

The Challenges of Directly Observed Treatment Shortcourse (DOTS) implementation for Tuberculosis management in Anambra State, Nigeria; A comparative analysis

Abstract

Aim: Several challenges have been hampering the DOTS strategy ranging from paucity of staff, laboratory consumables, drugs among others. This study therefore accessed the challenges facing TB-DOTS strategy in Anambra State, Nigeria

Study Design: A cross-sectional analytic study was done.

Place and Duration of Study: TB-DOTS accredited facilities in Anambra State, South-East Nigeria, September 2017-March 2018.

Methodology: Using questionnaires on 354 respondents, checklist on 32 DOTS accredited facilities, and Key Indept Interview (KII) guide which was administered on 14 focal persons in rural and urban facilities, including the State TBL coordinator was employed. Data was analysed using Chi-square and Fisher`s exact test with level of significance set at $p < 0.05$, while key themes from KII was thematically analysed.

Results: Both urban and rural respondents took nearly the same time to reach a DOTS centre, however, urban respondents spent more money to reach a TB centre and this was statistically significant, $p \leq 0.02$. Patients stated that the DOTS strategy could be improved by attending to them early, home visiting, having more staff, providing pocket money among others in urban compared to rural areas and this was statistically significant, $p \leq 0.03$. Checklist revealed that most patients in rural facilities 16(84.2%) compared to urban 11(84.6%) were not observed taking their medications while 11(57.9%) rural compared to 5(38.5%) urban had no functional microscope. Both rural and urban facilities specifically had challenges of Genexpert machines, needed more staff, and laboratories as well as adequate funds and retraining.

Conclusion: Challenges of DOTS may be myriad, however, Focal persons and Health workers should ensure direct observation of patients while the STBL coordinator informs government and policy makers on the need to employ more workers in TB management to help reduce waiting time. Frequent training and retraining of health workers is also recommended.

Key word: Challenges, TB-DOTS, Implementation, Anambra State.

1. Introduction

A brief historical preview shows that the Directly Observed Treatment Shortcourse (DOTS) started around the 1980`s when Styblo defined the model for the control of TB, at the International Union Against Tuberculosis and Lung Diseases (IUALTD) in the United Republic of Tanzania[1]. Furthermore, in 1991, the World Health Assembly also established the 70/85% targets for the year 2000. This percentages basically entailed the detection of 70% of all new sputum smear-positive cases arising each year and treating 85% of these cases successfully[2]. The World Health Organization (WHO), in 1993 also declared TB a global emergency[3], while in 1994, the new TB control framework was drawn up. This framework involved definition of terms such as New case, Relapse, Transferred in, Return after default, Failure case,

and 'Other case' for patient who do not fit into any of the categories above[4]. In 1995 at the London committee, Stop TB partnership, an all encompassing strategy was further launched[5]. This Stop TB strategy was therefore launched to fight the global tuberculosis epidemic. It addressed the current challenges facing countries responding to TB and how to continue scaling-up TB control activities while addressing TB-HIV co-infection and Multi-Drug Resistant Tuberculosis (MDR-TB)[5]. DOTS is at the core of the STOP TB strategy which has these six components; 1) pursue high-quality DOTS expansion and enhancement, 2) addressing TB/HIV, MDR and the needs of the poor and vulnerable patients, 3) contribute to health system strengthening based on primary health care, 4) engage all care providers, 5) empower people with TB and communities through partnership, 6) enable and promote research[6,7]. Further historical preview also shows that in the year 2000, the Amsterdam Declaration was made at a ministerial conference involving 20 high burden TB countries which agreed to effectively manage tuberculosis in adults and children as an integral part of primary health care. It also sought to improve the WHO-recommended DOTS strategy to combat tuberculosis by improving access to TB control programmes[7]. In the year 2001, six working groups and Global Drug Facility were launched. This was to build new international approaches towards ensuring universal access to, and effective national systems of procurement and distributions of anti-tuberculosis drugs. The Global Drug Facility was established to ensure uninterrupted access to high quality anti-tuberculosis drugs for implementation of the DOTS strategy[8]. In that same year also, Global Funds to fight AIDS (Acquired Immune Deficiency Syndrome), Tuberculosis and Malaria, Millennium Development Goals and Washington Commitment were also started. Global Fund was developed as an innovative and integral financing mechanism that would attract additional financial resources for the global fight against these three diseases in developing countries[9,10,11]. In the year 2002, the expanded framework on DOTS was established with emphasis that public health services should enhance DOTS implementation without compromising quality of case detection and treatment. It further stated that there should be community involvement in TB management, collaboration and synergy among public private partnership, and sustaining DOTS programme as an integral part of primary health care amongst other emphasis[12].¹⁶ This expanded framework reiterates the five essential elements of DOTS strategy while addressing HIV-TB co-infection and Drug Resistant forms of TB(DR-TB)[12]. In 2015, the Sustainable Development Goals also had the management of Tuberculosis in focus, alongside Malaria and AIDS in Goal 3[13].

The National Tuberculosis, Buruli ulcer, and Leprosy Control Programme (NTBLCP) treatment guidelines strongly recommended using a patient-centred case management approach, including DOTS, when treating patients with active Tuberculosis disease[10]. The DOTS is also specifically important for Multi-Drug Resistant TB, HIV infected patients either for treatment as co-infection or those on intermittent regimens like Isoniazid preventive therapy among others[10,11]. The DOTS strategy has emerged as an important strategy that handles the increasing number of tuberculosis cases in the world. It is a very important strategy that ensures availability of drugs that are dispensed to patients free, while ensuring supervision of drug supply and administration. This thus ensures adherence by patient's who take the medications and providers who render the services[12]. DOTS is administered basically by delivering the prescribed medications, checking for side effects, watching the patient

swallow the medications, documenting visit, and answering questions among other things. These are all expected to be initiated at the beginning of treatment[10,11,13].

Having these approaches in mind, the following challenges to DOTS strategy[12] have been reported while prospective solutions are proffered: (a) The need for expansion of DOTS coverage as the national coverage of 80% is still below the WHO 85% cure rate. (b) Private sector involvement which has not been adequate; this is important because most patients seek medical attention with private hospitals first, hence, the need to incorporate them. (c) Inadequate publication of Information, Education, and Communication (IEC) materials and health education (d) Multiplicity of control programmes which could lead to confusion in the mind of treatment providers hence a uniform control programme is needed, though Nigeria has one control programme so this is not a shortcoming (e) MDR-TB, hence DOTS plus; a complementary DOTS based therapy is advocated.

Other challenges included (f) Migratory population as these may be hard to track and would keep propagating the disease; it will be pertinent to educate and sensitize the society so that the populace will be abreast with the signs and symptoms while being the preferred gate keepers amongst themselves (g) Social stigma as notions restricting the acceptance of TB patients are still prevalent hence the need for proper education and IEC materials (h) involvement of the medical college and allied health professionals on the need to integrate DOTS implementation at all tier of the country. In Ghana it was also found that patients are likely to interrupt and default if they had less knowledge about tuberculosis, had superstitious belief e.g that TB is due to witchcraft, perceived service providers to be unfriendly and travelled long distances to obtain treatment amongst other things. In this view McLean [14] therefore categorised reason for non adherence into three factors as earlier stated i.e Healthcare factors, Treatment factors, and Patient factors which could pose great challenge to DOTS implementation.

The above Ghanaian study[15] noted that patients adherence to TB treatment was a complex behavioural issue involving several factors such as personal, social, and health care. These factors, while buttressing the foregoing points, reiterated that though patients' knowledge and perception contributed to default rate which could hamper DOTS strategy, a holistic view of these factors must be taken into consideration for a better DOTS implementation. Other factors on the side of healthcare providers include inadequate training and retraining as well as paucity of knowledge of the DOTS strategy. Inappropriate combination and use of TB medications though this has now been handled by fixed-dose combination, and inadequate supply of drugs, also play out as challenges to effective DOTS implementation. Poor surveillance on the part of health care providers cannot be overemphasized as well[14,15,16].

Another institutional based cross sectional study[17], conducted in Ethiopia among 112 private practitioners showed that only 33% of the private practitioners were able to list the correct first-line treatment regimen for all categories as recommended by National Tuberculosis and Leprosy Control guidelines. This study went further to conclude that a significant proportion of the practitioners did not have adequate knowledge and practice about DOTS and therefore, needs regular DOTS refresher course to improve on TB management.

Concerning findings relating to health workers and health system, it was also deciphered that challenges such as lack of trained healthcare workers, poor management, weak healthcare systems and inadequately equipped hospital and laboratories all affect Tuberculosis outcome[17,18]. Important also is the fact that HIV patients are more susceptible to Tuberculosis but the DOTS strategy assumes that the patient must be smear-positive whereas HIV-TB patients are less likely to be smear positive[17,18,19]. This challenge made the authors to even state that DOTS is not sufficient to handle TB with HIV and advised less emphasis on smear positive diagnosis.

Having stated the challenges above, similar occurrences may be seen in Nigeria where programmatic changes are not usually stepped down to resource persons especially at the lower cadre or those on the field and the non-availability of current guidelines to healthcare providers and doctors in DOTS accredited facilities. Also the issues of Internally Displaced Persons (IDPs) who may be likened to migratory population as earlier stated, and terrorist attacks are all challenges bedevilling the DOTS implementation especially in war torn areas and other hard to reach areas. The WHO reports that infection with HIV is another reason for failure to meet TB control targets[19].²³ However in Kwazulu, South Africa it was shown that factors like political strife and war, lack of political commitment from government, lack of resources to effectively manage and deliver healthcare, and poverty are all militating against DOTS strategy, a similar conditions are indeed not far-fetched in Nigeria[20]. In furtherance of the above, it was shown that poverty and malnutrition are important factors leading to a fall in immunity and contributing to preventable infectious diseases such as Tuberculosis, Pneumonia, and HIV in Nigeria[21,22]. It was further stated that the interplay of several factors such as biological, environmental and behavioural could affect TB prevalence and even treatment as they noted that immunization coverage in Nigeria largely depends on political commitment, so also is the DOTS strategy implementation[21,22,23].

In Nigeria also, TB occurred in 395,000 patient`s in 2007[23,24] and the DOTS programme then was estimated to have a coverage of 65% and case detection rate of 35% for smear-positive TB, which was below the target of 70%. However, due to paucity of facilities for sputum culture and sensitivity there is scarcity of data on prevalence of smear-negative TB[21,22,25]. In addition to this lack of facilities, an Ibadan study[26] in a 10 year review showed that 6.9% of smear-negative sputum samples were eventually culture positive. This goes a long way to indeed show that facilities, equipment, and man-power are not yet enough to tackle Tuberculosis and therefore calls for strengthening of the DOTS strategy implementation.

Nigeria has a comprehensive guideline/ manual for TB treatment and all DOTS accredited facilities are expected to comply with this. Patients are supposed to be observed as they take their medications and laboratory services with sputum AFB are done before commencement of treatment. Health education such as cough etiquette, indecent spitting, alcohol and tobacco ingestion, balanced diet, adherence to medications, amongst others are usually given to every patient and their treatment supporter before medications are started. It is also expected that copies of the most current guideline be made available in the facilities[27]. In the Directly Observed Treatment Short course strategy, the healthcare worker or treatment supervisor is required to observe the patient swallow his/her medications to ensure adherence to prescribed medications[25]. Poor adherence could lead to spread of the disease and

even lead to emergence of resistant cases[25,26-29]. However, this practice may not be so in South East Nigerian even though WHO stated that the type of healthcare staff involved in TB control varies between and within countries, and also government policies as well as institutional regulations determine the type of function performed by each cadre of staff. It is therefore important to state that there are virtually no data available in the area of human resources which may be the reason for incomplete direct observation of patients[27,28,29].

This research in Anambra State, therefore deciphered the challenges facing TB-DOTS implementation such as training for health workers in DOTS management, whether suspected TB patients are routinely screened for HIV as required by the guidelines for TB control, and also the existence and functionality of diagnostic and confirmatory equipment in DOTS accredited facilities.

2. Methodology

2.1. Study Area

This study was conducted in the selected rural and urban Local Government Areas (LGA) of Anambra State, Nigeria as follows Nnewi North, Idemili North, and Awka South designated as urban LGA`s and Anaocha, Dunukofia, Ayamelum, Oyi, and Njikoka known as rural LGA`s. Anambra State located at coordinates 6°20`N 7°00`E, and has 104 DOTS accredited facilities in the 27 Local Government Areas as at 2006 directory but newer facilities in these LGA`s was also utilized to complement closed or moribund facilities.

2.2. Ethical Approval

Ethical approval for this study was sought and obtained from the Nnamdi Azikiwe University Teaching Hospital Ethics committee with reference number NAUTH/CS/66/VOL.9/144. Informed consent was also obtained from the participants after explaining the study to them and also their privacy assured as neither their names nor any form of identification was not required. A letter of introduction from the Department of Community Medicine, NAUTH, Nnewi was also presented to facility heads prior to commencement of the study.

2.3. Study Design

This was a comparative cross-sectional study involving rural and urban areas implementing DOTS strategy in Anambra State.

2.4. Study Population

This comprised of 354 males and females that were aged 18 years and above, who were receiving TB chemotherapy in DOTS accredited centres of the selected LGA`s. The study population further included personnel and facilities of these accredited DOTS facilities that were also assessed.

2.5. Study Instrument

A pretested semi-structured, interviewer-administered, composite questionnaire was used for this study. The questionnaire originally developed by Gezahegn et al[28] and Xioxy et al was adapted[29]. It assessed provider`s and patients challenges to the practice of DOTS as a strategy for management of Tuberculosis.

Also a Key Informant Interview guide was also utilized for the focal persons, and the State Tuberculosis, Buruli ulcer and Leprosy coordinator **that were all interviewed.**

A checklist obtained from the Anambra State Ministry of Health was utilized **at** each of the DOTS facilities and assessed the structure, personnel, and services provided.

2.6. Sample Size Determination

The minimum sample size for this study was determined using the formular for comparing two proportions:[30]

$$n = \frac{\left\{ u \sqrt{[\pi_1(1 - \pi_1) + \pi_0(1 - \pi_0)]} + v \sqrt{[2\bar{\pi}(1 - \bar{\pi})]} \right\}^2}{(\pi_0 - \pi_1)^2}$$

Where n = minimum sample size

u = one sided percentage point of the normal distribution

corresponding to 100% - power (ie $1 - \beta$). For power of 90%, $u = 1.28$

v = percentage point of the normal distribution corresponding to the two sided significance level.

For $\alpha = 5\%$ or 0.05,

$v = 1.96$

$$\bar{\pi} = \frac{\pi_1 + \pi_0}{2}$$

π_0 = proportion in urban setting implementing a selected aspect of DOTS (66.7%) [34]

π_1 = proportion in rural setting implementing a selected aspect of DOTS strategy (48.9%) [34]

A total of 177 respondents per sub population was arrived at and the total sample size of 354 was therefore utilized for this study.

2.7. Method of data collection

A concurrent mixed method of data collection was used thus; the questionnaires for the respondents, the supervisory check list for the DOTS facilities, and the Key Informant Interview which was conducted in the offices of the State coordinator and focal persons respectively.

2.8. Data management

The data was collated, cleaned, coded, and checked for any data collection and coding errors, thereafter entered into International Business Machines-Statistical Package for Social Sciences (IBM-SPSS) version 21.0. Means, SD, and Pearson's Chi Square was employed for statistical significance, $p < 0.05$

Data from the checklist was analysed and frequency table with proportions of both subpopulations generated and compared. The qualitative data from KII was thematically analysed.

3. RESULTS

3.1. Challenges of DOTS Implementation

Table 1. Challenges of DOTS Implementation (Patients View).

Variable	Rural: N(%)	Urban: N(%)	Total: N(%)	p-value
Distance to facility (mins);				
Mean (SD)	28.2 (13.9)	29.2 (15.3)	354	0.430
Amount spent to facility(naira);				
Mean (SD)	129.4 (126.3)	158.1 (203.6)	340	0.002*
How to improve DOTS strategy.				
Attend to patient early.	8 (4.5)	4 (2.3)	12 (3.4)	*0.003**
Make all services available.	0 (0.0)	1 (0.6)	1 (0.3)	
Do not know.	40 (22.6)	47 (26.6)	87 (24.6)	
Home visiting.	2 (1.1)	15 (8.5)	17 (4.8)	
Everything is okay	3 (1.7)	4 (2.3)	7 (1.9)	
Information about the disease.	0 (0.0)	1 (0.6)	1 (0.3)	
More doctors.	15 (8.5)	8 (4.5)	23 (6.5)	
More workers.	8 (4.5)	9 (5.1)	17 (4.8)	
Privacy for patients.	3 (1.7)	5 (2.8)	8 (2.3)	
Provision of food.	44 (24.9)	29 (16.4)	73 (20.6)	
Provide pocket money.	4 (2.3)	2 (1.1)	6 (1.7)	
Provide multivitamins.	25 (14.1)	31 (17.5)	56 (15.8)	
Provide transport	18 (10.2)	15 (8.5)	33 (9.3)	
Provide water for drugs.	7 (3.9)	6 (3.4)	13 (3.7)	

*Statistically significant, $p \leq 0.05$

**Pearson Chi square test

Table 1 above showed that the mean distance to a rural DOTS facility was 28.2 minutes compared to 29.2 minutes in urban areas, while the mean amount to get to a rural facility was 129 naira compared to 158 naira and this was statistically significant, $p < 0.002$. Though most respondents were observed swallowing their medications, however 4(2.26%) was not observed and this was statistically significant in urban compared to rural areas, $p < 0.002$. It further showed that no health worker in both rural and urban facilities was seen to observe the patients other than parents, siblings, friends or neighbours. Further challenges faced by patients which could help improve DOTS strategy if handled included; more respondents in rural 8(4.5%) compared to urban 4(2.3%) wanted to be attended to early in the facilities. Also the need to make all services available in urban 1(0.6%) compared to rural 0(0.0%), more doctors needed in rural 15(8.5%) compared to urban 8(4.5%) and the provision of food, pocket money, and transport which was needed more in rural 44(24.9%), 4(2.3%), 18(10.2%) compared to urban 29(16.4%), 2(1.1%), and 15(8.5%) respectively. These suggested challenges occurring more in rural areas compared to urban was statistically significant, $p < 0.003$.

Table 2. Checklist data on laboratory structure, consumables and services (Providers Challenges).

Variable	Rural: N (%)	Urban: N (%)	Total
Laboratory appropriately located.			
Yes	8 (42.1)	7 (53.8)	15 (46.9)
No	11 (57.9)	6 (46.2)	17 (53.1)
GHW observe patients swallow drugs daily?			
Yes	3 (15.8)	2 (15.4)	5 (15.6)
No	16 (84.2)	11 (84.6)	27 (84.4)
Laboratory is neat.			
Yes	8 (42.1)	8 (61.5)	16 (50.0)
No	11 (57.9)	5 (38.5)	16 (50.0)
Laboratory is well ventilated.			
Yes	7 (36.8)	6 (46.2)	13 (40.6)
No	12 (63.2)	7 (53.8)	19 (59.4)
Functional microscope.			
Yes	8 (42.1)	8 (61.5)	16 (50.0)
No	11 (57.9)	5 (38.5)	16 (50.0)
Any GeneXpert machine?			
Yes	2 (10.5)	3 (23.1)	5 (15.6)
No	17 (89.5)	10 (76.9)	27 (84.4)
TB microscopist present			
Yes	7 (36.9)	7 (53.9)	14 (43.8)
No	12 (63.2)	6 (46.2)	18 (56.3)
Commodities in adequate quantity			
Yes	14 (73.7)	11 (84.6)	25 (78.1)
No	5 (26.3)	2 (15.4)	7 (21.9)
Commodities promptly supplied			
Yes	16 (84.2)	13 (100.0)	29 (90.6)
No	3 (15.8)	0 (0.0)	3 (9.4)

Table 2 above showed the frequency distributions of findings from the checklist. It was found that in rural facilities 11(57.9%) of the laboratories were not appropriately located compared to urban 6(46.2%). Of note also is the fact that only 3(15.8) rural and 2(15.4) urban facilities observed patients on the spot taking their medications. There was inadequate space, personnel and equipment more in the rural facilities 11(57.9%) compared to urban 6(46.2%). Also more rural facilities did not have neat laboratories 11(57.9%) as well as poorly ventilated 12(63.2%) compared to urban 5(38.5%) and 7(53.8%) respectively. Further results showed that in rural facilities 11(57.9%) and 17(89.5%) lacked functional microscope and GeneXpert machines compared to urban facilities 5(38.5%) and 10(76.9%) respectively. However, commodities availability and supply was inadequate in more rural 5(26.3%) and 3(15.8%) compared to urban facilities 2(15.4%) and 0(0.0%) respectively.

Table 3. Specific challenges of facilities (Providers Challenges).

Variable	Rural: N (%)	Urban: N (%)	Total
No GeneXpert	5 (26.3)	1 (7.7)	6 (18.8)
Need more laboratories & Scientists	8 (42.1)	5 (38.5)	13 (40.6)
Need more staff	1 (5.3)	5 (38.5)	6 (18.8)
Have adequate funds & retraining attended	2 (10.5)	0 (0.0)	2 (6.2)
Nil specific challenges	1 (5.3)	2 (15.4)	3 (9.4)
No AFB diagnostic centres	2 (10.5)	0 (0.0)	2 (6.2)

Table 3 above showed the specific challenges faced by DOTS facilities in rural and urban areas. More rural facilities required GeneXpert machines 5(26.3%), and laboratory facilities with laboratory scientists 8(42.1%) compared to the urban areas 1(7.7%) and 5(38.5%) respectively. Other challenges included funding and retraining which was grossly inadequate in as only 2(10.5%) rural facilities stated that they had enough fund and had attended retraining courses. The result also showed that 2(10.5%) rural facilities had no AFB diagnostic centres.

3.2. Qualitative Data; Key Informant Interview (Providers Challenges).

The key informant interviews was conducted with the 7 focal persons in 7 DOTS accredited facilities, 7 TBL supervisors and 1 State TBL coordinator at their respective offices. Key themes were elucidated as follows;

Concerning coordination and collaboration between government and stakeholders in TB management, positively affecting services provided and patient follow up, are there challenges you know?

The key informants in rural and urban facilities all opined that the coordination and collaboration between government and stakeholders in TB management has positively affected patient’s outcome. The focal person in one rural centre said *“there has been good treatment outcomes especially cure and completed treatment,”* while the State Tuberculosis and Leprosy Coordinator (STBLC) said *“it is going on well with General Medical Practitioners and Faith Based Organizations (FBOs), and cure rate is high.”* The key informants in both rural and urban DOTS facilities also posited that “challenges with the DOTS implementation included “government not meeting the financial obligations, poor political will, the need to institute appropriate sites and not mix TB patients and MDR.” One of the rural focal persons stated that *“....if donors withdraw, the programme will die,”* this consolidated the fact from the STBLC who buttressed that *“.....if donor fatigue sets in the programme will suffer”*. Other challenges include low GeneXpert coverage especially in rural areas and frequent out of stock for drugs like Rifabutin, and consumable that warrants need to source from other facilities.

Enough Human resource for DOTS implementation

The key informants in some rural areas stated that there are enough human resources for now but there might be need for more because they are engaged in other duties,

however the urban respondents and a few other rural persons stated that *“there are not enough human resources at all as they are saddled with many responsibilities.”* The STBL also stated that *“there is high rate of staff attrition and transfer of workers which affects the programme”*.

Provided funds for transport, procurement (logistics, phone calls etc). Any challenges.

The key informant in both rural and urban facilities stated that funds are provided but are not enough. One urban key informant said *“that funds are grossly inadequate and donors provide for logistics.”* The STBL also said *“there is provision for logistics but it is inadequate”*. A rural key informant also said that *“no fund is provided at all I do the tracking on my own personal cash”* while another rural informant stated that *“no funds for logistics, transport, nor even call, in fact we use our money sometimes”*.

Do you attend training for TB case management and how often? Any challenge

The key informants in the urban facilities have all attended training varying from 1-2yrs ago, however, among the rural key informants, some have not attended recently and those that went was about 2-3yrs ago. A rural key informant stated that *“I attend once in 2years but update is supposed to be yearly and some people are chosen on my behalf to go for trainings without my notice”*. An urban key informant stated that *“trainings are well attended depending on available fund and it is diversified, while a rural key informant said “he attends but not regular, however it is the NGO that pays all”*. Both rural and urban key informants stated the need for retraining.

Socio-economic status of patients affecting TB managements

All the key informants except in one rural facility agreed that socio-economic status of patients affects TB management. One rural key informant stated that *“it does affect outcome because of transport as they sometimes miss medications”*. Another urban key informant buttressed the fact that it affects outcome as *“most come and beg for transport and money for feeding, this might make them avoid or take less dose”*. Another urban key informant, stated that *“even ‘well to do’ people will not like to take treatment where they will be known, for fear of stigmatization”*. The rural key informant also said *“some don’t have transport and also beg for food when they come”*.

Current TB guidelines and difficulty in using them.

The key informants in both rural and urban setting mostly said they did not have enough guidelines. One copy was sighted in some rural facilities while some cannot find where they kept theirs. The rural key informant posited no challenges in using the guideline manual. Another urban informant stated emphatically *“that we do not have enough at all, Maybe 2016 is under review that is why it is not in circulation”*. The STBL coordinator also said the guidelines are not enough to go round though no challenges in using them like the other key informants opined.

Problems encountered with drugs and laboratory supplies and challenges.

The informants in some rural facilities stated that *“sometimes we encounter stock-out or expired drugs but we place emergency order, or borrow from nearby DOTS clinic”*. However, they also stated that poor storage and management of consumables

make their drugs spoil. The urban key informants also stated that sometimes they *“have expired drugs but inform logistics and destroy them and then request made to replenish stocks”*. They however stated that poor storage also affects their drugs.

Patient’s adherence to care and affectation of outcome

All the key informants in both rural and urban agreed that patients adhere but not completely. A rural key informant said that *“they may take the drug home and not swallow it or may not store it well”*. Another rural key informant also said *“that DOTS is working through supporters at home that monitor these patients”*. However an urban key informant reiterated that *“some patients are trying but a few about 1 in 10 defaults and MDR is increasing but by contact tracing we reach them”*. The STBL coordinator buttressed that *“there are loss to follow-up and Adverse Drug Reaction (ADR) occurs which may make patients not adhere hence MDR. Defaulters occur too but we call them to complete treatment, however the DOTS strategy is working”*.

Government committed to eradicating TB given the structure, process and outcome

The key informants in the rural facilities all opined that though the government seems to be trying but they are not doing enough. One rural key informants frankly stated *“no, they don’t contribute much at all”*, while another rural informant also concurred that *“no, I don’t think so, they should provide ventilated waiting area for patients, food, supplement and multivitamins to help patients just like the HIV clients”*. The urban key informant did not differ but stated that *“they are not doing enough for logistics, procurement for staff, and patients care are poor”* while the STBL stated *“government provide manpower and facilities but other funding are from donor agencies, government believes they pay salaries and provide structure but still need to do more.”*

Challenges of TB-DOTS implementation

The rural key informants outlined the following challenges, discrimination of patients by health-workers and relatives, no diagnostics centre as patient has to travel or sputum transported in some instances, difficulty in producing sputum by patients for diagnosis, no waiting area, not enough personnel, and no trackers. Other challenges included no seats for counselling patients in some facilities as they borrow seats from elsewhere, patient needs water dispenser to take drugs on sight, poor awareness/sensitization on TB, and as well as no GeneXpert machines. The urban key informants in addition to some of the rural challenges also stated that there are poor or dilapidated structures, poor funding or remuneration, no audio-visual awareness about TB, no community TB programme, no transport for returns, no recharge cards for calls, not enough staff and equipment, as well as inadequate orientation and seminar for workers. The STBL coordinator buttressed these facts by saying *“training for now is for new DOTS facilities but old sites need refresher, staff attrition is high, no fund for sensitization and awareness creation for the control activity, no fund for defaulter tracking, and not enough IEC materials to the public.”*

4. DISCUSSION

In this study, clinic accessibility, space, neatness and cross-ventilation of most facilities were good. Also case classification and sputum follow-up was also done in

line with national guidelines. However, only 3 (15.8) rural and 2 (15.4) urban facilities observe patients directly swallow medications on the spot. Also from the respondents' views, though many were observed, none of the patients mentioned a health worker, rather, only family members and friends. This findings contradicts the studies[31,32,33] which emphasized health worker supervised DOTS, and stated it was better than family member supervised DOTS because these family members may not know the importance of the disease, and the need for medication adherence. This important variable on direct observation has also been stressed to handle especially MDR and TB-HIV co-infection[2,33,34,35]but this study shows that no continuous direct observation was actually done by health workers in most facilities as the ones that gave patients their drugs only witnessed the swallowing of the first pill while the patient left with the remaining doses of the medication spanning about 2 weeks. This may be due to inadequate staffing, training, poor remuneration and allowances.

This study also found out that patients travels more than 20 minutes to get to the facility and also urban respondents spend about 29:00 naira (twenty-nine naira) more to get to a DOTS facility compared to rural. This amount spent and travel time may be a challenge to some patients` who finds it difficult to afford adequate meal per day. In the KII, it was also stressed that socio-economic status of patients affects their disease outcomes, furthermore, the respondents monthly income were less than the national minimum wage of 18,000 naira. Considering these challenges, the patients may miss or discontinue medication intake and that is why Erakene et al[37] stated that poverty, ignorance, and defective health care infrastructure as important factors that affect TB prevalence and outcomes. Also travel cost, lack of resources, illiteracy, and health believes are also challenges noted by McLean to compliment findings in this study[14,36,38].

While a good percentage in rural (87.57) compared to urban (84.18) never missed their drugs because they want to be better, cured, and alive. Some other respondents however, missed medications because their drugs finished at home, or they travelled, and forgot their drugs. Patients` who travelled or went for prayers in this study could be liken to migratory population on treatment[15] hence it will be better that the DOTS strategy employ easy accessibility for patients` to walk into a facility, show their card and get their drugs rather than running out of stock because the DOTS programme is Nationally controlled like immunization programmes for TB and others.

Others reasons for missing drugs include misplaced their drugs, took herbal medications, and pill burden. Findings from some studies[14,15] have also buttressed some challenges like large pills, and large number of pills, long duration of treatment, disruption of daily routines, health beliefs including cultural beliefs and attitude of patients may make them miss medications hence a challenge to effective DOTS implementation. These patient-centred factors were also found to compliment the checklist findings about neatness of laboratory, staff and consumables around the facilities being defective hence making patients not have confidence in the system. These findings thus corroborate the fact that defective health system can even worsen patients' ignorance because if they were well educated and counselled on the treatment and outcome, they will adhere to medications. Even while going for prayers they would take their medications and not missing their drugs hence being ignorant of negative outcomes[34-38]. However, information given to patients may not be stressed enough as stated in this study and this is why IEC materials and health

education checklist has been emphasized[12,14] because this will reinforce knowledge and serve as a reminder to help patients adhere to drugs while also reminding health workers to follow a guided protocol.

Furthermore if patient had swallowed their medications in front of the health worker as is expected of DOTS, or a health worker goes to the community to directly administer drugs, these patients` would not have to be stating these reasons, rather DOTS is not only initiated at the beginning of therapy but followed up till end of therapy[10]. DOTS therefore is a strategy in tandem with the findings of this study that should not only include proper education of patients but further stipulates delivering medications, checking side effects, answering questions from patients of which some clients in this study were not satisfied with completeness of information, and documenting regular visits[10,11]. Also these reasons could further be curtailed if there were enough treatment supervisors and adequate health education[12,14,37].

From the respondents` side also, this study shows that DOTS strategy in rural and urban areas could be improved by addressing some challenges like attending to patients early, making all services available in one facility to reduce running around of patients. Some facilities and KII views also pointed out poor management and poor political will as challenges. This is in tandem the fact that weak health systems, inadequately equipped hospitals and poor government interventions outplay as factors that hamper DOTS implementation[18]. Though this study found out that all TB patients were screened for HIV, it further noted the paucity of consumables with inadequate staffing for these procedures. This is not far from factors stated as challenges[12,14,18] where poor facility structure, commodities, consumables, and staffing affect DOTS implementation.

Conclusion and recommendations.

This study shows that the DOTS strategy is very important in Tuberculosis management, however, it is still faced with challenges ranging from paucity of staff and poor supervision, lack of equipment, drugs, and laboratory consumables among other needs. Hence, the need for government and stakeholders to strengthen the weak health system through proper interventional funding, operational research, and development partnering by ensuring it contributes the desired quota to ameliorate these challenges.

Reference

1. WHO. DOTS strategy for controlling TB, unit 5 part 1. Available from www.who.int/tb/publications/manual_for_participants_pp51-98. (Accessed January 12, 2016).
2. Laserson KF, Wells CD. Reaching the targets for tuberculosis control; the impact of HIV. *Bulletin of the World Health Organization*. 2007; 85(5):325-420.
3. Grange J, Zumia A. The global emergency of tuberculosis; what is the cause? *J R Soc Promot Health*. 2002; 122(2):78-81.
4. World Health Organization framework for effective tuberculosis control. WHO document 1994, WHO/TB/94. 179:1-7. Available from <http://www.who.int/iris/handle/10665/58717>. (Accessed January 16, 2016).

5. Glen T. WHO launches new Stop TB strategy to fight global tuberculosis epidemic. World Health Organization 2006. Available from www.prnews.com. (Accessed July 3, 2016).
6. World Health Organization fact sheet, No 104. Available from www.who.int/mediacentre/factsheets/fs104/en. (Accessed July 5, 2016)
7. Amsterdam declaration to Stop TB, March 2000. Available from www.stoptb.org/amsterdam_conference/declaration.pdf. (Accessed July 5, 2016).
8. Robert M, Timothy R. The Global Drug Facility: a unique, holistic and pioneering approach to drug procurement and management. *Bulletin of the World Health Organization*. 2007; 85(5):325-420.
9. Tiaji SB, Alexandria EK. The global fund to fight AIDS, Tuberculosis, and Malaria; issues for congress and U.S contributions from FY2001-FY2013. *Congressional Research Service*. 2012:7-570.
10. WHO. Scaling-up the response to infectious diseases: a way out of poverty. Report on infectious disease 2002. Available from http://whqlibdoc.who.int/hq/2002/WHO_CDS-2000.7. Accessed July 5 2016.
11. The global fund to fight AIDS, Tuberculosis, and Malaria. Available from <http://www.theglobalfund.org/en/about/history/>. (Accessed July 20, 2016).
12. WHO. An expanded DOTS framework for effective tuberculosis control. Available from www.who.int/hq/2002/WHO_CDS_TB2002.297.pdf. (Accessed March 5, 2016).
13. WHO end TB Strategy. Available from www.who.int/tb/post_2015_TB_Strategy. (Accessed February 10, 2016).
14. Mclean M. Adherence to treatment. *Guidelines for tuberculosis control in New Zealand*. 2003; 4: 1 – 33.
15. Norgbe GK, Smith JE, du Toit HS. Factors influencing default rates of tuberculosis patients in Ghana. *Africa Journal of Nursing and Midwifery*. 2011; 13 (2): 67 - 76.
16. Francis JC. ``DOT essentials: A training curriculum for tuberculosis control programs``, 2003. National Tuberculosis centre, and the New York City Department of Health. Available from www.health.state.mn.us/divs/idepc/diseases/tb/lph/dot.html (Accessed February 15, 2016).
17. Solomon AY, Carol HH, Gunnar AB. Assessment of knowledge and practice of private practitioners regarding tuberculosis control in Ethiopia. *J Infect Dev Ctries*. 2012; 6(1) : 13-19
18. Interactive core curriculum on Tuberculosis (web based), CDC. Available from <http://www.health.state.mn.us/divs/idepc/diseases/tb/lph/dot.pdf>. (Accessed May 2016).
19. Arora VK, Gupta R. DOTS strategy in India- The challenges. *Current Medical Journal North Zone*. 2002; 8(4): 1-8.

20. Naidoo S, Taylor M, Jinabhai C. `Critical risk factors driving the Tuberculosis epidemic in Kwazulu, South Africa`. South Afr J Epidemiol infect. 2007; 22 (23) : 45-49.
21. New York City Department of Health. `Management: Directly Observed Therapy. 2001. Available from www.health.ny.gov/publications/3705.pdf. (Accessed May 2016).
22. Kaneene JB. Tuberculosis and HIV/AIDS co-infection: Epidemiology and Public Health Challenges. Centre for Comparative Epidemiology, 2015. Michigan state university.
23. World Health Organization. International conference on AIDS/TB Geneva. 2010.
24. Akambi MO, Ukoli CO, Erhabor GE, Akanbi FO, Gordon SB. The burden of respiratory disease in Nigeria. Afr Journal of Respiratory Medicine. 2009; 8:10-17
25. World Health Organization. Global Tuberculosis control: Surveillance, Planning, and Financing. WHO Report 2007. Geneva.
26. Kehinde OA, Ige OM, Dada-Adagoke HO, Obaseki FA, Ishola OC. Pulmonary tuberculosis in Ibadan: a ten year review of laboratory reports. Afr J Med Sci. 2006; 35:475-8.
27. National Tuberculosis, Leprosy, and Buruli ulcer management and control guidelines 2015.
28. Gezahegn G, Gezahegn T, Mitiku TH, Negussie D. Quality of Tuberculosis care in private Health Facilities of Addis Ababa, Ethiopia. Tuber Res Treat.2014; 2014: 1-20
29. Xioxy Y , Xiaochen T, Yeqing T, Rui Y, Yunxia W, Shiyi C, Hong F, Feng W, Yanhong G, Ping Y, Zuxun L. Development and Validation of a Tuberculosis Medication Adherence Scale. PloS one. 2014; 7(12); 1-7.
30. Araoye MO. Research Methodology with Statistics for Health and Social Sciences. Ilorin: Nathadex Publishers. March 2004. 120-122.
31. Dosumu EA. Compliance in pulmonary tuberculosis patients using directly observed treatment short course. Afr J Med Sci. 2001; 30:111-114.
32. Stop TB at source, Geneva, World Health Organization, 1995. Available from [www.who.int/bulletin/archives/80\(6\)471.pdf](http://www.who.int/bulletin/archives/80(6)471.pdf). (Accessed January 18, 2016).
33. WHO. Assessment of human resources and time needed to implement the DOTS strategy for TB control in health facilities: survey instrument and guide to implementation. Available from www.who.int/htm/tb_2008.399_eng.pdf. (Accessed November 10, 2015).
34. Elsadig M, Mohamed O, Mohamed A, Sawsan A, Khalid M, Hatim S, Waqas S. Patients satisfaction with Tuberculosis services of directly observed therapy programs in Gezira State of Sudan. Arch Clin Infect Dis. 2014; 9(4): 1-5.
35. Patrick OE, Winifred A. Success of the control of Tuberculosis in Nigeria. A review Int J Health Res. 2009; 2(1) : 3-14.

36. Umar A. Nigeria: Why tuberculosis is on the increase. Available from <http://allafrica.com/stories/2008122>. (Accessed 17 May 2016).
37. Ekraene T, Igeleke CL. Prevalence of pulmonary Tuberculosis among active and passive smokers of cigarette in Benin City, Nigeria. *Int J biomed & hlth sci*. 2010; 6(1) : 1-6.
38. Nepal AK, shiyalap K, Sermisri S, Keiwkarnka B. Compliance with DOTS among tuberculosis patients under community based DOTS strategy in Palpa District, Nepal. *Int Infect microbial*. 2012; (1) 14-19.

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