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Full Length Research Paper

Challenges of DOTS implementation strategy in the treatment of tuberculosis in a tertiary health institution, Ilorin, Nigeria

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Despite the fact that Directly Observed Treatment Strategy (DOTS) short course has recorded significant improvement in the tuberculosis (TB) disease detection, treatment and control in Nigeria, neither the set target for the TB detection rate nor the cure rate has been achieved nationwide, as several challenges detract its effective implementation. The objective of this study was to examine the challenges of DOTS implementation strategies in the treatment of TB patients with the view to determine factors militating against its effective implementation. Majority (75.3%) of the patients were within the age bracket of 16 - 45 years, while half (52.8%) of the patients that received proper counseling on medication at the hospital did not adhere to anti-TB drug dosage regimen. However, dark urine features prominently (72.1%) as side effects of anti-TB drugs among the patients followed by nausea and vomiting (25.4%), impaired vision (1.8%) and yellowish eyes (0.7%). There is a positive effect of finance on the TB patients and only very few patients could afford to purchase anti-TB drugs during stock-out due to financial constraints. Patients' defaulted rates were 22.3 and 14% among the males and females respectively. Low treatment failure rates of 7.2 and 7.9% were also recorded in both men and women respectively. For effective DOTS strategy in eliminating TB nationwide, there is dire need for holistic approach in reaching all the patients with high-quality health care services even in the remote areas. Also, literacy level and social economic status of Nigerian citizens should be improved to enhance effective DOTS implementation.

Key words: Tuberculosis treatment, DOTs strategy, Nigeria.

INTRODUCTION

Tuberculosis (TB) is an infection often caused by *Mycobacterium tuberculosis*, transmitted exclusively by inhalation of infective droplets from patients with pulmonary tuberculosis through coughing, sneezing, talking or spitting. The patients suffered severe inflammation of the lungs and tissues necrosis with impairs pulmonary functions and can spread to other organs (Aguwa, 2004). Despite that the disease is preventable and curable; the landmarks in developing effective TB treatment continued to be a major problem all over the world (WHO, 1996). Among the factors that contributes to individual's risk of exposure of the disease includes concentration of droplet nuclei in contaminated air, the period a person breaths in air and immunity level (susceptibility to infection). Also, improper diagnosis and treatment, poor adherence to medication, presence of multi-resistant TB and recently the pandemic of HIV/AIDS led to deterioration of the disease (WHO, 2009a).

A person once infected with TB causing bacteria, can live a normal life without development of the disease, but the disease can be aggravated in low immune system especially by HIV/AIDS infection (Zeind et al., 1996). Poverty, poor nutrition, overcrowding, substandard living and interaction with other diseases increase risks to TB disease. Also, high rates of re-infection increases morbidity

Abbreviation: TB, Tuberculosis; **DOTS,** directly observed treatment strategy; **WHO,** world health organization; **HIV,** human immune deficiency virus; **AIDS,** acquired immune deficiency syndrome.

and mortality in patients. After 5years without treatment, 50% of primary TB patients often die, 25% will remain ill with chronic infectious TB and the remaining 25% will be spontaneously remitted by strong immune defenses without treatment (WHO, 1996).

Nigeria ranks fifth among the 22 countries with the higher TB burden in the world, with about 450,000 estimated new cases annually and 150,000 deaths every year (WHO, 2009a). It is known that drug therapy for TB is very effective, provided strict patients adherence can be ensured, but it may be complex, difficult and prolonged. As a result of complexity in taking the drugs and long duration of treatment for TB, it has been observed that patients do not adhere strictly to the instructions on the use of their medication. Patients who take their TB treatment in an irregular and unreliable way are at greatly increased risk of treatment failure, relapse and the development of drug-resistant TB strains. TB drug treatment however, relies heavily on the co-operation of the patients for self-administration, as patients adherence is an important link between medical process and treatment outcomes (WHO, 2005). As a result of this non-adherence attitude of patients towards their medication and continued death rate, the World Health Organization (WHO) in 1995 declared TB as a global emergency and called for TB control through adoption of the Directly Observed Therapy Short course (DOTS) strategy (WHO, 1994). DOTS strategy is a short course chemotherapy (a minimum of six months) that combines appropriate diagnosis of TB. It starts from registration of each patient detected, followed by standardized multi-drug treatment with a secure supply of high quality anti-TB drugs for all patients in treatment.

It also encompasses individual patient outcome evaluation to ensure cure and cohort evaluation to monitor overall programme performance through delivering the prescribed medication, checking for side effects, documenting the visit, counseling and answering patient questions. DOTS programme not only proven to be a highly effective and affordable strategy for controlling TB and prevention of emergence and spread of drug-resistant TB, but also valuable in resource-poor communities. DOTS programme also involves someone watching the patient swallowing every dose of the drug. It is important especially in the initial phase of treatment. A degree of patients' cooperation with healthcare providers is required because they may conceal tablets in their mouth or try to avoid taking medications. Therefore, careful vigilance is required by the person administering therapy throughout the whole treatment period.

Presently, more than 3,000 DOTS centres have been covered in all the States and Local Governments of Nigeria of which 75% of the population are under the DOTS programme (Umar, 2008; Patrick and Winifred, 2009). Although the case notification rate of TB in Nigeria has increased over the years, but recent figures put the DOTS detection rate of new sputum smear positive to be very low (20%), while the treatment success of new sputum smear positive still falls below the WHO target of 85% (WHO, 2008). Currently, WHO's report on the status of the TB pandemic and progress in control of the disease includes assessment of progress towards the newer impact targets related to incidence, prevalence and mortality that have been set within the framework of the Millennium Development Goals (MDGs) and by the Stop TB Partnership (WHO, 2009b). Information on the success of TB control in Nigeria has been recorded with significant improvement in the disease detection and treatment. However, neither the set target for the TB detection rate nor the cure rate has been achieved by the DOTS programme nation-wide, as several challenges detract its effective implementation. The present study was therefore conducted to examine the challenges of DOTS implementation strategies in the treatment of TB patients with the view to determine factors militating against its effective implementation.

MATERIALS AND METHODS

This study was conducted at the out-patient clinic of pulmonary unit of University of Ilorin Teaching Hospital (UITH), Ilorin, Nigeria. A sample size of 300 patients out of the total population of the TB patients that visited the clinic was used for the study. The patients that met the inclusion criteria were selected.

Inclusion criteria

(i) The patients that have been on anti-TB drugs for more than one month, (ii) The sputum of the patients should contain *Tubercle bacilli* on direct smear and / or culture, (iii) The patients showing cardinal clinical features of pulmonary TB, such as chronic cough, haemoptysis, weight loss and night sweats and (iv) Patients age range should be between 15 and 75 years and (v) Patients with HIV/AIDS.

Exclusion criteria

(i) Children below the age of 15 years, (ii) Psychiatric and prisoner patients at the hospital and (iii) Newly diagnosed patients. Twenty patients did not meet the inclusion criteria; therefore two hundred and eighty (280) patients were interviewed. All smear-positive cases in this study were at the maintenance phase receiving Ethambutol 15 mg/kg and Isoniazid 300 mg daily for 6 months. Patients with sputum containing *Tubercle bacilli* at the end of 6 months course continued their drugs until they are smear negative.

Research design

Research method instruments used to obtain information from TB patients were; structured questionnaires, patients' medical record folders and interview schedule. The structured questionnaires and interview guide were developed based on critical and detailed consideration of the research questions. The pre-designed questionnaires were administered to patients with the following sections; (a) Demographic and socio-economic characteristics such as age, occupation and education, (b) General information on TB, such as TB patients' knowledge about DOTS strategy and TB patients with HIV/AIDS co-infection and (c) Drug information; such

Table 1. Goals, targets and indicators for TB control.

MDG reference	Indicator
MDG 6:	Combat HIV/AIDS, malaria and other diseases:
Target 6.C	Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases
Indicator 6.8	Incidence, prevalence and death rates associated with tuberculosis
Indicator 6.9	Proportion of tuberculosis cases detected and cured under DOTS (the internationally recommended strategy)
	Stop TB partnership targets
By 2005	At least 70% of people with sputum smear-positive TB will be diagnosed (that is, under the DOTS strategy) and at least 85% cured. These are targets set by the world health assembly of WHO.
By 2015	The global burden of TB (per capita prevalence and death rates) will be reduced by 50% relative to 1990 levels.
By 2050	The global incidence of active TB will be less than 1 case per million population per year.

MDG, Millennium development goal.

as anti-TB drugs counseling, side effects of anti-TB drugs and ability of the patients to purchase drugs during stock-out.

Ethics approval

Ethical approval was sought from University of Ilorin Teaching Hospital Joint Institutional Review Committee before the questionnaires were administered to the patients. Also, the consent of the patients was sought and obtained before questionnaires were administered to them.

Data analysis

Analysis of the completed questionnaires was carried out using Genstat statistical package (Genstat, 1995). The data were subjected to the descriptive statistics which involves the use of frequency distribution and percentages, while the quantitative techniques includes partial regression analysis of finance on anti-TB drugs by TB patients to determine factors militating against effective DOTS implementation.

RESULTS

The global targets and indicators for TB control have been developed with the framework of the MDGs, Stop TB partnership and WHO's world Health Assembly (Table 1). These were developed to halt and reverse TB incidence by 2015, half prevalence and death rate by 2015, while by 2050, a total elimination of TB as a public health problem with one case per one million population insinuated. The outcome targets were to achieve a case detection rate of 70% under DOTS and to reach a treatment success rate of at least 85%. In this study, demographic and socio economic characteristics of TB patients receiving DOTS at UITH, Ilorin, Nigeria is presented in Table 2. One hundred and nine (28.9%) of the patients age range between 16 and 30 years, 102 (36.4%) with a ranged of 31 - 45 years, 49 (17.5%) with 46 - 60 years, while only twenty (7.2%) of the patients age ranged between 61 and 75 years. Based on the educational career, 113 (40.4%) had no formal education, while the majorities (59.6%) were literates. On the occupation of the patients, 71 (25.4%) were students, 69 (24.6%) were professionals, while 49 (17.5%) and 91 (32.5%) were civil servants and traders respectively. The outcome of TB patients on DOTS (Table 3) showed that few patients (23.6%) had the knowledge of DOTS strategy, while majority were ignorant. 151 (53.7%) of TB patients on DOTS programme adhered strictly to their medications, while 149 (46.3%) refused taken their drugs according to instructions. During stock-out of anti- TB drugs, only few (5.7%) of the patients could afford to purchase these drugs outside the hospital, while the larger population 94.3% were financially handicapped. Globally, HIV/AIDS prevalence in incident TB cases recorded was 10% (Table 4). However, out of 280 TB patients interviewed 81 (28.9%) had HIV/ AIDS as co-infection with TB, while the majority (71.1%) had TB alone. About half (52.8%) of the patients that received proper counseling on medication at the hospital did not adhere to anti-TB drug dosage regimen. However, dark urine features prominently (72.1%) as side effects of anti-TB drugs among the patients followed by nausea and vomiting (25.4%), impaired vision (1.8%) and yellowish eyes (0.7%). Partial regression analysis of effects of finance on TB patients under DOTS programme (Table 5) showed that there is a positive effect of finance on the TB patients. On the treatment assessment rate of TB patients (Table 6), patients defaulted were 22.3 and 14% among the males and females respectively. Similarly, treatment failure rate was low in both men and women with 7.2 and 7.9% failure rate respectively under DOTS strategy.

DISCUSSION

DOTS adopted by WHO in Nigeria involves political commitment at all levels for the provision of free TB services to all citizens through laboratory diagnosis of TB and ensuring that patients take drugs according to the studied guidelines. In this research, out of a total number of two

Table 2. Demographic and socio economic characteristics of TB patients at University of Ilorin Teaching Hospital, Ilorin.

Parameter studied	Classification	Number	Percentage (%)
Age in Years	16–30	109	38.9
	31–45	102	36.4
	46–60	49	17.5
	61–75	20	7.2
Occupation	Students	71	25.4
	Professionals	69	24.6
	Civil servants	49	17.5
	Traders	91	32.5
Education	No formal education	113	40.4
	Primary school certificate	45	16.1
	Secondary school certificate	87	31.1
	Diploma/NCE	22	7.8
	HND/ First degree	8	2.8
	Masters and above	5	1.8

Table 3. Outcome of patients with tuberculosis at University of Ilorin Teaching Hospital, Ilorin.

Parameters Studied	Classification	Number	Percentage (%)
TB patients' knowledge about DOTS strategy	Patients with the knowledge	66	23.6
	Patients without the knowledge	214	76.4
Ability of the patients to purchase drugs during stock-out	Patients that can afford	16	5.7
	Patients that cannot afford	264	94.3
TB patients with HIV/AIDS co-infection	Patients with HIV/AIDS co-infection	81	28.9
	Patients without HIV/AIDS co-infection	199	71.1
Counselling of anti-TB drugs medication to TB patients at the pharmacy department	Patients who adhere	148	52.6
	Patients who do not adhere	132	47.2
Side effects of Anti-TB drugs	Yellowish eyes	2	0.7
	Nausea and vomiting	71	25.4
	Dark urine	202	72.1
	Impaired vision	5	1.8

hundred and eighty questionnaires administered to TB patients, majority (75.3%) of the patients were within age bracket of 16 - 45 years (Table 2). This implies that TB constitutes a strong economic burden, which could cripple the work force of the nation. Low level of educational attainment of the patients recorded also means that majority could not understand their disease state and lack the ability to read the instructions of dosage regimen on the labels. This corroborates with Gopi et al. (2007) in India, who found that 39% of DOTS patients were illiterates. Therefore, increase in western education attainment by the populace would go a long way in reducing illiteracy and improve the economy, as education is the bed rock for economy growth and development. However, majority of TB patients were ignorant of DOTS programme. The need for effective enlightenment campaign on the TB and DOTS strategy is crucial for the attainment of WHO targets in both rural and urban areas of Nigeria. The community leaders should be co-opted in the dissemination of TB manifestation, causes and modalities for treatment. Furthermore, DOTS programme should be strengthened by covering the remaining 69 Local Government areas of the country with health facilities on free anti-TB drugs and related services to every

Table 4. Estimates of TB epidemiology in Nigeria as at 2008.

Characteristics	Total
Incidence (all new cases)	449,558
Incidence (all new cases per 100,000 population)	311
Incidence (new sputum smear positive [ss+] per 100,000 population)	137
Prevalence (per 100,000 population, including HIV-positive)	615
TB mortality (per 100,000, population, including HIV-positive)	81
HIV prevalence in incident TB cases	9.6%

World health organization (WHO). Global TB database and country profiles. 2009.

Table 5. Partial regression analysis of finance on anti-TB drugs by the TB patients.

	Un-standardized coefficient	Standard error	standardized coefficient	t	Sig.
Finance	0.148	0.061	0.109	1.833	0.068

Table 6. Treatment assessment rate of TB patients under DOTs programme at University of Ilorin Teaching Hospital, Ilorin in 2008.

Description	Gender			
	Males		Females	
	Number	Percentage(%)	Number	Percentage(%)
Complete treatment or cured	117	70.5	89	78.1
Default rate	37	22.3	16	14.0
Failed treatment rate	12	7.2	9	7.9
Total	166		114	

community within 5 km radius in order to achieve its set goals of 5,000 DOTS centres instead of the present 3, 000 centres.

Quality healthcare outcomes depend upon patients' adherence to recommended treatment regimen. Patients' non-adherence cannot only be a pervasive threat to health, but also carry an appreciable burden as well as human well being (Martin et al., 2005) . In this research work, almost half of the TB patients did not adhered strictly to instructions after counseling on anti-TB dosage regimen (Table 3). This commensurates with the work of Fakeye et al. (1997) in Ibadan, who reported that 44.4% of the patients did not adhere with medication. The treatment failures could encourage the transmission of resistant TB in the community and hindering the targets of DOTS strategies. Scientifically, it has been estimated that every case of TB resistant strain can affect about 12 - 15 other citizens leading to multi-drug resistant. Multi-drug resistant TB (MDR-TB) is defined as a case caused by a strain of *M. tuberculosis* that exhibits resistance to at least two anti-TB drugs. These multi-drug resistant TB patients are dangerous to the community because once an innocent person is infected, then he or she cannot be cured (WHO, 1994). To summon these challenges, every possible means should be taken to provide language-specific, clear instructions regarding the timing of medication, quantity to be administered and easy accessibility to health services. Also, there must be mutual cooperation between the patients and health care providers.

One of the major components of DOTS strategies is the provision of free, regular and uninterrupted supply of high quality TB drugs. The drugs were donated by International agencies such as USA's Agency for International Development (USAID), Canadian International Development Agency (CIDA), WHO, Global Drugs Facility, Bill Gates and British Government. On rare occasions, stock-out of these drugs exists in the hospital pharmacy. In this study, there was a positive effect of finance on the TB patients and only very few numbers of the patients could afford to purchase anti-TB drugs during stock-out due to financial constraints. This could lead to interruption and failure of treatment and ultimately resulting to multi-drug resistant TB. The government and other stakeholders should provide financial support and ensure regular, adequate and effective distribution of anti-TB drugs to all health centres nationwide.

However, patients' tolerance to anti-TB drugs is not only very important for treatment outcomes but also for TB control in general. TB treatment is for eight to nine months and only few patients successfully complete their

full course of anti-TB chemotherapy without significant side effects. In this study, the patients experienced varying degrees of adverse effects including dark urine, yellowish eyes and impaired vision/blindness. Patients with yellowish eyes could be scared to continue medication in order to avoid liver damage, while the patients experiencing poor vision can stop their medication. This is supported by Richard (2006) that many patients have adverse reactions that complicate treatments and invariably influenced treatment outcomes. Therefore, close monitoring and counseling on adverse effects of anti-TB drugs are imperative for ensuring sustainable solutions to the patients by health care providers.

However, as far as HIV/AIDS is a public health burden in Nigeria, TB will continue to be a problem in the country. The HIV infection knock-up the immune system and predisposes an individual to reactivation of TB (Patrick and Winifred, 2009). Although very few patients had TB and HIV as co-infection in this study, knowledge of their HIV status is necessary. Such knowledge allowed them to plan for their future and exhibit attitudinal change to protect others. Counseling of TB patients on their sero-status will also alleviate anxiety for those tested positive for HIV and motivate them to adopt life saving skills.

TB patients defaulters are those who completed at least one month of treatment and are smear positive after at least eight weeks of interruption of treatment. In this study, the proportion of default rate among the males and females was low but default rate of men were higher than the women. Default from treatment has been reported to be highest during the continuation phase of treatment generally, while HIV-positive patients had twice the risk of default during the intensive phase of the treatment than HIV-negative individuals. Also, men were more likely to default than women (Daniel et al., 2006) . Throughout the world, TB patients were burdened with a wide range of medical and social problems. Also, Chiang et al. (2005) suggested that HIV/TB co-infected patients are more likely to default from treatment as they experience progressive deterioration in their health status compared to other patients. However, side effects of anti-TB drugs are worrisome to the patients and could increase defaulting rates. Treatment failure occurred when the TB patient still remain smear positive after 5 months of treatment. The treatment failure rate recorded could be as a result of multi-drug resistant TB in which *M. tuberculosis* exhibit resistance to at least Isoniazid and Rifampicin. Burman et al. (1997) reported that anti-TB drug non-adherence was associated with 10 folds increase in the occurrence of poor outcomes from treatment and this accounted for most treatment failures. Such TB patients with treatment failure should be on extensive chemotherapy for up to 2 years of treatment.

Conclusion

For effective DOTS implementation strategy in eliminating TB worldwide, there is dire need for holistic approach in reaching all patients with high-quality care. In Nigeria, all stakeholders are to be involved from a wide array of public, private, corporate and voluntary health-care providers. The patients need education on TB and importance of DOTS. Therefore, enlightenment campaign and counseling are crucial for the objectives of the DOTS to be accomplished. Literacy level and social economic status of Nigerians should be improved to reduce barriers of DOTS programme. A reduction in stress, exposure to environmental pollution, overcrowding, poverty with better nutrition and interaction with healthcare workers reduces the risk of infection and progression of the disease. DOTS appropriately require investments in strengthened health systems including trained personnel, an effective procurement and drug distribution system and an effective monitoring and surveillance system. Making high-quality services widely available and accessible to all those who need them even in the remotest areas, including the poorest and most vulnerable to the disease could enhance effective implementation.

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