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Assessment of Tuberculosis Drugs and Diagnostics in Katsina Central, Katsina State, Nigeria

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Abstract

Tuberculosis is one of the deadliest bacterial infections globally, and Nigeria accounts for an estimated 4.4% of the global TB burden. This study aims to assess the availability and inventory management of tuberculosis drugs and diagnostics at Directly Observed Treatment Short Courses (DOTs) centers in Katsina Central Senatorial District. A cross-sectional descriptive survey involving qualitative and quantitative methods was carried out using a semi-structured questionnaire adapted from the USAID logistics system assessment tool. Ten (10) DOTs centers were selected using a multi-stage sampling method. Data was collected through direct observation and interviews of the DOTs Officers, Local Government Tuberculosis Supervisors, the Logistics Officer of the Tuberculosis Program, and pharmacists from the State Drugs and Medical Supply Agency. It was found that all the drugs for the treatment of Drug Sensitive Tuberculosis were in stock at the central store; however, for the treatment of Drug-Resistant Tuberculosis, only moxifloxacin, clofazimine, and protionamide were in stock. At the DOTs centres, all the drugs for the treatment of Drug Sensitive Tuberculosis were in stock in 9 (90%) of the facilities, and 6 (60%) of the facilities had access to sputum microscopy tools for the initial diagnosis of tuberculosis. Some drugs for the treatment of Drug-Resistant Tuberculosis were in stock in only 1(10%) of the facilities. The drugs in stock cannot complete any of the treatment regimens for Drug-Resistant Tuberculosis. Only 3(30%) of the facilities can detect rifampicin-resistant Mycobacterium tuberculosis using either Gene Xpert or Trunat, while none of the facilities have the capacity to detect M. tuberculosis resistance to isoniazid and other second-line drugs. Stock cards were available in all DOTs centres where drugs are available, but 6 (56%) of the facilities update them in real-time, and 7(67%) of the facilities conduct a periodic physical inventory. First-line drugs for the treatment of tuberculosis were generally available, and the availability of initial diagnostic tools/machines for tuberculosis was fairly adequate. However, the drugs for the treatment of Drug-Resistant Tuberculosis were generally out of stock. Furthermore, the inventory management of the Tuberculosis commodities needs improvement

Keywords: Diagnostics, Directly Observed Treatment Short Courses, Drugs, Inventory Management, Tuberculosis

INTRODUCTION

Tuberculosis (TB) is the most common cause of death from a bacterial infection worldwide. An estimated 1.4 million deaths among HIV-negative individuals and 187,000 deaths among HIV-positive individuals were reported in 2022 Mbewana *et al.* (2023). Nigeria accounts for an estimated 4.4% of the global TB incident cases and, together with 7 other countries, accounted for two-thirds of the global TB burden (Abayomi *et al.*, 2022). According to the World Health Organization, Nigeria is one of the 10 high TB burden countries where the best estimates for treatment coverage are below 50% (WHO, 2022a). TB statistics are a cause of concern in Katsina State, as the state contributes significantly to the number of unreported cases

of tuberculosis: together with 12 other states and the Federal Capital Territory, they accounted for more than half of all unreported cases in Nigeria (Bajehson *et al.*, 2019). Therefore, these states were given priority for an intensified intervention package, including active case-finding, by the National Tuberculosis, Leprosy, and Buruli Ulcer Control Programme (NTBLCP). New diagnostic tools and a structured laboratory network system were implemented nationwide as part of the 2014 National Strategy Plan for TB Elimination (FMOH, 2015).

The success of the World Health Organization's (WHO) END-TB strategy is being threatened by the rise of drug resistance to antimicrobials by Mycobacterium tuberculosis. According to WHO estimations, the percentage of Drug-resistant tuberculosis patients in Nigeria is 4.3% among new cases and 25% among individuals who have already received treatment (Onyedum *et al.*, 2017). Nigeria is one of the 30 high-burden countries for tuberculosis (TB), multidrug-resistant tuberculosis (MDR-TB), and tuberculosis/HIV (Nneka, 2020). In Nigeria, the programmatic management of drug-resistant tuberculosis (DR-TB) began in 2010, supporting the care of all patients with isolates of any strain of rifampicin-resistant tuberculosis (RR-TB), multidrug-resistant tuberculosis (MDR-TB), or extensively drug-resistant tuberculosis (XDR-TB) (WHO, 2017). In 2022, WHO updated the hierarchy of anti-TB drugs by the WHO (WHO, 2022b). However, not much is known about the availability of drugs for drug-susceptible (DS), multi-drug-resistant (MDR)/rifampicin-resistant (RR), pre-extensively drug-resistant (pre-XDR), and extensively drug-resistant (XDR) TB. (Manalan et al., 2020; Feuth et al., 2021) Previous research from the nearby state of Kaduna demonstrated the presence of minor hiccups in the quality and provision of anti-tuberculosis medications because of logistical issues, laboratory services, reagent shortages, and irregular electricity supplies (Adamu and McGill, 2018; Ibrahim *et al.*, 2021). As a result, it is necessary to evaluate the tuberculosis drugs' and diagnostics' availability and inventory management in the Katsina central senatorial district to detect whether these or other hiccups are present or otherwise, as this directly impacts the availability of drugs for managing tuberculosis, and has consequential broader impacts on public health.

MATERIALS AND METHODS

Study Area

Katsina central senatorial district (Figure 1) is one of the 3 senatorial districts of Katsina state, which consists of 11 local government areas (LGAs). The LGAs include the state capital (Katsina LGA), which has the highest population in the state, together with 10 other LGAs, which are Charanchi, Rimi, Batagrawa, Dutsinma, Safana, Danmusa, Kurfi, Jibia, Batsari, and Kaita. Katsina state is divided into 34 LGAs with an estimated population of over 7.8 million consisting of slightly more males (50.8%) than females (49.2%) (City Population, 2023). The state is one of the 36 States of the Federal Republic of Nigeria situated in the Sahel Savanah of the North-Western region of the country and covers a land area of 24,192 square km (Milaham *et al.*, 2022). The state is relatively flat and lies within the tropics between latitude 11°00' to 13°25'N and Longitude 6°45' to 9°05E, and Kano and Jigawa states bound it to the east; Kaduna state on the South; Zamfara state on the west and shares international borders with the Republic of the Niger on the North (UN, 2023).

Study design

The study was carried out using a descriptive cross-sectional study design. Data was collected at a given point of time at the study sites, and this information was used to describe the availability of the TB drugs and diagnostics together with the assessment of their inventory management in Katsina Central Senatorial District. The study used both quantitative and qualitative methods. The quantitative method was employed to assess the availability of the drugs and diagnostics tests at the health centres and also the utilization of basic inventory management tools. The qualitative method was used in describing the inventory management procedure for tuberculosis drugs and laboratory diagnostic commodities.

Study Population

All the DOT sites in the 11 Local Governments of Katsina Central Senatorial District were included in this study, encompassing primary health facilities, secondary health facilities, and the

State Tuberculosis, Leprosy and Buruli Ulcer Control Program (STBLCP) office. The State Drugs and Medical Supply Agency was also included, as it is responsible for the procurement and storage of tuberculosis drugs and consumables

Ethical Approval

This study was approved by the Health Research Ethical Review Committee (HREC) of the Katsina State Ministry of Health, and an ethical clearance certificate was granted (HREC number = MOH/ADM/SUB/1152/1/717)

Sampling Technique

The sampling was done according to the WHO guidelines on the assessment of the availability of drugs (WHO, 2015). Multi-stage sampling technique was used for the selection of local government and health centres. The first stage was the selection of the LGAs to be studied among the 11 local governments in the district. Katsina local government was first selected which is housing the STBLCP office. The second stage was selecting an additional 4 LGAs from the 9 local remaining using simple random sampling. As a result, Batagarawa, Kaita, Rimi, and Jibia were selected and, together with Katsina, made a total of 5 LGAs for the study. The third stage used stratified random sampling by grouping DOTs centres in each local government into primary and secondary health centres, two health centres were then randomly selected from each group. This gave us a total of 10 DOTs centres across 5 local government areas.

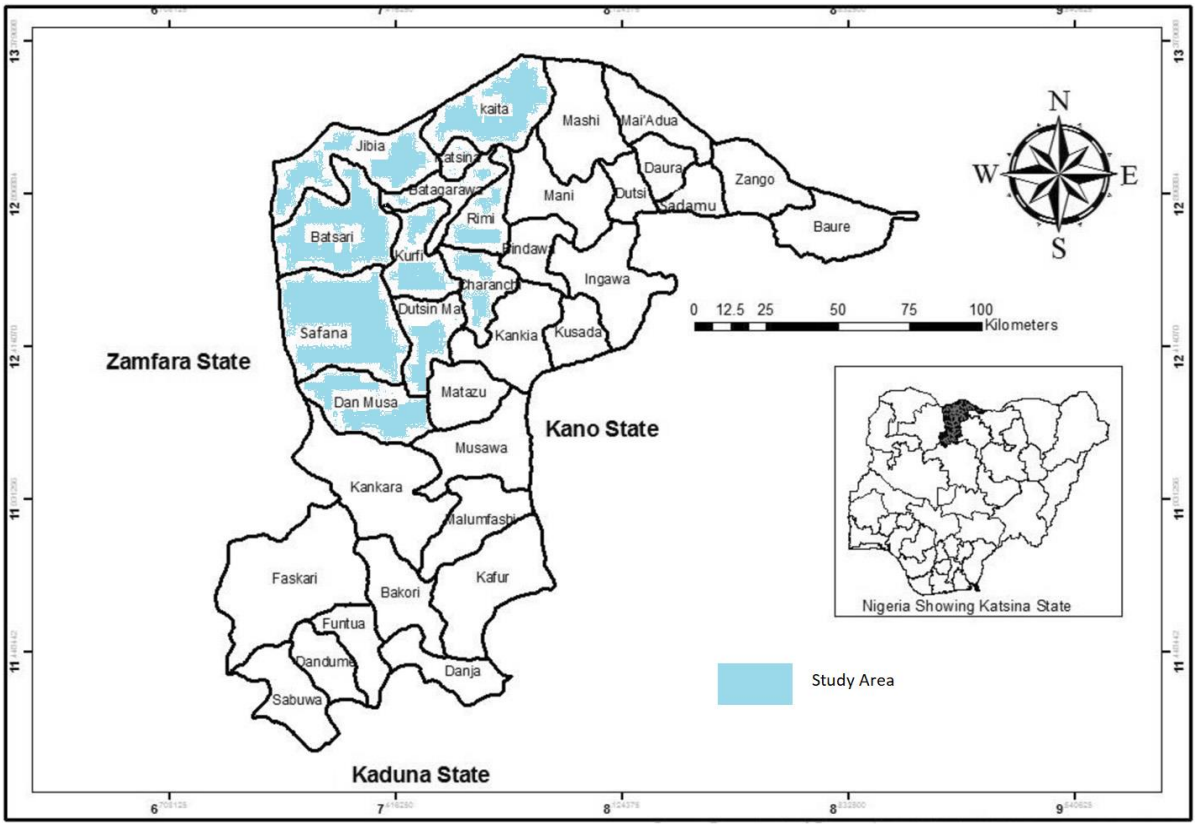

Figure 1: Map of Katsina state highlighting the study area. Source: Ibrahim *et al*. (2016)

Data Collection Instruments

The primary data were collected by administering semi-structured questionnaires. The questionnaire was used to interview the participants and also guide the researcher on direct observation. Secondary data was collected from the patient registers, stock cards, requisition and issue vouchers. Close-ended questions were mostly used, but there were a few instances where open-ended questions were used.

Validity and Reliability of Data

Abridged questionnaires and checklists adapted from the Logistics System Assessment tool (LSAT)

prepared by the USAID DELIVER Project was used for the assessment of the availability and stock management (USAID | DELIVER PROJECT, Task Order 1, USAID, 2009). The Medical and patient data was collected using the global fund TB indicators (Global Fund, 2023). These standard tools were developed and used by international organizations and, therefore, were valid and reliable.

Data collection

The principal investigator on site did the data collection. Each facility was visited, and interviews were conducted using the questionnaire. The components of the questionnaire were first introduced to the participants, and then the in-depth interview was conducted, and direct observation was done in the process. Data collected included the current availability of the drugs and diagnostics, stock outs history, information that described the procedures followed when ordering and receiving tuberculosis medicines, how stock levels were managed as well as how they respond to cases of stock outs. The key informants identified were the DOTs Officers, Medical Laboratory Technicians & Medical Laboratory Scientists (where applicable), Local Government TB supervisors (LGTBS) (when available in the facilities), the Logistic Officers of the STLBCP, and Pharmacists at the State Drug Management and Supplies Agencies. The interviews were tape-recorded with the consent of the interviewees. After the interviews, 2021, 2022 and 2023 patient data were collected from respective patient registers.

Data Analysis

Data analysis was done immediately after the completion of data collection. Data was entered manually from the questionnaires into an Excel sheet. The data was then checked and cleaned by a system of double entries into two separate spreadsheets, and the spreadsheets were then compared and cross-checked. The Microsoft Excel software was used to analyze the data to generate frequencies, percentages and averages.

RESULTS

In Table 1 below. The results revealed that centers had recorded varying numbers of cases, with the highest cases for drug-sensitive tuberculosis recorded in Katsina Center 1 (307) in the year 2022. Results of drug-resistant tuberculosis cases showed very low prevalence in the studied area. In addition, an account of successfully treated (cured) cases were given in Table 1 below, and the percentages of documented treatment outcomes are presented in Table 2, with the exception of some years which weren't considered because the patients were still in the process of receiving treatment, i.e., therapy is ongoing.

Figure 2 below shows that the first-line drugs for the treatment of drug-sensitive TB were generally available, while those for the treatment of Drug-resistant TB have were out of stock across the facilities.

The number of facilities where each diagnostics test and its consumables are available among the studied facilities is presented in Table 3. It also showed the number of facilities where stock out occurred in the last 12 months for each test and its consumable and the percentage of facilities where the stock out occurred among the studied facilities. The graphical presentation of the availability of diagnostics tests across the DOTs centres surveyed is shown in Figure 3 below.

The parameters assessed for the inventory control are the presence of the updated stock card and the conduct of periodic physical inventory at both the central store and the DOTs centres. The program made provisions for stock cards, which also serve as dispensed to user records at the DOTs centres. It was found that there was no stock card for all the items in central stock. However, quarterly inventory was conducted as it is a prerequisite for placing quarterly orders. For the DOTs centres, Table 4 below and Figure 4 show the compliance of the inventory control measures across the facilities.

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Table 1: Proportion of Documented and Cured Drug-sensitive and Drug-resistant Tuberculosis Cases in the Study Area

	Total TB cases						Cured					
	2021		2022		2023		2021		2022		2023	
	S TB	R TB	S TB	R TB	S TB	R TB	S TB	R TB	S TB	R TB	S TB	R TB
KTN_1	286	0	307	2	195	2	120	0	101	0	18	N/A
KTN_2	69	0	101	0	72	0	0	0	0	0	0	N/A
JBY_1	86	0	110	1	62	0	18	0	39	0	4	N/A
JBY_2	N/A	0	N/A	0	N/A	0	N/A	0	N/A	N/A	N/A	N/A
RMY_1	99	5	91	2	89	3	18	4	16	2	3	N/A
RMY_2	7	0	2	0	10	0	0	0	0	0	0	N/A
BTG_1	38	0	53	0	28	0	0	0	0	0	0	N/A
BTG_2	N/A	0	10	0	20	0	0	0	0	0	0	N/A
KAT_1	149	0	263	0	235	0	72	0	1	0	32	N/A
KAT_2	8	0	6	0	6	0	0	0	2	0	0	N/A

Keys: KTN- Katsina, JBY- Jibiya, RMY- Rimi, BTG- Batagarawa, KAT- Kaita, NA-Not Applicable, S TB- Drug Sensitive Tuberculosis, R TB- Drug Resistant Tuberculosis.

Table 2: Percentage of Treated Drug-Sensitive and Drug-resistant Tuberculosis Cases in the Study Area.

	% Treatment Outcome Documented					
	2021		2022		Average	
	DS TB	DR TB	DS TB	DR TB	DS TB	DR TB
KTN_1	120 (41.9)	0	101(32.8)	0	110(46)	0
KTN_2	0	0	0	0	0	0
JBY_1	18 (20.9)	0	39 (35.4)	0	29 (29.9)	0
JBY_2	N/A	N/A	N/A	N/A	N/A	N/A
RMY_1	18(18.1)	4(80)	16(17.5)	2(100)	17(17.3)	4(90)
RMY_2	0	0	0	0	0	0
BTG_1	0	0	0	0	0	0
BTG_2	N/A	0	0	N/A	0	N/A
KAT_1	72(48.3)	0	1(0.38)	0	37(36.5)	0
KAT_2	0	0	0	2(33.3)	0	0

Keys: KTN- Katsina, JBY- Jibiya, RMY- Rimi, BTG- Batagarawa, KAT- Kaita, NA-Not Applicable, DS TB- drug sensitive tuberculosis, DR TB- drug resistant tuberculosis.

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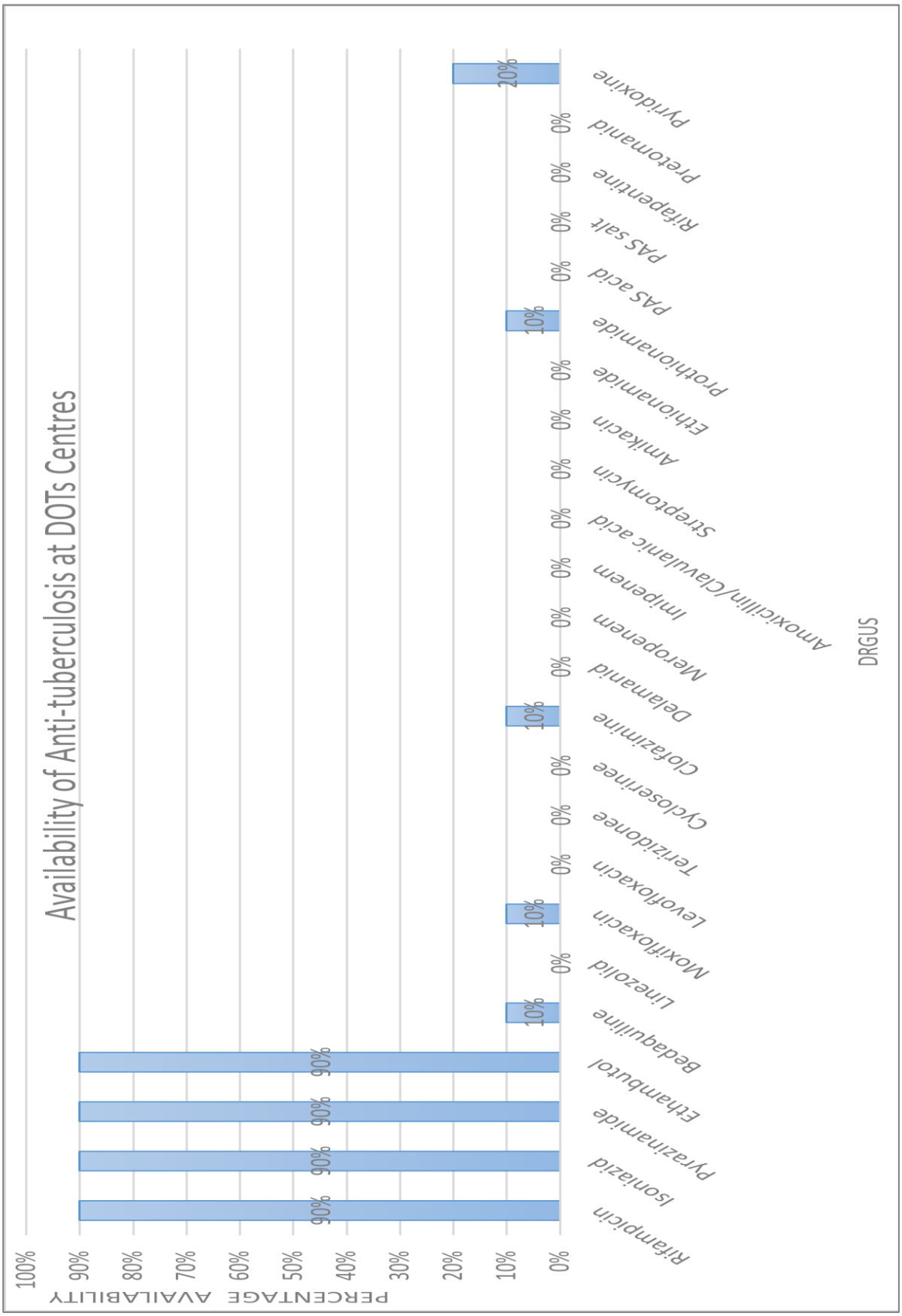

Figure 2: Availability of Anti-tuberculosis at DOTs Centers

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Table 3: Availability and stock-outs of TB test consumables at DOTs centers

Test/Consumable variable	Availability N=10 (%)	Stock out last in the last 12 Months N=10 (%)
Sputum Microscopy	6 (60)	1 (14)
0.3% carbol fuchsin	6 (60)	1 (14)
0.3% methylene blue	6 (60)	1 (14)
Acetone	6 (60)	1 (14)
Slides	6 (60)	1 (14)
Immersion oil	6 (60)	1 (14)
GeneXpert MTB/RIF rapid testing	2 (20)	1 (33)
Catridges	3 (30)	0%
Line Probe Assays	0 (0)	N/A
Nipro NTM + MDRTB detection kit 2	0 (0)	N/A
MTBDRplus assay	0 (0)	N/A
Culture Methods (DST)	0 (0)	N/A
BACTEC 460/960	0 (0)	N/A
Löwenstein-Jensen	0 (0)	N/A
7H10/7H11 agar	0 (0)	N/A
1G/2G Color plates	0 (0)	N/A
Chest X-ray	1 (10)	0%
Other diagnostics available*	2 (20)	0%

* 1 facility have TB LAMP, and another has Trunat and TB LAMP

LAMP- Loop-Mediated Isothermal Amplification

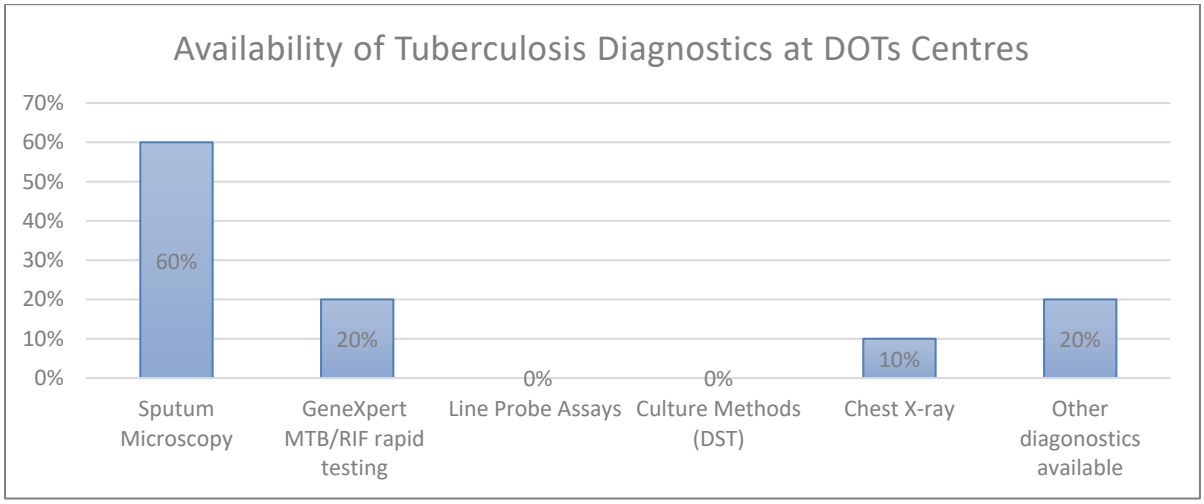

Figure 3: Availability of Tuberculosis Diagnostics at DOTs Centre

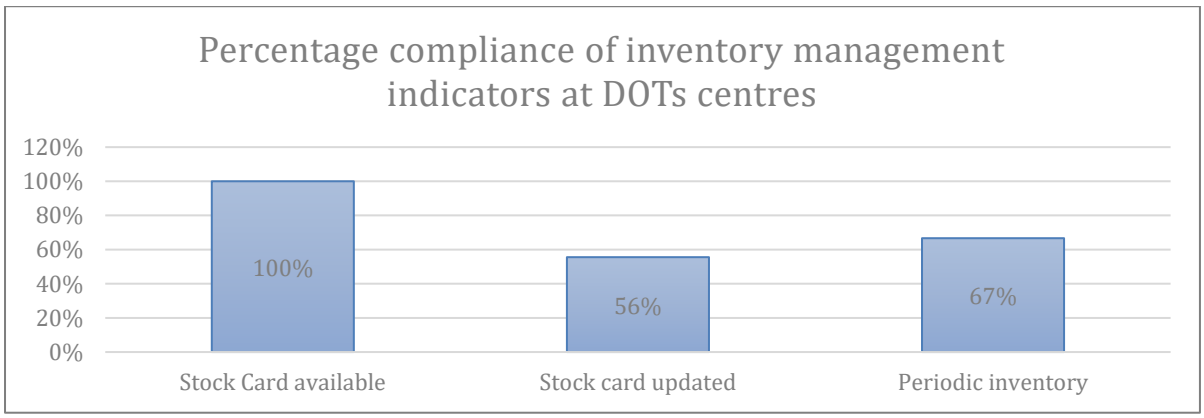

Figure 4: Compliance of inventory management indicators at DOTs centers

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Table 4: Compliance of inventory management indicators at DOTs Centres

	Stock Card available	Stock card updated	Periodic inventory
KTN_1	Y	Y	Y
KTN_2	Y	Y	Y
JBY_1	Y	Y	Y
JBY_2	N/A	N/A	N/A
RMY_1	Y	Y	Y
RMY_2	Y	N	Y
BTG_1	Y	N	N
BTG_2	Y	N	N
KAT_1	Y	Y	Y
KAT_2	Y	N	N
Percentage Compliance	100%	56%	67%

Key: Y- Yes, N-No and NA- Not Applicable

DISCUSSIONS.

The 10 DOTs facilities that were included in this study have varying volumes of activities, with a facility having as high as 307 cases of tuberculosis in a year to a facility that has zero for drug-sensitive tuberculosis. The facility with zero patients claimed that they used to have patients, but they refer them to other facilities due to drug stock-out. Overall, there are not many drug-resistant tuberculosis cases in healthcare facilities; only three centers reported a case in the previous three years. Additionally, the percentage of drug-resistant tuberculosis cases compared to drug-resistant tuberculosis patients is lower than the national average (WHO, 2017). This could be an indicator that there is a low burden of drug-resistant tuberculosis across Katsina Central Senatorial District. The drugs for the treatment of drug-sensitive tuberculosis were supplied at regular intervals (full supply commodities) and are available in 90% of the facilities surveyed. This is in agreement with the findings of Oyediran (2019) that the vast majority (92%) of institutions evaluated in Nigeria had first-line TB medications on hand on the day of data collection, and 85% of patients with drug-resistant TB (DR-TB) had begun second-line therapy within the previous year. Even so, above both the global average (61%) and the national average (44%) (WHO, 2022a). The only facility that had no drugs for the treatment of drug-sensitive tuberculosis had no patients in the last 3 years. However, from a program management perspective, keeping drugs where there are no patients will lead to waste due to expiries. There was no stock-out in the 90% of facilities in the last 12 months for drug-sensitive tuberculosis medications. However, the above findings were in contrast to the findings of Adamu *et al.*, 2024 which reported more than a quarter of DOTs centers in Niger states having unavailability of TB Drugs.

The availability of drugs for the treatment of drug-resistant tuberculosis is generally inadequate across the DOTs centers. At the central store, only Moxifloxacin, clofazimine, and Prothionamide were in stock, and they have experienced stock out in the last 12 months. None of the drug-resistant tuberculosis drugs were fully supplied commodities. Therefore, they were not received at any regular intervals. In resource-constrained environments like West Africa, the availability of these second-line medications may be restricted, which could impact the capacity to treat all DR-TB patients who have been diagnosed appropriately. For instance, o f the 1,131 MDR-TB cases that were diagnosed in Ghana between 2018 and 2022, 956 (84.5%) underwent therapy (Otchere et al., 2024). At the DOTs centers, only 1 facility had Bedaquiline, while another one had Moxifloxacin, Clofazimine, and Prothionamide. The latter had these drugs by virtue of being at the same location as the central store. This outcome differs from that of Europe, where Gunther et al. (2023) observed that imipenem/meropenem (40%)—a combination of medications used in the treatment of XDR-TB—had the lowest drug availability.

In summary, neither the central store nor the DOTs centers had enough drugs to make any of the 3 regimens recommended by the WHO for the treatment of drug-resistant tuberculosis. The unavailability of the drugs could be attributed to the low burden of drug-resistant tuberculosis. There is still a need for drugs in order to control the spread of drug-resistant tuberculosis. The facilities data might also not be conclusive, given the poor documentation of the treatment outcomes of drug-sensitive

tuberculosis. Therefore, there is a possibility of the development of resistance that might not be detected. The unavailability of drugs can lead to an increase in healthcare costs (Bateman, 2013; Magadzire *et al.*, 2014) and antimicrobial resistance (Harries *et al.*, 2007; Pasquet *et al.*, 2010; Adamu *et al.*, 2024).

According to WHO (2013), Gene Xpert is the current gold standard in the initial diagnosis, detection of rifampicin resistance, and confirmation of cure. This study found that it is only available in 20% of the facilities which are all secondary. In the absence of Gene Xpert, 60% of the health centers relied on sputum microscopy for the initial diagnosis of tuberculosis. In addition to sputum microscopy, TB LAMP is available in 2 facilities, while Trunat, which is also capable of detecting rifampicin resistance, is available in 1 facility. Some of the facilities (40%) which are primary healthcare facilities have no access to any diagnostic tool for tuberculosis and these facilities are all primary healthcare facilities. This unavailability of diagnostics at primary healthcare centres and the availability of Gene Xpert at secondary facilities only confirms Odume *et al.* (2023) findings about the uneven distribution of TB diagnostics across the tiers of healthcare facilities. However, there is at least one diagnostic tool for the initial diagnosis of TB in every local government, and referrals can be made from nearby facilities that have no diagnostic tool.

Furthermore, these facilities, which have no diagnostic tools, are not located at the LGA headquarters. This agrees with Amenuvegbe *et al.* (2016), who reported that only facilities at a district capital have access to TB diagnostics tests. Stock-outs on the consumables of these tests were not reported in the past 12 months, neither in the facilities nor the central store.

As for the detection of rifampicin resistance, 3 facilities across 3 local governments have either Trunat or Gene Xpert for the detection. Other facilities make referrals to these facilities. These referrals mean more transportation costs to the patient, which goes against the WHO's End TB strategy, where one of its objectives is to ensure no patient suffers catastrophic costs as a result of the disease (WHO, 2015). The state did not have access to other diagnostics like NAATs, DST, and LPAs, which are used to detect resistance to isoniazid and second-line drugs. This is in contrast to findings in Europe, where 75% of facilities had DST for levofloxacin, 82% had moxifloxacin, 48% had bedaquiline, and 72% had linezolid (Gunther, 2023)

The limited availability of Gene Xpert and the unavailability of the diagnostics for the detection of resistance to Isoniazid and the second-line drugs could be the reason for the low detection of drug-resistant tuberculosis across the facilities. Furthermore, the unavailability of the diagnostics could be the reason why the treatment outcome was poorly documented, as shown in section 4.1 above.

The inventory management was accessed in terms of storage, forecasting, ordering, distribution, and inventory management indicators. For the forecasting, each facility sends the patients' data and inventory data to the Local Government TB and leprosy supervisors (LGTBLS) who will subsequently forward it to the state TB control program. This data is used to forecast the quantities needed for each facility for the next quarter. Some of the inventory management practices are in line with the logistics management system of the NTBLCP guideline (FMOH, 2015) and the global best practices, while some practices are contrary to that. With regards to the forecasting, it is done using the quarterly report, requisition and issue form (QRRIF) in line with the NTBLCP guideline. However, while ordering, they don't have input on what to send to them, which is contrary to what is the NTBLCP guideline. In the guideline, orders should be placed from the facility by calculating Months of Stock (MOS) using the previous quarter's consumption and then ordering the quantities based on the physical inventory and maximum stock. This was not done in practice, and this predisposed the facilities to either having overstock or stockouts.

Inventory control measures are one of the key measures in ensuring the availability of medicines (Singh *et al.*, 2013). Therefore the compliance of the inventory measures was measured in this study. At the DOTs centers, stock cards are available in all the centers where drugs are available; however, only 56% of the facilities updated their stock card in real-time, and quarterly inventory was done in 67% of the facilities. This practice implies that the stock is not monitored in real time, therefore exposing the system to stock outs.

The major challenge identified, which is the key contributor to the above gap mentioned, is the human resources. Pharmacists are healthcare professionals with expertise in pharmaceutical

supply chain management (Chukwu *et al.*, 2017). However, at the STBLCP, there is no single pharmacist in the program, and the personnel responsible for the inventory management are not pharmacists. This exposes the program to loopholes in terms of inventory management. At the DOTs facilities, there is a high turnover of staff responsible for the DOTs, which has a huge impact on the expertise of the staff. At the facility level, STBLCP has only the TBLS on its permanent roster; the DOTs officers are the employees of the facility they are working at. After being trained on the DOTs activities and gaining experience in the TB program, they can be transferred to another facility and assigned work that is not TB-related. This will lead to assigning another person to be the DOTs officer who has no experience in TB program management.

CONCLUSIONS

This study found that the health facilities in Katsina Central Senatorial District have drugs for treating DS-TB. However they do not have adequate drugs for the DR-TB treatment regimen. Similarly, all Local Government Areas (LGAs) in the study area offer diagnostic tests for tuberculosis testing, but only three facilities offer tests for rifampicin resistance detection. Even though the federal government provides quarterly supplies of medications and consumables for diagnostics, there is still the need for improved inventory management procedures and storage conditions.

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