Knowledge, Beliefs and Levels of Compliance with Medication Regimens in Patients with Tuberculosis accessing Services at a National Tuberculosis Centre in Nigeria

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ABSTRACT

Tuberculosis (TB) has remained a public health problem, with growing number of cases. Some point to non-compliance to treatment as explanation for the increase. Recent data on compliance of patients to their drugs and their perception about these treatments are lacking. This study aimed to assess the knowledge, beliefs and level of compliance among patients receiving treatment at the National Tuberculosis Treatment centre in Nigeria. Adopting a descriptive cross-sectional study design, data were collected through a researcher-constructed questionnaire from 60 consecutive patients with tuberculosis at the centre. Data collected were analysed descriptively, with the aid of SPSS version 24.0. Findings revealed predominantly male patients aged between 34 and 40 years, with low literate level (70% of participants did not have any formal education). Based on the multiple responses given, majority (75%; n=45) correctly see TB as an infectious disease; others incorrectly see TB as a congenital disease (55%), hereditary disorder (12.5%), or spiritual attack (7.5%). On its mode of transmission, only 37.5% correctly identifying the route; 55% of them believe it is congenital. Results further indicate that most patients (70%) do not comply with or adhere to the treatment regimen, due to following reasons: use of alternative medicine therapies (55%), low level of awareness about adherence and complete cure (17.5%), the big size of prescribed tablets for swallowing (15%), and the side-effects of the drugs (12.5%). Nearly half were made to discontinue therapy due to side effects of drugs. The study concludes that there is high non-compliance with TB treatment, linked to patients' belief more using folk remedies, which is considered cheaper and healthier, especially during the continuation phase. The demographic variables of patients seem to be associated with this low compliance level. These facts should guide future intervention towards strict adherence to treatment through patient and community education. Such efforts should improve the compliance level a great deal in ensuring strict adherence to treatment. Examining the drug resistance among these patients should be a future study at the treatment centre.

1. INTRODUCTION

Tuberculosis (TB) is an infectious disease, an air-borne infectious disease caused by bacteria of the genus mycobacterium tuberculosis (World Health Organization, WHO, 2013). The disease was declared a global emergency in 1993 (WHO, 1994), and it is one of the top ten leading causes of hospital admissions and leading causes of morbidity and mortality in adults. TB is a disease associated with poverty and over-crowding. TB is a serious public health problem in Nigeria but it is both preventable and curable, with about one-third of the over 6 billion world populations is estimated to be infected, and the lifetime risk of developing the disease for each person can be over 10%. TB disproportionately affects people in resource-poor settings, particularly in Africa and Asia, posing a significant challenge to developing economies as it primarily affects people during their most productive years (Harris, 2013). More than 90% of new TB cases and deaths occur in developing countries. In Nigeria, it is one of the diseases for routine notification to the Federal Ministry of Health via the Integrated Disease Surveillance and Response mechanism. Both diagnosis and treatment are free, the WHO, government and donor agencies finance the services (Federal Ministry of Health, 2015). The global fund to fight AIDS, Tuberculosis and malaria (GFATM) is an organ of the WHO that supports TB control programs.

The burden of TB in Nigeria has been on the rise, placing Nigeria 4th among the 22 high burden countries in the world and second in Africa, with the highest prevalence of TB cases appearing among males and those aged 35-54 years (Federal Ministry of Health, 2015; WHO, 2012; WHO report, 2009). The Nigeria National Prevalence Survey report showed an estimated adult TB prevalence rate of 318 per 100,000 population (95% CI, 225-412) smear positive and 524 per 100,000 population (95% CI, 378-670) bacteriologically for smear positive and/or culture positive cases, respectively. The prevalence of smear-positive TB among men is higher (484, 95% CI: 333-635) than in females (198, 95% CI: 108-289). A similar situation was found in the bacteriologically positive cases, with 751 (95% CI: 538-965) and 359 (95% CI: 213-505) per 100,000 males and females respectively.

The World Health Organization (2013) recommends a regimen for strong antibiotics for the treatment of tuberculosis disease (streptomycin, rifampicin, erythromycin, isoniazid and pyrazinamide for 6 months to 2 years) because some strains of the disease are usually drug-resistant which grow from the patients' bacteria and with a variety of drugs determine the most effective treatment. The treatment of tuberculosis disease thus involves a long course of antibiotics lasting several months because tuberculosis is a serious condition that can be fatal if left untreated. Death is rare if treatment is completed. The usual treatment is a combination of antibiotics, comprising of two antibiotics (isoniazid and rifampicin) for Six months and two additional antibiotics (pyrazinamide and ethambutol) for the first two months. It may take several weeks or months before the patient starts to feel better. There is therefore a lifelong risk of relapse.

Multi-drug resistance (MDR), according to WHO Global TB report, was estimated to be 3.5% (95% C.I.: 2.2-4.7%) of new cases and 20.5% (95% C.I.: 13.6-27.5%) of previously treated cases with MDRTB worldwide in 2013. For Nigeria, the WHO estimated MDRTB prevalence of 3.1% and 10.1% among new and retreatment cases respectively in 2012 (WHO Report, 2012; Niederweis, *et al.,* 2010). The treatment of tuberculosis requires the use of multiple drug combinations to minimize the development of drug resistance. Multi-drug-resistant mycobacterium tuberculosis (MDRTB) strains, defined as strains resistant to at least Rifampicin (RIF) and Isoniazid (INH), are emerging as major global public health problem. These MDRTB scenarios are associated with many factors most especially non-adherence to TB treatment (Ajema, *et al.,* 2020). The emergence of HIV/AIDS has increased the incidence of TB worldwide and made both clinical management and laboratory diagnosis more complicated and difficult (Anthony, 2005). Among all TB cases, the global average of isoniazid resistance without concurrent rifampicin resistance was 9.5% (95%CI: 8.0–11.0%) in 2013. In new and previously treated TB cases respectively, the global averages were 8.1% (95%CI: 6.5–9.7%) and 14% (95%CI: 11.6–16.3%) (The Center for Disease Control and Prevention, 2008).

One of the authors as a healthcare provider in the research setting has equally observed patients presenting with such resistant phenomenon. In the Nigerian survey report, any resistance to Isoniazid (not considering concomitant resistance to Rifampicin or to any other drug) was found among all cases). Generally, 9.6%; 95% CI: 8.1 – 11.3% of respondents tested by Line Probe Assay. Stratified by treatment category, there were a prevalence rate of 7.2% (95% CI: 6.0 – 8.8%) among new TB cases and 20.0% (95% CI: 15.2 – 25.6%) among retreatment TB cases (Federal Ministry of Health, 2013). Any resistance to Rifampicin (not considering concomitant resistance to Isoniazid or to any other drug) was found in 115 (7.9%; 95% CI: 6.6 – 9.5%) among all cases (generally) tested by Line Probe Assay. Stratified by treatment category there were a prevalence rate of 4.4% (95% CI: 3.4 – 5.6%) among new TB cases and 24.9% (95% CI: 19.6 – 30.9%) among retreatment TB cases (Federal Ministry of Health, 2013).

Non–compliance of patients with tuberculosis treatment has been a topic of serious attention in the overall management of tuberculosis. In Nigeria, reports indicate that about 81% of patients are not complying with treatment, for varying length of time (WHO, 2009). Even before presenting at health facilities, most patients would have visited several treatment outlets including traditional healers, for several reasons, which may include low level of knowledge about the disease, high cost of treatment, transportation, and high (Tachfouti, *et al.,* 2013).

Drug resistance to tuberculosis can occur when the drug that is administered for the treatment of tuberculosis is misused, and has been a problem of treatment failure over the years (Fouad, 2003; WHO, 2009; United Nations/ MDG Report, 2010; Chonde, *et al.,* 2010; El-Shabrawy and El-Shafei, 2017; Iweama, *et al.,* 2021). Some of these factors for this are broadly presented as patients' individual characteristics, health workers' and drug factors (Tachfouti, *et al.* (2013). The individual characteristics include lack of

knowledge, low income, patients' age and gender, and stigma and lack of social support. On the other hand, health workers' and drug factors are poor quality of drug, wrong prescription, drug side effects, and unavailability of proper drug (Tachfouti, *et al.*, 2013). The Center for Disease Control and Prevention (2008) and Mekonnen & Azagew (2018) presented other reasons why patients fail to take their medications are as follows: 1) patient's complaint that medicines must be taken on empty stomach to facilitate absorption, making it difficult for patients to follow especially waking up an hour earlier than usual just to take medications on empty stomach; 2) the big size of tablet. Side-effect of the drugs can also lead to patients' non-complacence to treatment; 3) issues on denial, stigmatization, emotional distress, cultural and life style make patients not to comply to treatment; and 4) other factors including poverty, transportation, religion, and attitudes of health workers. Being off drugs for more than 8 weeks after completing at least one month of treatment is an operational definition to guide health worker in the decision of using a retreatment second line regimen if the patient comes back to the health faculty after defaulting (WHO, 2013; Gugssa, *et al.,* 2017). In most of the studies, the majority of the losses to follow up occur during continuation phase; indicating that most of the patients default during the intensive phase. The study assessed the level of compliance among patients living with tuberculosis; the level of knowledge and factors affecting level of compliance to treatment by patients. Compliance is used interchangeably with adherence in this study, to mean discontinuation, temporarily or continuously, with prescribed drugs or patients' inability to continue with the medicines as prescribed for them, due to many factors.

2. RESEARCH METHODOLOGY

2.1 Research Design
The survey designed was used in the study survey research is a method of collecting information or data as reported by individuals.

2.2 Setting
The study was carried out in National Tuberculosis and Leprosy Training Centre (NTBLTC), Saye, Zaria, in northern Nigeria. It provides treatment for both tuberculosis and skin diseases including leprosy, serving as a referral for tuberculosis and leprosy treatments. The centre is adequately serviced by professionals (doctors, nurses and other health workers). The setting was chosen as the only centre for training and service for TB; it is suitable in terms of human and material resources including the target population. The population of study comprises of TB patients of various years brackets.

2.3 Sampling Technique
The purposefully selected centre is the only Tuberculosis and Leprosy Training in (northern) Nigeria; the study participants were selected using availability and convenience sampling, consecutively and snowballing into 60 study participants.

2.4 Instrument for Data Collection
The instrument for data collection was well structured questionnaire consisting of two sections: Section A consists of respondent's personal data; and Section B made up of general questions on knowledge, beliefs, perceptions and compliance issues. The tool was constructed from the elaborate literature review to identify the factors responsible for level of compliance with treatment regimen. After developing the questionnaire, it was pretested for reliability after validity (face and content) was ascertained

2.5 Method of Data Collection and Ethical considerations
Ethical approval was obtained (Number: NHREC/NTBZA/05-23/VOLXIII/02A, dated 8th May 2023). Working relationships were established the heads of units/ward selected for the study while informed consents were obtained from subjects. Throughout the period of the study, respondents' privacy was respected and confidentiality maintained, and all personal information and other records were anonymised. The questionnaire was personally distributed to participants, face to face, and collected by the third author; this ensured a maximum return rate. The questionnaire was used as an interview guide to elicit information from non-literate participants while a few educated others who needed assistance were also guided.

2.6 Method of data analysis
The data gathered were edited, coded and entered into SPSS 24.0 version and analyzed descriptively. The data were presented relative proportions using charts and frequency tables.

3. RESULTS

3.1 Demographic Characteristics of Respondents
The socio-demographic variables include age, gender, occupational status, marital status, religion and educational background. As shown in Table 1, 15% of the patients are between the ages of 15 and 20 years, 20% aged 21-26 years, 30% ages of 27-33 while 35% (21) between the ages of 34-40. This indicates that patients are mainly in their most economically productive years of life. Gender distribution indicates that three-quarters (75%) of them are male with only 25% females. On occupational affiliation, they are mainly farmers (32.5%) and petty traders (30%), while 22.5% are civil servants, and 15% students. Marital status indicated that 45% of all study participants is married, 27.5% single, 10% divorced, and 17.5% are widows/widowers. This marital profile is a highly relevant because of its association with compliance in many studies. Patients were predominantly Muslims (77.5%) with 10% Christians, and 7.5% African traditional religionists. On their level of education, almost half (45%, n=27) of them is not formally educated; only one-quarter (25%) had tertiary education. The socio-demographic profile of the patients is characteristic of

TB-prone populations; low literate, low-income male farmers in their prime of life. The faith of the patients coincides with the study setting being predominantly Muslim community (Zaria is an Hausa community, an Islamic adherents).

Table 1: Socio-demographic Characteristics of Patients

Age (in years)	Frequency	Percentage (%)
15-20	9	15
21-26	12	20
27-33	18	30
34-40	21	35
Total	60	100
Sex		
Male	45	75
Female	15	25
Total	60	100
Occupation		
Trader	18	30.0
Civil servant	13	22.5
Student	9	15.0
Farmer	20	33.5
Total	60	100.0
Marital status		
Married	27	45.0
Single	16	27.5
Divorced	6	10.0
Widow/widower	10	17.5
Total	60	100.0
Religion		
Islam	46	77.5
Christianity	6	10.0
Africa traditional religion	4	7.5
Preferred not to mention	3	5.0
Total	60	100
Educational background		
No formal education	27	45
Secondary education	15	25
Primary education	3	5
Tertiary education	15	25
Total	60	100

3.2. Knowledge of tuberculosis

The level of knowledge of patients on tuberculosis is presented under the following: Understanding what tuberculosis is. From Figure 1, the multiple responses of patients show that 75% (n=45) of patients correctly believe tuberculosis is an infectious disease, while others incorrectly see TB as a congenital disease (55%; n=33), heredity disorder (12.5% (n=7) and spiritual attack (7.5%' n=4).
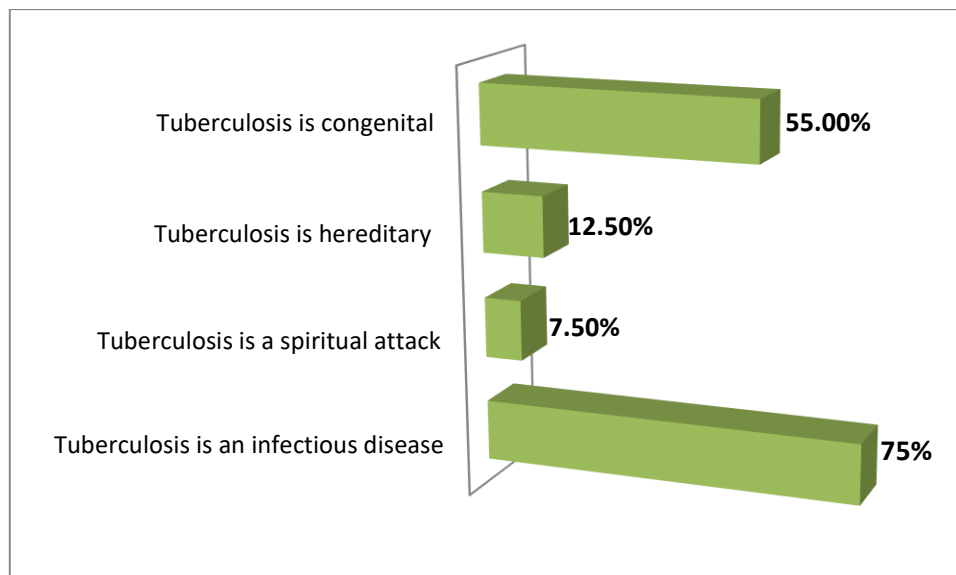
Fig.1: Understanding Tuberculosis

Further analysis shown in Table 2 shows the other aspects of knowledge about TB: on the causes of tuberculosis, only 47.5% have correct knowledge of the cause of TB (mycobacterium tuberculosis) while on the mode of transmission, 37.5% (n=22) stated airborne/droplets (from cough or sneeze) can lead to tuberculosis transmission, thus correctly identifying the mode of transmission as the respiratory route.

On DOTS as the Treatment regimen, most (60.0%) patients correctly stated that DOTS regimen is used for TB; the rest incorrectly stating that it is used to treat infertility (2.5%), malnutrition (15%), and malaria (2.5%).

On the vaccine to prevent tuberculosis, only 37.5% (22) correctly mentioned BCG (*Bacilli Calmette Guerrine*) while the others wrongly mentioned polio vaccine, hepatitis B vaccine and tetanus toxoid prevent tuberculosis.

For responses on the duration of TB disease, only 7.5% (n=4) believes tuberculosis is a life-long disease while majority (93.3%; n=56) do not think so.

Table 2: Knowledge about tuberculosis disease, its causes and its effects

#Understanding what tuberculosis is:	Frequency	Percentage (%)
An infectious disease	45	75
A spiritual attack	4	7.5
A hereditary disease	7	12.5
A congenital disease	33	55
	#	
Micro-organism causing tuberculosis		
Plasmodium	10	17.5
Virus	7	12.5
Mycobacterium tuberculosis	28	47.5
	55*	
Mode of transmission of tuberculosis		
Torching a n infected person	10	17.5
Playing with an infected person	15	25
Inhalation of droplets from cough or sneezed	22	37.5
Use of personal ions belonging to infected person	12	20
	59**	
Does the current treatment regimen cause:		
Infertility	7	12.5
Malnutrition	9	15
Malaria	7	12.5
Tuberculosis	36	60
	59**	

Which vaccine prevents tuberculosis?		
Oral polio vaccine (OPV)	13	22.5
Hepatitis B vaccine	15	25
Tetanus toxoid	9	15
BCG	22	37.5
Total	59**	
TB. Is a life- long disease.		
Yes	4	7.5
No	56	93.3
Total	60	100.0

 # multiple responses   **Missing data=5*   ***Missing data =1*

3.3 Compliance with Tuberculosis Treatment

From Fig 2, only 30.0% (n=18) of respondents report compliance with treatment regimen; majority (70.0%; n=42) dd not.
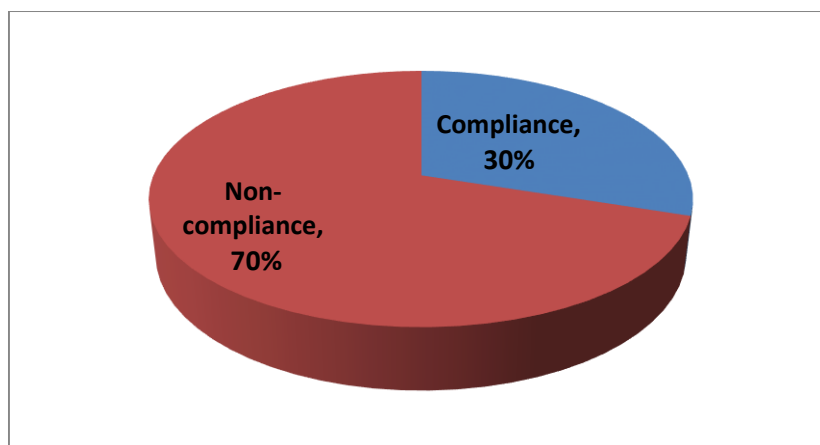

Fig 2: Compliance with TB Treatment Regiment

3.4 Factors affecting Compliance to Tuberculosis Treatment

Table 3 shows 15% (9) of the respondents claimed the big size of tablet cause them their non-compliance, 17.5% reported less awareness the about importance to adherence to the therapy   for complete cure, while 12.5% faulted side-effects of the drugs while 55% reported the resort to alternative medicine (home remedies).

Table 3: Factors affecting patients' non-compliance

Factors	Frequency (N=42)	Percentage (%)
Big size of tablets	9	15
Less awareness about adherence	10	17.5
Side-effects of the drugs.	7	12.5
Use of CAM (natural)	33	55

#Multiple Responses

3.5 Patients' Perception of the Importance of Treatment Compliance

In Table 4, majority (75%) do not think that adherent to treatment regimen is important while 25% (15) think so. Also 75% do not think that TB can damage body organs if not properly treated while 25% think so. From the analyzed data, 25% of the respondents think adherence to treatment is important while 75% don't think so. As well, 25% of the respondents think TB can damage body organs if not properly treated while 75% do not think so.

Beliefs about the disease and treatment, such as perceived wellness or cure, perceived risk, and perceived barriers over the benefits, were influencing factors for non-adherence to TB medication.

Table 4: Importance of treatment compliance

Do you think adherence to treatment is important?	Frequency	Percentage (%)
Yes	15	25
No	45	75
Do you think TB can damage body organs if not properly treated		
Yes	15	25
No	45	75

3.6 Strategies to improve patient's acceptance of care and treatment of tuberculosis

Table 5 presents patients' opinions on how best they wished treatment regimen compliance can be improved. Most of them (87.5%; n=52) opined that patients should be given instructions regularly about the use and importance of the anti-TB drug providers; 80% (n=48) believe that TB patients should receive comprehensive information about TB at the time of diagnosis through health education; 87.5% (n=52) wished they can be shown patients with tuberculosis who those convalescing. These strategies would improve compliance to treatment.

Table 5: Strategies to improve patient's compliance with treatment of tuberculosis

Strategies	Frequency	Percentage (%)
Instruction about the use and importance of the anti-TB drugs from drug providers. Yes	52	87.5
No	7	12.5
Total	59*	100.0
Comprehensive information at the time of diagnosis through health education Yes	4	80
No	12	20
Total	60	100.0
Showing TB patient those who are convalescing from the disease would help to improve compliance to testament. Yes	52	87.5
No	8	12.5
Total	60	100.0

1 missing data

4. DISCUSSION OF FINDINGS

4.1 Demographic Characteristics of Study Participants

This study assessed the level and predictors of compliance among tuberculosis patients receiving treatment at a National Tuberculosis Treatment centre in northern part of Nigeria. The patients were predominantly aged below 40 years (middle-aged population), representing the period of physical, mental and occupational stress, as similarly reported in other studies (Ajema *et al*., 2020; El-Shabrawy and El-Shafei, 2017; Mohammed, 2010; Kamal, 2006; Fouad, 2003; Kanwal and Majeed, 2020). This study finding on gender of mostly males, are consistent with the reported epidemiology of tuberculosis, being more exposed to infection than female (El-Shabrawy and El-Shafei, 2017), attributable to occupational, or social factors preventing females from seeking medical services (Raviglione and Uplaker, 2006). Like Ajema *et al*. (2020)'s findings, where 30.9 % of respondents were farmers, the present study also found more farmers. Study results obtained by El-Shabrawy and El-Shafei (2017) reported several-fold increase in the incidence of tuberculosis among farmers and traders compared to civil servants. Contrary to this study, Suthar *et al*. (2012) reported that marital status is not a significant predictor of medication adherence among TB patients. However, from the results, the widowed and married TB patients were more likely to default in their TB medication adherence than the single TB patients. The plausible explanation for the finding could be that widowed TB patients may lack adequate funds for out-of-pocket expenses such as transportation costs and the cost of other drugs for treating underlying ailments or comorbid conditions not covered by the DOTS program.

In addition, the widowed TB patients may lack social support for treatment adherence due to their spouse's death. Spousal death may also be a strong risk factor for poor mental outcomes such as loneliness and depression. Thus, the widowed TB patients require

adequate financial support from family members and non-profit organizations that support the less-privileged persons in the communities (Iweama *et al*., 2021). Contrary to this study, Suthar *et al*. (2012) reported that marital status is not a significant predictor of medication adherence among TB patients. However, from the results, the widowed and married TB patients were more likely to default in their TB medication adherence than the single TB patients. The plausible explanation for the finding could be that widowed TB patients may lack adequate funds for out-of-pocket expenses such as transportation costs and the cost of other drugs for treating underlying ailments or comorbid conditions not covered by the DOTS program.

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4.2. Knowledge of and beliefs about tuberculosis

Knowledge of the causes, mode of transmission and beliefs on causes are significant indices for medication compliance. The belief that tuberculosis is either a spiritual attack, and congenital or hereditary disease (70.0%) indicates the need for further education. An education-based intervention study is a possible option in this centre. Even the low knowledge of causative organism and mode transmission (less than 50% respectively) further indicate this need.

4.3 Compliance with Tuberculosis Treatment and related factors

The low level of compliance to medication (only 30.0% adherence) is most likely a product of these, apart from the reasons put forward by the patients, such as large size of tablets, associated side-effects of the drugs, and resort to complementary and alternative therapeutic options which patients consider as natural. These probably consisted of spiritual consultations and herbal medicines based on the beliefs and knowledge of causes of tuberculosis. The high level of TB medication non-adherence in our study (70%) is probably not new, as other researchers (Kidenya *et al*., 2017; Iweama *et al*., 2021) recently reported similar concerns. The observations may not be unconnected with perception about TB in general and the medications in particular. Most cases of non-adherence rate among the patients occur during the continuation phase of treatment, after acute symptoms subside. The long duration of treatment and frequency of medication administration especially in low-income settings like ours could also be contributory. Studies had reported that non-adherence among TB patients occurs most frequently in low-and-middle-income countries (LMICs) during this phase (Tachfouti *et al*., 2013; Mekonnen and Azagew, 2018). One study conducted in SNNPR also reported that belief in traditional healing influenced non-adherence to TB medication (Gugssa *et al*., 2017). The study setting is a Service and Training Centre for tuberculosis and leprosy. The low level of knowledge may mean that as a research and training centre delivering, more patient education is required.

4.5   Patients' Perception of the Importance of Treatment Compliance and Strategies to improve patient's compliance

This study reports most patients (three-third) discountenanced adherence to treatment regimen while believing that TB cannot damage body organs. This finding is disturbing because this perception might have detrimental consequences on the overall management. If persons on TB treatment do not think that the disease can damage body organs, there is the need to correct that misconception. Beliefs about the disease and treatment, such as perceived wellness or cure, perceived risk, and perceived barriers over the benefits, were influencing factors for non-adherence to TB medication. On ways to improve adherence, patients suggested regular and comprehensive education on the use and importance of the anti-TB drug. Patients on treatment need both institutionalized and community-based health education on possibility of drug resistance in TB treatment. Studies at the centre on drug resistance may be critical to provide empirical state of this poor compliance to TB treatment at the setting.

5. IMPLICATIONS OF THE STUDY

The findings this study provides recent data for healthcare workers, researchers, and policy-makers working on the tuberculosis services in low-resource areas, and additional awareness and knowledge of patients to guide patient education, and health administration. Family members can also help understand the need for strict compliance, thus reducing the burden of the disease on the family, community and the government and programme supporters. This implies family and community education.

6. LIMITATIONS OF THE STUDY

In the pursuit of this study, several limitations were experienced. The first was the limited sample size, over short period of time due cost in terms of time, effort and finances to carry out an extensive and exhaustive research. The researchers wished to engage more patients over longer periods of time, and even to diversity the methods to include focus group discussions and in-depth interviews. The paucity of funds could not allow for more expanded scope. In addition, the demanding schedule of respondents made it very difficult getting the respondents to participate in the survey. As a result, retrieving copies of questionnaire in timely fashion was very challenging. The second was the number of patients; patients accessing services at the centre presented charges of

insecurity, and economic burden of transportation to the centre. Some of the patients come from far and challenges of transportation are clear. However, in spite of the challenges, all efforts were made to ensure a successful study. The setting is the only specialized treatment centre in the whole of Nigeria; therefore, the patient population is representative of patients with TB in the region. Data provided should be instructive.

7. CONCLUSION AND RECOMMENDATION

The level of knowledge about causes is surprisingly still a mixture of cultural interpretation and the biological causation. This may account for the low compliance level found in the study. The reasons and factors associated with TB drug non-adherence included use of complementary and alternative medicine (natural) which is considered cheaper and healthier. This could occur more during the continuation phase. The demographic variables associated with this low compliance should guide future intervention towards strict adherence to treatment. It is therefore recommended that nurses, doctors, and public health education experts at the health facility and community levels should implement a more intensive patient-specific education program to improve people's knowledge of TB and its treatment. Similarly, the judicious implementation of the tuberculosis control program and providing supervised treatment at least for patients with parameters considered predictive for non-compliance is paramount.

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