http://dx.doi.org/10.4314/jpb.v9i2.9
Vol. 9 no. 2, pp. 116-121 (September 2012)
http://ajol.info/index.php/jpb

Journal of
**PHARMACY AND BIORESOURCES**

# Assessing the effectiveness of Directly Observed Therapy short-course (DOTs) for tuberculosis in a Nigerian hospital

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Received 18th June 2012; Accepted 24th August 2012

**Abstract**
This study was set out to determine the effectiveness of Directly Observed Therapy, short-course (DOTs) for tuberculosis, and to compare the effectiveness of DOTs with Non-DOTs in Plateau State Specialist Hospital, Jos Nigeria. Retrospective data made up of 241 DOTs treatment cards from February 2001 to September 2002 and 128 Non-DOTs medical files of in-patients from 1993 to 2000 was collected and analyzed using ANOVA with the aid of statistical package IBM-SPSS Version 19.0. Majority of TB cases occurred between ages 21-30 (28%) in both DOTs and Non-DOTs cases, while the least occurred in the extreme of ages (very young and old, 1.2% -5.5%). There were more males than females with TB in both cases (59% males, 41% females-DOTs; 65% males, 35% females-Non-DOTs). Civil Servants had the highest incidence of TB in DOTs (25%) while the unskilled and semi-skilled workers had the highest incidence in Non-DOTs (21%). Majority of the DOTs patients were diagnosed by sputum smear examination (84%), while most of the Non-DOTs patients were diagnosed by chest X-ray (89%). Successful treatment in terms of treatment completed and cured was 67.2% for DOTs and 64.1% for Non-DOTs, giving a percentage difference of 3.1%. There was no significant difference in the percentage difference. An integration of the strengths of both programs should be employed to improve patient adherence and other treatment outcomes.

*Keywords*: DOTs; Non-DOTs; Tuberculosis treatment outcomes.

## INTRODUCTION

The declaration by the World Health Organization (WHO) in 1993 that Tuberculosis (TB) constitutes a global emergency has led to the revitalization of the WHO'S TB control programme (De Cock, 1997). This is because of the global resurgence of TB, the emergence of Multi-Drug Resistant TB (MDR-TB), increase in the incidence of HIV/AIDS and the fact that a third of the world's population (about two billion people) are infected with TB (AIDS Action, 1995). The recommended strategy was for countries to strive to detect at least 70% of new smear-positive cases of the disease and ensure a total cure of at least 85% of these detected cases (FMoH, 2008). WHO in 1994 recommended that National TB programmes should adopt the strategy of "Directly Observed Therapy short-course" (DOTs) in order to achieve 85% cure. This strategy involves observing the patients taking their drugs daily especially at the intensive phase of treatment. This aims at ensuring high levels of adherence and completion of TB treatment at home or in the hospital. The

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ISSN 0189-8442 

observer otherwise known as the treatment supporter or supervisor who is usually trained before the patient commences therapy may be an appointed health worker, reliable family member, teacher or church leader. The health worker is however the main supervisor and ensures that the other observers listed above do their job well by visiting the patient regularly especially during the continuation phase of treatment. It was observed that many supervisors do more than required; reminding forgetful patients, tracing defaulters and educating the community about TB (Walley, 2001). By 2005, it was reported that 182 countries had adopted and were implementing DOTs in their national programmes (FMoH, 2001). TB is a bacterial infection characterized by the formation of necrotic caseating nodules (Aguwa, 1996).

In Nigeria, TB still constitutes a very serious public health problem. Though, there has been no national survey in the past several years to determine the burden of TB in the country, the WHO estimated rates for Nigeria in 2005 were not very encouraging. A prevalence rate of 546 per 100,000 population and an incidence rate of 293 per 100,000 population for all forms of TB were estimated for the country. In addition, a smear positive rate of 126 per 100,000 population was estimated. With these statistics, Nigeria ranked fourth amongst the 22 high burden TB countries and the country with the highest TB burden in Africa (Volmink, 2002). It was estimated that 380,000 (293/100,000 population) new cases occurred in Nigeria annually of which 60% (123/100,000 population) were smear positive (Youmans, 1979).

The WHO DOTs strategy was adopted in Nigeria as a policy for control of TB in 1993. In collaboration with several TB partners in the country, the National Tuberculosis and Leprosy Control Programme (NTBLCP) is presently implementing the DOTs strategy in the 36 states and the Federal Capital Territory. The goal of the NTBLCP is to reduce significantly the burden, socio-economic impact and transmission of TB by 2015. This is with the objective of reducing the prevalence of TB to a level at which it will no longer constitute a public health problem in the country (FMoH, 2009). In 2005, the national programme registered a total of 66,848 of all forms of TB, 35,048 of which were sputum smear positive. There were 2,009 recorded relapses, 1,056 treatment failures, 1,802 returns after default (RAD) and 1,392 "other" cases. The TB case-detection rate as at 2005 was 27% while the treatment success rate was estimated at 78.6%. For the same year, the rate of MDR-TB among new cases was put at 1.7%. The age-group that was worst hit was between 15-34 years and essentially 59% of the new cases were males while 41% were females (Crofton *et al*., 1999).

The Non-DOTs or self-supervised/traditional method of treatment does not involve supervision and monitoring of the patient therapy. Rather, the patient is told to buy and take the drugs for nine months to one and a half years (FMoH, 2001). Reported cases of the efficacy of DOTs include: 75% cure rate in nomadic people of northern Kenya in 1996, 92% cure rate in Mongolia in 1995, an increase in cure rate from 43% to nearly 80% in ten years in Tanzania, over 90% adherence in Botswana in 1996 (Tsogt *et al*., 1999).

The study was aimed at assessing the effectiveness of DOTs by comparing it with Non-DOTs in Plateau State Specialist Hospital, Jos, Nigeria.

## EXPERIMENTAL

**Study setting.** The study was carried out in the DOTs Clinic of Plateau State Specialist Hospital (PSSH), Jos, Nigeria. The staff strength of 3 professional health workers, a uniform air-flow system and standard

operational procedures are required in such specialized clinics.

**Data collection.** DOTs data was collected at the outpatient nurse station using designed pre-tested forms, while data on Non-DOTs was collected in the medical record library of PSSH following due permission sought from the hospital's ethical committee. Retrospective data was made up of 241 DOTs treatment cards and 128 Non-DOTs treatment files for in-patients from 1993 to 2002.

**Data analysis.** Data obtained were analyzed using ANOVA and Student's t-test with the aid of statistical package IBM® SPSS® Version 19, 2011 for means, standard error of means and cross-tabulations at $p = 0.05$ level of significance for variables measured.

## RESULTS

Table 1 showed the highest incidence of TB in males and females occurring between ages 21-30 years for both DOTs and Non-DOTs. The total incidence of TB in males was higher than in females. Table 2 revealed that the highest incidence of TB occurred among civil servants (24.8%) in DOTs and among semi-skilled workers (23.4%) in Non-DOTs.

## DISCUSSION

The age distribution in Table 1 showed that tuberculosis was more prevalent between ages 21-40 for both DOTs and Non-DOTs. This age range corresponds to the productive age. The incidence was much lower in infants probably due to the fact that the BCG preventive therapy given at birth lasts for about 15 years. Thus, cell-mediated immunity would be quite high.

**Table 1:** Age and sex distribution

| Age range (Years) | DOTs | | | | Non-DOTs | | | |
|---|---|---|---|---|---|---|---|---|
| | Male | | Female | | Male | | Female | |
| | Freq. | % | Freq. | % | Freq. | % | Freq. | % |
| 0-5 | 6 | 2.5 | 5 | 2.1 | 10 | 7.8 | 4 | 3.1 |
| 6-10 | 2 | 0.8 | 1 | 0.4 | 0 | 0 | 2 | 1.6 |
| 11-20 | 7 | 2.9 | 13 | 5.4 | 4 | 3.1 | 4 | 3.1 |
| 21-30 | 33 | 13.7 | 34 | 14.1 | 16 | 12.5 | 20 | 15.6 |
| 31-40 | 37 | 15.4 | 24 | 9.9 | 21 | 16.4 | 5 | 3.9 |
| 41-50 | 44 | 18.3 | 8 | 3.3 | 16 | 12.5 | 5 | 3.9 |
| 51-60 | 7 | 2.9 | 12 | 5.0 | 6 | 4.7 | 2 | 1.6 |
| 61-70 | 2 | 0.8 | 2 | 0.8 | 4 | 3.1 | 2 | 1.6 |
| 71 & above | 4 | 1.7 | 0 | 0 | 6 | 4.7 | 1 | 0.8 |
| Total | 142 | 58.9 | 99 | 41.1 | 83 | 64.8 | 45 | 35.2 |

**Table 2**: Occupation distribution

| Occupation | DOTs | | Non-DOTs | |
|---|---|---|---|---|
| | Freq. | % | Freq. | % |
| Pupils | 17 | 7.1 | 17 | 13.3 |
| Students | 42 | 19.1 | 14 | 12.1 |
| Civil Servants | 60 | 24.8 | 25 | 21.7 |
| Applicants | 8 | 3.3 | 7 | 6.1 |
| Housewives | 40 | 16.5 | 20 | 17.3 |
| Business people | 15 | 6.2 | 17 | 14.7 |
| Semi-skilled | 55 | 22.8 | 27 | 23.4 |
| Clergy | 2 | 0.8 | 2 | 1.7 |
| Force-men | 2 | 4.5 | 3 | 2.5 |
| Retirees | 4 | 1.6 | 0 | 0 |

**Table 3**: Diagnosis distribution

| | DOTs | | Non-DOTs | |
|---|---|---|---|---|
| Diagnostic Assessment | Freq. | % | Freq. | % |
| Sputum smear positive | 105 | 43.6 | 8 | 6.3 |
| Sputum smear negative | 136 | 56.4 | - | - |
| Sputum Conversion | 85 | 80.9 | - | - |
| Chest X-ray | 105 | 43.6 | 114 | 89.0 |
| Mantoux test | - | - | 6 | 4.7 |
| Pulmonary TB | 228 | 94.6 | 124 | 96.9 |
| Extra pulmonary TB | 13 | 5.4 | 4 | 3.1 |

Sputum conversion rate = (85/105) × 100 = 80.9%

**Table 4**: Outcome for successful treatment using DOTs and Non-DOTs

| | DOTs | | Non-DOTs | |
|---|---|---|---|---|
| | Freq. | % | Freq. | % |
| Treatment Completed | 140 | 58.1 | 82 | 64.1 |
| Cured | 22 | 9.1 | - | - |
| Total | 162 | 67.2 | 82 | 64.1 |

**Table 5**: Outcome for unsuccessful treatment using DOTs and Non-DOTs

| | DOTs | | Non-DOTs | |
|---|---|---|---|---|
| | Freq. | % | Freq. | % |
| Failure | 2 | 0.8 | 4 | 2.3 |
| Death | 25 | 10.4 | 38 | 29.7 |
| Defaulters | 45 | 18.7 | 7 | 5.5 |
| Transfer-out | 9 | 3.7 | 2 | 1.6 |
| Total | 81 | 33.6 | 51 | 39.1 |

**Table 6**: Analysis of results for DOTs and Non-DOTs (trial from Plateau State, Nigeria)

| | |
|---|---|
| Successful Treatment DOTs | 67.2% |
| Successful Treatment Non-DOTs | 64.1% |
| Percentage difference | 3.1% |

**Table 7**: Meta-analysis of four trials of 1603 participants from South Africa, Thailand and Pakistan 1998-2001

| | |
|---|---|
| Successful Treatment DOTs | 72.54% |
| Successful Treatment Non-DOTs | 70.83% |
| Percentage difference | 1.71% |

(Volmink, 2002)

However, Youmans in 1979 reported that typical primary tuberculosis is most frequently seen in infants and children due to their under developed immune system (Youmans, 1979). The incidence of TB in males was higher than in females in both DOTs (59%, 41%) and Non-DOTs (65%, 35%). In females, the highest incidence was in the child bearing age in both cases (21-40). This was similar to the study that reported that women often develop PTB following childbirth probably due to blood loss at that age that results in decreased immune levels. The female incidence tended to drop rapidly after childbearing years (50 and above). The overall prevalence of TB in women was lower and the rise with age less steep than in men (Crofton *et al*., 1999).

The Occupation Distribution showed the highest incidence of tuberculosis in civil servants (24.9%, 19.5% for DOTs and Non-DOTs respectively. These fall in the productive age group, which also has the highest incidence of TB. Majority of indigenes of Plateau State are civil servants. In addition, the nature and degree of exposure

to hazards as seen for example with medical or health workers, factory workers who may be exposed to dangerous gases or other substances that can decrease their immunity. These workers are also more prone to being infected with the Human Immunodeficiency Virus (HIV) since they are more liable to promiscuity than the extreme of ages and TB is known to increase with increased incidence of HIV (De Cock, 1999; FMoH, 2008).

The Diagnosis Distribution in Table 3 showed that diagnosis of TB in DOTs is mainly by sputum smear examination (43.6% in PSSH), which is the standard diagnostic test for detection and monitoring of therapy (FMoH, 2008). Except if the sputum smear examination is negative would diagnosis by chest x-ray be considered, if the patient presents with signs and symptoms of TB. In Non-DOTs however, diagnosis was largely based on chest x-ray (89% in PSSH). The incidence of diagnosis by Mantoux test was Nil and 4.7% for DOTs and Non-DOTs respectively. This low incidence is due to the fact that diagnosis by Mantoux test is not confirmatory because patients with very low immunity for example in HIV-AIDS will have negative results but can be infected with TB. Also immunized children may have false positive results.

The sputum conversion rate for DOTs was (80.9%). None was obtained for Non-DOTs because sputum smear examination was not repeated during or at the end of therapy. The sputum conversion rate being high is an index for effective therapy and good patient response. This would also imply a decrease in the spread of the contagious pulmonary tuberculosis.

The incidence of defaulting was higher in DOTs (18.7%) than Non-DOTs (5.5%) probably due to the limitation of DOTs as stated by the Cochrane review summary that DOTs moves back to a tradition medical approach where the patients passively receives advice and treatment (Volmink, 2002). Patients especially adults may not be comfortable with the idea of coming to the health center every day and being watched as they take their drugs, or being observed at home by an appointed health worker, family member or community member where the observer would have to travel to the patient with the drugs. The desired defaulting rate would be less than 5%, if there were no intimidating approach to treatment schedules. If the defaulting rate were greater than 5%, problems related to patient adherence, organization of services and other factors ought to be investigated. The proportion cured plus completed treatment (called treatment success) was 67.2% and 64.1% for DOTs and Non-DOTs respectively. This should increase towards 100% and reach at least 85% with good case management (FMoH, 2008).

No cure rate was recorded for Non-DOTs because no laboratory test especially sputum smear test was done at the end of therapy. The percentage difference in successful treatment between DOTs and Non-DOTs was 3.1%. Further statistical analysis showed non significance between the percentage differences of DOTs and Non-DOTs. This was similar to 1.71% obtained from the meta-analysis of four trials (Two in South Africa, one in Thailand and one in Pakistan published between 1998 and 2001) which provided reliable evidence showing that people with tuberculosis are not statistically significantly more likely to be cured or take all of their anti-tuberculosis drugs if they receive directly observed therapy (DOTs), when compared to supervising themselves (Non-DOTs) (Volmink, 2002).

A recommendation would be to integrate the strengths of both programs (DOTs and Non-DOTs). An integration of the National TB Program (NTP) into the Primary Health Care (PHC) system can also be done, where the primary Health Care approach can be adopted for programme implementation.

The PHC workers at the health centers are expected to make diagnosis and start treatment of smear positive cases. The medical doctor in the General Hospital will make diagnosis of smear negative cases and place them on treatment. The tuberculosis supervisors are expected to supervise the primary health care workers and maintain central TB registers.

The percentage difference of 3.1% obtained from the DOTs/Non-DOTs program was not significant for program type or occupation type to rule out chance as being the result of the outcome measured.

A complete contrast could not be established between the two programmes due to lack of certain information in the Non-DOTs files that were in the DOTs records. Update of data could not be done because of the unavailability of Non-DOTs treatment cards/files as Non-DOTs was stopped immediately DOTs started.

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