, the number of presumptive TB patients (in private facilities) whose samples were referred for diagnosis increased from 743 to 21,280. Further, the engagement with the private sector through both the IHVN approach and other approaches such as USAID-funded SHOPS Plus engagement increased the private provider contribution to national TB notifications from 19% in 2019 to 36% in 2020 (Fig. 3). The early placement of a GeneXpert machine (via SHOPS Plus) in the El-Lab, a private laboratory in Lagos, served as an early proof of concept (Fig. 4). The enthusiasm and motivation of this individual owner – and the resulting high throughput usage and high diagnostic yield – were instrumental in setting the groundwork for broader uptake and acceptance in other labs.

In 2021, approximately 100 GeneXpert machines are being added to the existing 400 machines in the system. These machines will be fairly distributed across the six geopolitical zones of Nigeria with plans to link them all to a national sample referral network. IHVN and NTBLCP are involved in deciding the allocation of these machines by assessing the TB prevalence, diagnostic capacity, as well as the resources available to support the machines being allocated to the facilities. For instance, Zankli reference laboratory and El-Lab Lagos which are 2 high burden labs are allocated 2 machines each to meet the demand.

### 6. Stakeholder perspectives

Private providers collaborate with the public sector for a variety of reasons. We obtained the perspectives of various stakeholders engaged in the PPM model in Nigeria, these are outlined in Box 1.

#### Box 1. Stakeholder perspectives on the PPM model

##### 5.1 Why do you think private laboratories are interested in collaboration on TB diagnostics with the national TB program? What is the benefit for the private lab?

*“In the order of priority: (i) The visibility to a wider population; (ii) The incentives that will be added income; (iii) The bridge in knowledge gap; (iv) Other benefits they tend to get such as optimization of their laboratory with solar panels and HR (Ad-hoc) staff.”*

– KNCV Tuberculosis Foundation (Nigeria) Staff, working with private laboratories

##### 5.2 Why are you interested in the collaboration on TB diagnostics? What is the benefit for your lab?

*“I see my participation as a means of contributing my quota to ending TB in Nigeria, as a social service. The TB program makes available materials and tools like microscopes, GeneXpert systems and consumable free to us as incentive to encourage us which we appreciate.”*

– Secretary General/Focal Person PPM, Guild of Medical Laboratory Directors, Lagos State

##### 5.3 Since you pay the lab from the program/donor funds, do you pay per test or a fixed amount per month? How do you verify that the patient is not being charged too much?

*“In spite of the mechanism put in place to eliminate out-of-pocket expenditure for patients accessing TB care in the private sector, we are aware that some patients (like walk-in patients) still get to pay a fee for TB diagnosis. This calls for continuous surveillance on financial transparency and advocacy through the umbrella bodies.”*

– Senior Program Officer, (Clinical) at Institute of Human Virology, Nigeria

### 7. Challenges and opportunities under the PPM Model:

While there are some challenges while working with private laboratories, there are many opportunities that could be leveraged to strengthen the engagement. These are outlined in Box 2 and Box 3.

#### Box 2: Challenges in working with private laboratories

- o Given that TB services are free in Nigeria, it is difficult to balance the need to provide services at a minimal cost to the patient with the for-profit nature of the private sector. Private labs engaged under the PPM grant are not allowed to charge

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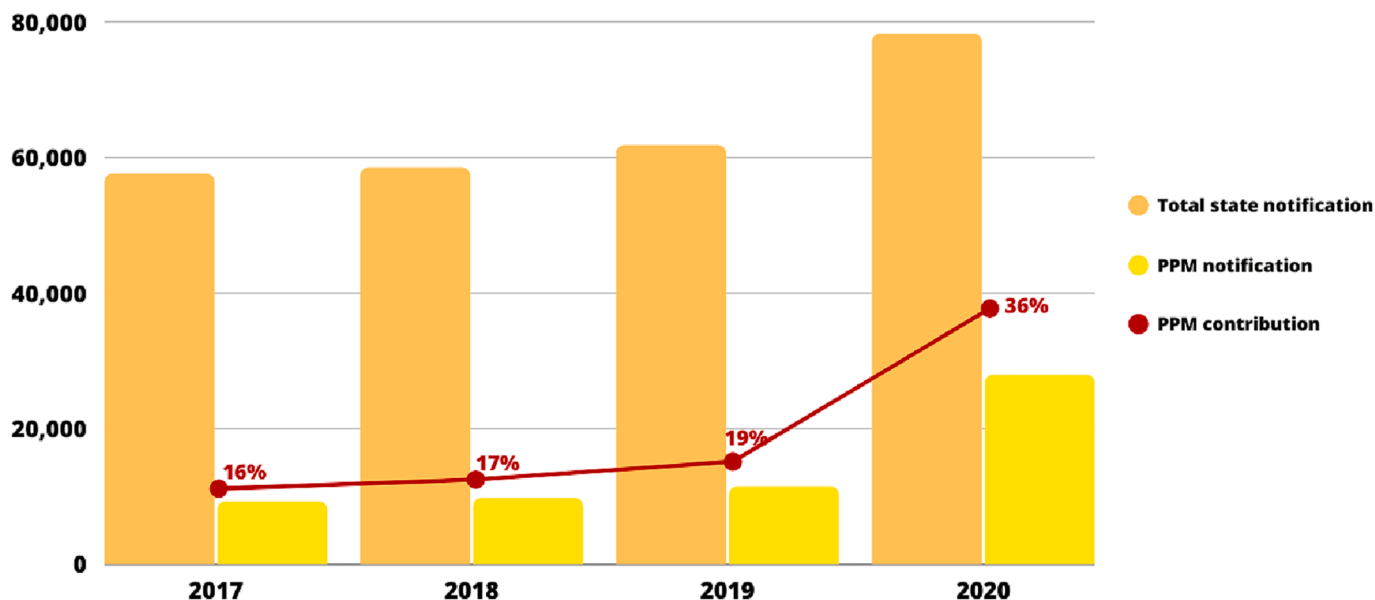


Fig. 3. PPM contribution to TB case notification in twenty-one States in Nigeria.



**Fig. 4.** Private laboratory work in Nigeria. (A) A medical laboratory scientist operating the 16 module GeneXpert machine in PPM facility: El-Lab Lagos (early placement of GeneXpert via SHOPSplus); (B) A medical laboratory scientist operating the 4 module GeneXpert machine in PPM facility: Zankli Reference laboratory Bingham University Karu Nasarawa state; (C) A medical laboratory scientist doing sample processing in a BSC for TB culture and DST in PPM facility: Zankli Reference laboratory Bingham University (Private sector) Karu Nasarawa state; (D) A medical laboratory scientist reading liquid cultures in a MGIT machine for TB culture and DST in PPM facility: Zankli Reference laboratory Bingham University Karu Nasarawa state.

(continued)

#### Box 2: Challenges in working with private laboratories

patients, however, there have been a few cases where facilities were charging the patients despite the agreement. On a case-by-case basis, these are addressed through the engagement of the facility leadership. It remains a challenge that there is no control over how much is charged.

Insurance efforts with TB packages in Nigeria are only in the early stages of development and implementation. Therefore, the government of Nigeria currently lacks routine payment channels required to reimburse the private sector.

Attempts to harmonize the incentive packages are sometimes not flexible enough to suit the demands of individual laboratories. As a result, some labs in high TB burden areas that are crucial to engage do not find engaging with the national program sufficiently lucrative.

While the current model is providing GeneXpert systems and other diagnostic supplies, private labs still face a bottleneck and are dependant entirely on the program to meet their needs. Even though machines have been provided to private facilities, they remain dependant on the program for commodities and reagents, instead of having control over their business planning.

Lack of access to quality assured commodities and PPEs is a supply challenge – especially during the COVID-19 pandemic.

The lack of regulation of private providers, especially within certain groups like informal providers, is a major challenge.

The standardization of practice across private labs and retention of laboratory personnel continues to be a challenge and needs more training and mentorship. The National Quality Assurance program has yet to fully integrate most of the private laboratories especially for microscopy while that of GeneXpert has a better uptake since there are less than 15% of GeneXpert systems in private laboratories. Routine mentoring and supportive supervision are conducted by the Local and State TB programs who also ensure that data from these private labs are integrated into the national database.

#### Box 3: Opportunities in working with private laboratories

Overall, engaged private laboratories have access to a multitude of incentives including financial incentives, staff trainings organized by NTBCLP and partners, free machines, equipment, reagents, consumables, commodities, and PPEs. They are permitted to use the equipment or supplies for other non-TB diagnostic tests for which they can receive a fee. For instance, microscopes can also be used to diagnose for malaria parasite, multiple chemical sensitivity, and other investigations.

Currently, a National PPM Steering Committee for TB (inaugurated in 2007 and  
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#### Box 3: Opportunities in working with private laboratories

revitalized in 2019) has been established and plans to decentralize to the states are in place. The coordination between private laboratory structures and national bodies for regulatory support has been a vital step. For instance, umbrella bodies such as the Guild of Medical Lab Directors have been actively engaged in the National PPM steering committee.

In addition to extensive and continuous surveillance, the private sector must have access to updated guidelines and SOPs (such as treatment guidelines, patient education SOPs, drug charts). Increasingly, policy documents and guidelines are now made available to private care providers. Some of these documents are also included in the national sample shipment and equipment maintenance network.

With private facilities increasingly engaging with the national TB program, quality assurance becomes critical. The NTBCLP engaged the private labs through the Quality Assurance Officers of the State TB Control Programs. Letters were written to the facility management of the private hospitals on the requirement to participate in the national EQA program. NTBCLP is scaling up the External Quality Assessment Proficiency Testing (EQA PT) program, to provides quality assurance for AFB smear microscopy, GeneXpert, TB culture and drug susceptibility testing (DST) at all PPM sites. The private labs were sensitised about this initiative during the initial trainings and were welcoming of this effort.

## 8. Conclusion

This partnership with the private sector is collaborative and thus ensures the commitment of the private sector to the national TB control response. The COVID-19 pandemic has shown the world the critical importance of early and rapid diagnosis [15] for clinical management of illness as well as for containing outbreaks, highlighting the importance of laboratories within the healthcare system. Building capacity in the private sector can help strengthen the overall response to TB.

#### Declaration of Competing Interest

The data on SHOPS Plus in this study is from a project that was funded through Sustaining Health Outcomes through the Private Sector (SHOPS) Plus, a 5-year cooperative agreement (AID-OAA-A-15-00067)

funded by the United States Agency for International Development (USAID). The project strategically engages the private sector to improve health outcomes in family planning, HIV, maternal and child health, and other health areas.

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