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Impact of Sputum Samples Logistics Coordination on TB Diagnosis in Nigeria

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Abstract: *The quality of Tuberculosis (TB) laboratory diagnosis and effective treatment of pulmonary tuberculosis is dependent on the accessibility of TB patient to diagnosis and the quality of the sputum sample tested. This study assessed the impact of sputum samples logistics coordination on TB diagnosis in Nigeria. This laboratory-based descriptive cross-sectional study was carried out in the Federal Capital Territory Abuja – Nigeria, using a questionnaire to collect information from 32 laboratory personnel in all 16 GeneXpert laboratories in Abuja. Data was quantitatively and qualitatively analyzed through the use of tables and figures. Descriptive data analysis was carried out with SPSS version 24 and Microsoft Excel version 2016.The study found that sputum samples are being handled by the right set of professionals. However, most centres only give instructions to patients on how to obtain samples without adequate or proper monitoring system and patients are mostly allowed to cough out in open. It was also found that samples delivery and result collections are mostly handled by non-professionals (drivers and patients). The study discovered that 3PLs were the most reliable coordinators of sputum samples and results transport logistics but their involvement in the processes is very limited. It is therefore concluded that for better and effective sputum sample logistics coordination, total involvement of 3PLs is imperative as this will increase the quality of sample in line with standard guidelines, timely sample submission, and result pick-ups among other benefits.*

Keywords: *Sputum, 3PL, logistics, Tuberculosis, diagnosis.*

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I. Introduction

Tuberculosis still represents an important global public health threat and it is one of the global leading causes of death[1,2]. The cumulative human suffering and economic losses caused by TB in Nigeria is immense. In Nigeria, there are limited facilities with TB services (GeneXpert Diagnosis). In 2015, the gap between the incidence and notified cases globally was 4.3 million. Nigeria is among the three countries (India, Indonesia & Nigeria) that accounts for 50% of this gap[3].

There are over 36,000 health facilities in the country[4]. Of this number, DOTS (Direct Observed Treatment, Short-course) facility is in only 20% of the primary healthcare facilities and 26% of all health facilities[4]leaving a huge gap of facilities that are yet to be involved in DOTS services. In this light, of this effective TB samples, referral or logistic system will help to increase access to TB services in facilities or community without TB services.

Out of over 36,000 health facilities in the country[4], there are only 382 GeneXpert Diagnostic sites in the country[5].Despite the ongoing active TB case search as declared by the Nigerian Minister of Health, interventions by foreign partners and non-governmental organizations, there is still limited access to TB diagnosis in Nigeria. This is basically due to challenges around quality sputum samples collection, samples packaging, and inadequate logistics coordination especially hard to reach rural areas. Limited access to TB diagnosis can result in increased drug resistance among confirmed TB cases, loss to treatment follow up and increase cases of undiagnosed TB. The major objective of this study is to evaluate the impact of sputum samples logistics coordination on TB diagnosis in Nigeria, focusing on GeneXpert laboratories perspective.

This study is very significant at this time because, in Nigeria, logistics and supply chain management is yet to be fully integrated into laboratory medicine (medical laboratory practice) especially in the area of laboratory diagnosis and samples movement. Hence the limited activities of logistics and supply chain industry in the sector. The reported activity of supply chain and logistics industry has been around laboratory reagent and commodities. Sample referral and coordination seem to not to have been given due attention. With the growing demand for customer satisfaction, access to laboratory diagnosis and effective health laboratory program intervention and implementation, the need for a robust relationship between the diagnostic companies (Medical laboratories) and supply chain & logistics industry is inevitable. The project identified the business potential for supply chain companies and also explored efficient ways to ensure cost-effective operation in the sector. It is also of importance to the health industry, to the government and other stakeholders. The project explored possible ways of increasing access to Nigerians to TB diagnosis with the aim of providing increased access to treatment. This ultimately is expected to reduce TB associated morbidity and mortality rate, reduce the disease burden in the society and reduce the risk of exposure to the disease by individuals who are vulnerable.

This study was carried out in the Federal Capital Territory in Abuja, Nigeria. The scope of the study included questionnaire-based interviews on TB testing platforms, available samples collection sites, distance of the collection sites to the communities, samples pick-up time, time of samples analysis and result return time. The quality of samples transport in line of compliance to WHO guideline was analyses. The laboratory personnel (TB testing laboratories) were engaged using questionnaire and analysis of key indicators or data.

II. Methodology

The study area is the Federal Capital Territory (FCT), a federated territory in central Nigeria. It is the area that hosts Abuja. It was carved out in 1976 from parts of Nasarawa, Niger, and Kogi states in the central parts of Nigeria. The territory is located just off the confluence of the River Niger and Benue River. It is bounded by the state of Niger to the west and north, Kaduna to the northeast, Nasarawa to the east and south, and Kogi to the southwest. It is laying between latitude 8.25 and 9.20 north of the equator and longitude 6.45 and 7.39 east of Greenwich Meridian. The FCT has a landmass of approximately 7,315 square kilometers of which the actual city, Abuja, occupies 275.3 square kilometers. Its natural resources include marble, tin, mica, zinc, lead tantalite and clay. FCT is governed by a Minister (appointed by the President) who heads the Federal Capital Territory Administration (FCTA). FCT is made up of six local area councils: Abuja Municipal, Gwagwalada, Kuje, Bwari, Kwali and Abaji area councils.

The target population of this study was 16 GeneXpert laboratories set aside for sputum test in Abuja, Nigeria. The staffs directly involved in sputum processes were chosen to participate in the survey. The sample size comprised 8 people from management categories, 10 supervisory cadre and 14 operational staffs from the 16 GeneXpert laboratories. The discriminate sampling process was used to systematically select eligible to avoid bias and/or lack of precision which are associated with convenience sampling[6].

A questionnaire was developed to capture the various variables under study and for the independent variables. The questionnaire contained both closed and open-ended questions. The closed-ended questions were aimed at giving precise information which minimized information bias and facilitated data analysis, while the open-ended questions gave respondents the freedom to express themselves.

To access the impact of 3PLs in expanding access to sputum sample testing, the questionnaire used contains explicit questions which were divided into four sections A – D. Section A contains respondent's details which include gender, state, local government, profession and name of the institution. Section B contains questions on specimen handling and management. Section C contained sputum sample laboratory workload section D contains challenges on diagnosis and management of sputum sample testing. Informed consent was written in the simplest form and was given to the subject prior to the survey. Informed consent contained the aims and objectives of the survey. The subjects were not required to sign an informed consent to ensure total anonymity. The survey questions were printed on paper and handed to the participants for completion.

The questionnaire was self-administered to the respondents and two research assistants were recruited and trained so that they were able to get quality results. Secondary data was collected from published sources such as libraries, internet, and research done by other scholars. The target participants were laboratory staff who filled in the questionnaires. These target participants had adequate knowledge about the challenges of sputum sample testing as well as impact of 3PL in sputum sample testing, considering their crucial role in management involvement.

Data Analysis

The returned and duly filled questionnaires were verified, coded and tallied according to the themes and thereafter quantitatively and qualitatively analyzed through the use of tables and figures. The findings of the survey were analyzed. Quantitative analysis was done and results presented in tables and figures. This analysis

was based on the responses obtained from the respondents. Descriptive data analysis was carried out by the use of SPSS version 24 and Microsoft Excel version 2016.

III. Results

Majority of respondents were males (19, 59.4%) while 13 (40.6%) were females.

Who collects specimen for the requested test?

Participants were asked to mention those involved in collection of sputum tests for requested tests. In all, 100% confirmed that Nurses were involved in specimen collection, 34.4% mentioned clinicians, and 53.1% confirmed lab scientists while 43.8% confirmed caregivers (Figure 1).

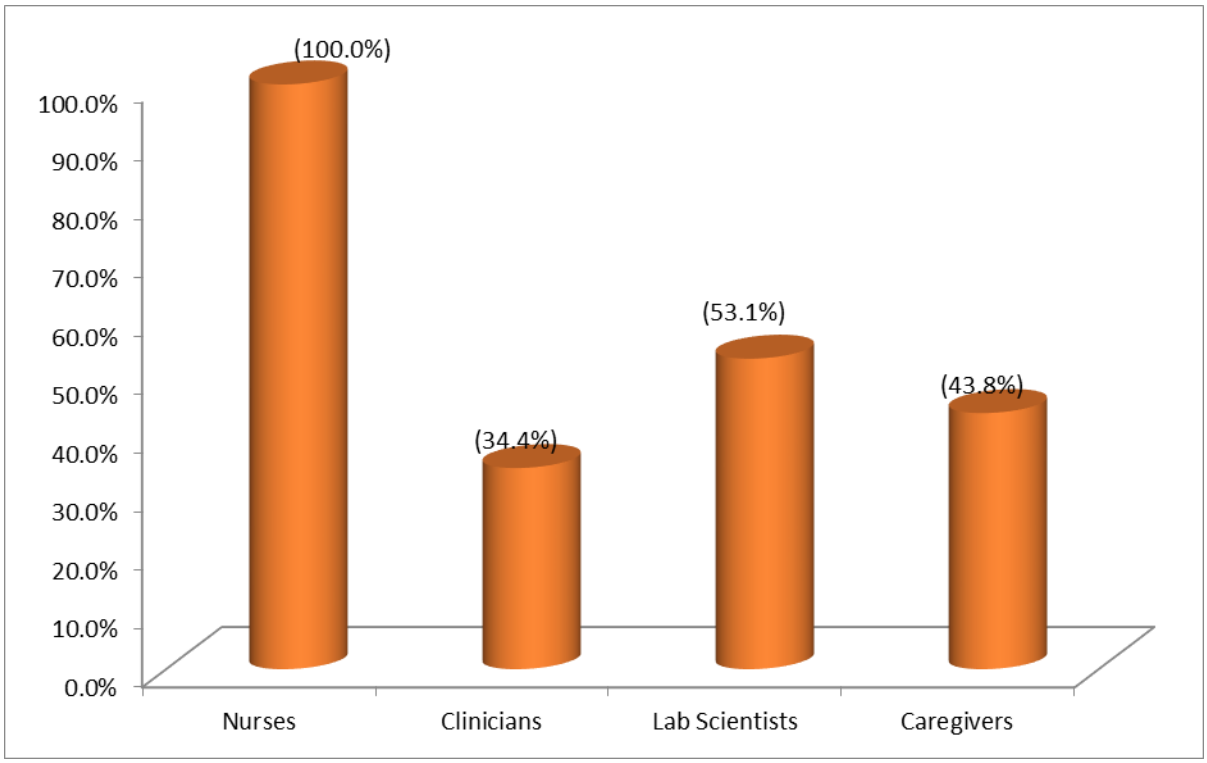

Figure 1: Who collect sputum samples for the required test

How does your facility collect sputum specimen?

As shown in Figure 2, the most common method of collecting the sample is by giving instructions to patients on how to get samples ready for testing. Other means of collecting samples include giving container to patients (19.0%), asking patients to cough outside the laboratory (17.5%) and 9.5% of the total population refer patients to DOT clinics while 11.1% affirmed that patients sometimes bring samples from home.

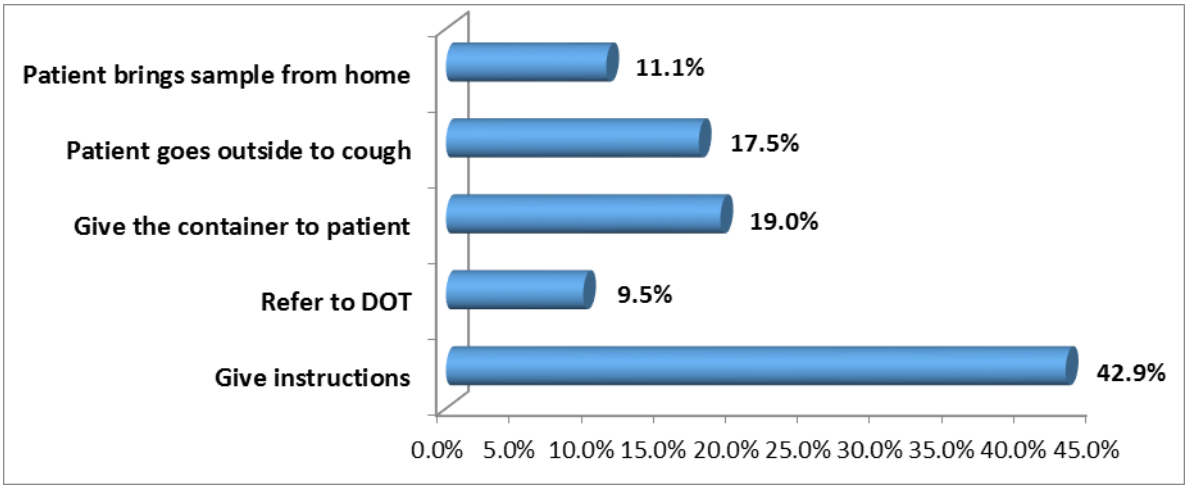

Figure 2: How specimen is collected

Where is specimen collection done?

In the majority of the laboratories, samples are collected in open space (outside the lab), 32.8% and clinics 25.4%. Some centres collect samples in the laboratory (22.4%) while some also collect samples in the wards (19.4%), (Figure 3).

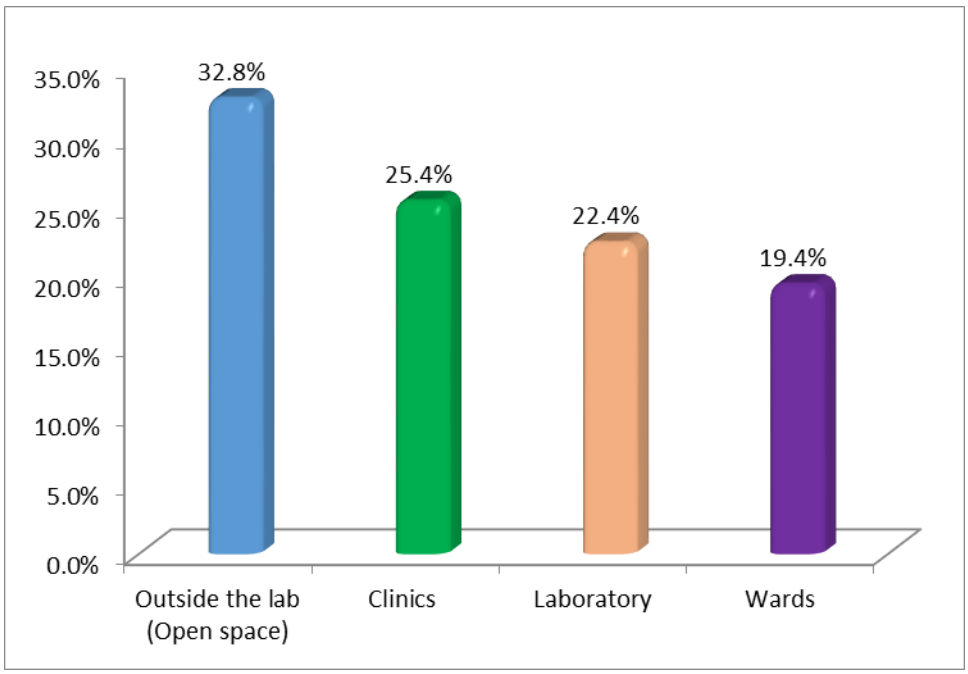

Figure 3: Place of sample collection

Sample submission and result pickups

Personnel involved in sample submission and result collection

Table 1 shows that 31.0% of those who take samples to GeneXpert laboratories are drivers (31.0%) followed by patients/relatives (28.0%) while clinicians/Nurses and #PL staff recorded 24.0% and 17.0% respectively. Table 2 shows a comparison of 3PL services with others who brings the specimen to laboratories for tests. All Respondents (100.0%) confirmed that only 3PL transport specimens in cold chain, use transport box labeled as dangerous, adequately document transport temperature and have functioning temperature monitoring devices (thermometers).

Table 1: Who bring samples or collects results

	Who brings sputum specimen	Who collects results
Drivers	31.0%	34.8%
Patients/Relatives	28.0%	27.5%
Clinicians/Nurses	24.0%	23.2%
3PL staff	17.0%	14.5%

Table 2: Comparison of 3PL services with other sources involved in transporting samples and results

Comparing parameter	3PL	Others
Transport sample in cold chain	100.0%	-
Transport box labeled as dangerous	100.0%	-
Transport temperature documentation	100.0%	40.0%
Timely sample drop off and result pick up	80.0%	50%
Sample rejection	-	30%
Proper record documentation	85%	80%
Knowledge of guidelines/SOP/Manual	90%	30%
Functional temperature monitoring device	100.0%	-
Sample quality	96%	63%
Communication with the lab	85%	35%
Triple packaging	100.0%	<10%

Checks for sample delivery

Participants were asked questions related to checks for sample delivery in their facilities. The findings showed that 30.3% of total participants confirmed that samples did not usually get to their facilities at the normal temperature of 2 ^{0}C to 8 ^{0}C. All participants admitted that samples can be taken to their facilities without prior appointment; only 50% confirmed that samples are most times accompanied with all required documentation; 36.3% stated that only sometimes do sample transporters record arrival date and time on sample transport forms; 56.7% affirmed that samples are sometimes rejected while 33.3% stated that samples are mostly rejected (Table 3).

Table 3: Checks for sample delivery

Conditions	Not at all	Sometimes	Most times
Samples arrive at 2^{0}C to 8 ^{0}C and documented on sample transport forms	-	30.3%	61.7%
Samples are brought for testing lab only on appointment	100.0%	-	-
Samples are accompanied with all required documentation? (sample transport form and patient test request form)	10.0%	40.0%	50.0%
Arrival time and date are documented in the sample transport form?	-	36.3%	66.7%
Duplicate copies of signed sample transport forms are left at the testing sites	16.7%	83.3%	-
Sample are rejected	-	66.7%	33.3%

Challenges in specimen referral system with recommended ways out

Participants were asked to mention the challenges being faced by their centers in relation to sample logistics. Table 4 shows a summary of the challenges. All participants mentioned late arrival of samples and limited access to hard-reach areas as important challenges faced in specimen referral system 93.0% mentioned non-compliance with transport conditions, 85.0% confirmed that samples were not usually submitted in triple packaging. Other challenges include poor sample quality (76.2%) and poor record documentation (65.0%).

All participants (100.0%) recommended the use of 3PLs in sample coordination and all (100.0%) suggested regular training for all personnel involved in sputum sample testing processes. Other suggestions include functioning communication system for easy sample coordination (75.0%), proper record documentation (85.0%) and regular supervision/monitoring (73.0%) as shown in Table 5.

Table 4: Challenges in the specimen referral system

Challenges	Average % rating
Late arrival of the specimen	100.0%
Non-compliance with transport conditions such as packaging, temperature	93.0%
Sample not in triple packaging	85.0%
Limited access to remote areas	100.0%
Poor sample quality	76.2%
Poor record documentation	65%
No technology/software for real times result ina return to patients/collection centres	100.0%

Table 5: Recommendations for proper sample coordination

Way out	Average % rating
Use of 3PL	100.0%
Creation of a functioning communication system for easy sample and result pickups	89.4%

Use of internet for easy access to results	75.0%
Regular training of patients and staffs	100.0%
Proper record documentation	85%
Regular supervision/monitoring	73%
Expansion of DOTs to hard-to-reach areas	100.0%

IV. Discussion

The discussion is broken into specimen management/handling, sample/result transportation, the impact of sample logistics coordination on TB diagnosis, the challenges and the way out in sputum sample logistic coordination.

Impact of specimen management/handling of TB diagnosis

The findings of this study showed that the collection of specimens for testing is mostly handled by experts such as Nurses, clinicians, and laboratory scientists. This might not be unconnected to the fact that the focused laboratories for this study are specially designated to handle sputum testing or because most referring centres were fully aware that the GeneXpert laboratories may reject specimens not comply with standard requirements.

It was also found that most facilities just give instructions to patients on how to get a specimen for testing, some merely give containers to patients and leave them to go and bring samples while some ask patients to go out and cough. However, samples brought from home are also accepted while only a few centres refer patients to DOT clinics for sample collection. Over 30% of the participants confirmed that sputum samples are rather collected in open space (outside the laboratory) while just 25% use DOT laboratories. This implies that about 75% of the facilities collect sputum samples outside DOT clinics. The mode and place of specimen collection might be because the samples needed are just sputum which might not require the assistance of experts. However, the possibility of other people being infected with TB should be considered, most especially patients are asked to go and cough in open space where it is possible to have people that are not currently being infected with TB. This is a concern as it has been documented that TB is spread from person to person through the air. When people with lung TB cough, sneeze or spit, they propel the TB germs into the air. A person needs to inhale only a few of these germs to become infected[1,7,8]. It has even been recorded by WHO that about one-quarter of the world's population has latent TB, which means people have been infected by TB bacteria but are not (yet) ill with the disease and cannot transmit the disease[8]. According to Zaman [9], Tuberculosis (TB) is an ancient disease that has affected mankind for more than 4,000 years. It is a chronic disease caused by the bacillus *Mycobacterium tuberculosis* and spreads from person to person through air. He further suggested that one of the ways to avoid rapid spread of TB include the development of an effective surveillance system [9].

Impact of sample/result transportation on TB diagnosis

This study found that specimens were being taken to and results collected from laboratories by drivers/riders who were not registered 3PL staff. It was also discovered that patients/relatives even clinicians/nurses do take samples to laboratories. The 3PL services were not fully involved in sample logistics system as they recorded less than 20% involvement in taking samples to laboratories and less than 15% involvement in taking transporting sample results to patients or referral points. This might not be unconnected to the high cost of 3PL services or poor awareness of the importance and services of 3PLs in sputum sample logistics

Despite the low involvement of 3PLs in sputum sample logistics, they had the record of best services because only the 3PLs transport samples to the laboratories in cold chains, use transport box labeled as dangerous, have good transport documentation, have functioning temperature monitoring devices and the only ones who deliver samples in triple packaging. Only samples from 3PLs are not usually rejected. They deliver samples in time and collect results timely. They also deliver high-quality sputum samples, unlike other sources which usually face sample rejection. Due to poor sample collection, transportation, and handling, previous reports have reported poor sputum qualities [10–12]. Aparna *et al.*[13]emphasized the need of proper patient education before obtaining the sputum sample and timely monitoring during collection time can be helpful to obtain good quality sputum to enhance the diagnostic yield of sputum based molecular diagnostic tests to facilitate timely treatment which is the main goal of the TB control program.

Nayak et al.[14]conducted on the effectiveness of sputum collection and transport model for the diagnosis of Tuberculosis and its impact on case notification in Chhattisgarh, India. In India, non-governmental organization/private sector supported sputum collection centres were established across the country in order to improve the reach and access of TB diagnostic services to the needy populations. However, there were concerns about the quality of sputum specimens transported from the collection centres and the low yield of sputum positive cases in such specimens. They finally found out that samples from these centres only accounted for about 11% of all smear-positive. There is, therefore, need for proper monitoring of sputum sample transport.

Challenges of sample logistics coordination on TB diagnosis and the way

It was found through participants that only 3PL logistics deliver sputum samples at a temperature between 2 ^{0}C to 8 ^{0}C but not so for others. Also, most times, samples are not accompanied with all required documentations except the samples from 3PLs. A similar challenge is being experienced with arrival time and date on transport documentation. So, samples are sometimes rejected except those from 3PLs.

The major challenges faced by all centres include late arrival of specimens, non-compliance with transport conditions, samples not in triple packaging, distance barrier (for hard to reach areas) poor sample quality, poor record documentation as well as lack of technological (software) means for real-time return of results to patients or collection centres.

To overcome the challenges of sputum sample logistics coordination, participants suggested full involvement of 3PLs, creation of easy communication system for easy sample coordination, use of the internet, regular training for patients and staff as well as proper record documentation.

There have been similar challenges and recommendations reported in previous studies. Zaman [9]reported that there were several challenges which need to be addressed for effective control of TB, particularly in developing countries. These include the development of an effective surveillance system, accelerated identification of cases, expansion of DOTS to hard-to-reach areas, strengthening of DOTS in urban settings, ensuring adequate staff and laboratory facilities, involvement of private practitioners, treatment facilities for MDR cases, identification of TB among children and extra-pulmonary cases, and effective coordination among healthcare providers[9,13,15,16].

V. Conclusion

This study found that sputum samples are being handled by the right set of professionals. However, most centres only give instructions to patients on how to obtain samples without an adequate or proper monitoring system. It was also found that patients are mostly allowed to cough out in open spaces apart from DOTs, which may cause further spread of the disease. It was also found that samples delivery and result collections are mostly handled by non-professionals such as drivers and patients and only on few occasions do train personnel such as clinicians, Nurses or 3PL staff handle sample transport logistics. The study showed that 3PLs were the most reliable coordinators of sputum samples and results in transport logistics but their involvement in sputum testing processes is very limited. It is therefore concluded that for better and effective sputum sample logistics coordination, total involvement of 3PLs is imperative as this will increase the quality of sample in line with standard guidelines, timely sample submission, and result pick-ups among other benefits.

Conflict of interest

The authors declare that there is no conflict of interest.

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