A Comparative Study Of Home-Based Lay Worker Supervised And Facility-Based Health Worker Supervised Dots In Enugu, Nigeria.

By

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SUMMARY

Setting: The chest clinic of the University of Nigeria Teaching Hospital, Enugu Nigeria, the main referral tuberculosis treatment centre for Enugu and its environs.

Objective: To compare the efficacy of home-based lay worker supervised DOTS with facility based health worker supervised DOTS during the intensive phase.

Design: 600 consecutive newly diagnosed and previously untreated smear positive pulmonary tuberculosis patients were randomly assigned to either of 2 groups: study and control. A relation trained as DOTS supervisor supervised each study group patient at home while the clinic nurses supervised the control group patients at the clinic.

Results: At the end of the study, 77.3% of the study group compared with 72.7% of the control group achieved sputum conversion ($X^2 = 1.7422$; $P > 0.05$). Similarly, 92% of the study group compared with 90% of the control group completed treatment ($X^2 = 0.7326$; $P > 0.05$).

Conclusion: Trained lay supervisors were able to supervise DOTS at home during the intensive phase, and patients supervised by them achieved slightly better results than those supervised by clinic nurses, though the differences were not statistically significant.

It is therefore recommended that home based DOTS using trained lay supervisors be incorporated into the national tuberculosis control programme in Nigeria.

Key Words: *Tuberculosis, Control Programme, DOTS supervision, Nigeria*

INTRODUCTION

The World Health Organisation (WHO) has declared tuberculosis (TB) a global public health emergency [1]. With an annual global incidence estimate at 8 million and an annual TB-related death of 2 million, re-emergent TB constitutes a major public health problem[2]. The highest incidence is observed in sub-Saharan African countries where a rate of 100-300/100,000 populations of all forms of TB is reported [3]. Nigeria is the most populous country in Africa with a population estimate of about 120 million. In 1994, 7919 cases of all forms of TB were notified and by 2001, case notification has increased to 29,560 out of which 18,882 were sputum smear positive[4]. At the current rate of annual increase of case notification, it is estimated that 77,846 cases of all forms of TB will be notified by the year 2005 [5]. It must be noted that these figures represent a gross under representation of the true situation in Nigeria as only 19 out of the 36 states of the federation are currently implementing DOTS. Though the remaining 17 states and the federal capital territory undertake some TB control activities, they do not notify cases to the central National Tuberculosis and Leprosy Control Programme (NTBLCP) [6].

The on-going HIV/AIDS epidemic is worsening the TB epidemic in the developing countries [7]. Current data suggests that between 5- 15% of persons who are dually infected with

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Mycobacterium tuberculosis and HIV will develop TB each year as against less than 0.2% of persons infected only with *Mycobacterium tuberculosis* who will develop TB [7-8]. Thus by the end of the year 2000, about a third of the 36.1 million people living with HIV (PLWH) worldwide were co- infected with *Mycobacterium tuberculosis*, and 68% of those live in sub- Saharan Africa [7]. In Nigeria, TB/HIV infection co- prevalence has risen from 2.4% in 1989 to 17% in 2000 [9]. By the year 2001, 24% of adults (15- 49 years) with TB were estimated to be HIV positive [10].

The morbidity and mortality burden of TB in the world today is great. More adults die from TB every year than from any other infectious disease [3]. About 3.5 million deaths from TB occurred in the year 2000. Adults in their most productive years are mostly affected, sometimes leaving orphans in their wake. What makes this scenario particularly tragic is that TB is easily treatable. The failure to treat is an operational one. Put simply, we have the means of controlling the epidemic, but we are not applying those [11]. One proven strategy is the use of directly observed therapy short course (DOTS) in the community [12]. The better results from DOTS than from older methods of treatment supervision is the result of the observation of patients taking every dose of medication, which results in improved adherence to the complex multi- drug regimen thereby preventing the spread of TB and the emergence of resistant strains of *Mycobacterium tuberculosis*.

Adequate control of TB requires huge resources that are simply not available in Africa [13]. According to the WHO and the International Union Against Tuberculosis and Other Lung Diseases (IUATLD), current limitations to the provision of widely accessible tuberculosis care include: (a) inadequate health service infrastructure in many countries; (b) insufficient decentralization to ensure adequate access to care; and (c) human and financial resource requirement that exceed locally available resources.[14-15] Supervised therapy is labour intensive and DOTS requires a regular meeting of the patient and the supervisor, which unless it involves the minimum of travel and waiting could cause considerable disruption to a patient's life [16], which in itself could become an obstacle to accessibility of treatment and compliance. Nigeria is a high burden country (HBC)[4] with very low health facility coverage [17]. Thus it is unrealistic to rely on the existing government health services to achieve tuberculosis control, especially where these services are not managing to cope with an increasing tuberculosis burden related particularly to the global HIV pandemic [18].

It is envisaged that if lay people from patients' homes and or communities were trained to supervise DOTS at home, TB control programmes could become more accessible and more cost-effective. It could also become possible to implement TB control activities in localities that are distant to health facilities. This study was designed to investigate the feasibility of recruiting and training relations of newly diagnosed and previously untreated smear positive TB Patients as DOTS supervisors, and using them to supervise the intensive phase of DOTS at home, and to compare the efficacy and cost effectiveness of this strategy of DOTS supervision with the current control programme strategy of facility based health worker supervised DOTS. Sputum conversion and treatment completion rates, as well as the cost to the patient in taking the treatment at the end of the intensive phase were the primary out-come measures compared. This paper reports on the efficacy of the home- based lay worker supervised DOTS (the study group) as compared with the facility based health worker supervised DOTS (the control group).

PATIENTS AND METHODS

This prospective comparative study of two strategies of DOTS supervision was carried out at the chest clinic of the University of Nigeria Teaching Hospital (UNTH) Enugu, a foremost referral centre for TB treatment for Enugu and its environs. New sputum-positive

Tuberculosis patients consecutively admitted into this-service who were on ambulatory care in the clinic during the intensive phase of the short course chemotherapy (SCC) between May 1998 and September 2000 were used for the study. All re-treatment cases were excluded. Diagnosis was based on Ziehl Neelsen (ZN) staining for acid-fast bacilli (AFB) by simple microscopy

TB patients in UNTH who were not severely ill as to warrant an admission reserve the choice of either to be ambulant (in which case they come to the hospital daily for purposes of being observed to swallow their medicine) or to be admitted into the ward during the intensive phase of SCC. All those who had previously chosen to be ambulant and who met our inclusion criteria were approached and the purpose of the study explained to them. Those who gave written consent were recruited into the study. These were randomly allocated into the study or the control group. The clinic nurses administered the randomization. The study group patients were required to nominate a supervisor from his/her home who was trained and used to supervise the intensive phase of DOTS at home. Clinic nurses supervised the control group patients at the facility. Most patients nominated the people who brought them to the hospital.

The training covered such topics as the cause of TB, its method of spread, method of treatment and the concept of DOTS. They were also taught how to mark the patient's treatment card. This was done at the end of work each clinic day and the training sessions lasted about 1 hour. After the training, the supervisor of each study group patient received the patient's treatment card as well as a two-week dose of the patient's drugs. The patient was required to come back every two weeks with his/her treatment card for re- supply of drugs. Thus each study group patient required only 4 visits to the hospital to complete the intensive phase. During such re- visit, the treatment card was inspected to ascertain that the markings were being correctly done. Any patient that defaulted treatment was promptly traced and brought back to treatment not later than 5 days after such default. All such defaulters were dropped from the study and had their intensive phase DOTS supervised thereafter at the clinic daily. A random 10% sub-sample of the study group patients was paid surprise visits at home for on the spot monitoring.

Through the use of a questionnaire, demographic data of the trained supervisors were obtained. The variables of interest were the age, sex, educational status, religion, occupation, relationship with the patient and residence (if different form patient's own). Using the same questionnaire, information was obtained from every patient on the cost of transport each day he/she came for treatment as well as the number of patients who could not continue with their normal businesses as a result of the demands of the treatment protocol. The patient's treatment card contained information on his/her age, sex and the pre and post-intensive phase sputum status. This card also furnished information on whether the patient completed treatment or not. These were fed into the computer. Statistical analysis was done using the EPINFO version 6 software package. Statistical calculations were carried out at the 5% significance level. Chi- square statistics was used to compare proportions. The result of the comparative efficacy from this study is reported below. The data on the socio-demographic characteristics of good lay supervisors and the cost effectiveness of this lay worker supervision of DOTS are reported elsewhere.

RESULTS

Age and Sex Distribution of Patients

The age range of the patients is from 10-72 years. The mean age of the study group was 33.9 years with a standard deviation of ±15.2 years while the mean age of the control group patients was 33.5 years with a standard deviation of ±14.3years. The difference between these 2 means is not statistically significant ($Z= 0.001$, $P > 0.5$). The sex distribution shows that 51% of the study group was males and 49% was

females while in the control group 57.7% were males and 42.3% were females. Again the difference in proportion was not statistically significant (X^2 = 2.664, df = 1; P 0.10), see Table 1.

Table 1 Age Distribution of Patients.

Age	Patients		Total
	Study Group	Control Group	
10-19	39	33	72
20-29	114	117	231
30-39	63	72	135
40-49	24	30	54
50-59	33	27	60
60-69	24	15	39
70-79	3	6	9
TOTAL	300	300	600
Mean $\bar{x}$	33.9 years	33.5 years	
Standard deviation	± 15.2 years	± 14.3 years	

Z = 0.001; P > 0.05

Educational Status

Both groups shared the same modal class- secondary education. While 40% of the study group had secondary education, 42.7% of the control group had secondary education. There was also no statistically significant difference in the educational status of the two groups (X^2 = 2.480; df = 3, P > 0.05), see table 2.

Table 2 Educational Qualification of the Patients

Educational Level	Group		Total
	Study	Control	
No Formal Education	25	18	43
Primary Education	108	122	230
Secondary Education	125	123	248
Tertiary Education	42	37	79
Total	300	300	600

X^2 = 3.418; df =3; P> 0.05

Sputum Conversion Rate

At the end of the study, 232 (77.2%) of the study group became smear-negative and 68 (22.7%) remained smear-positive while 218 (72.7%) of the control group became smear-negative and 82 (27.3%) remained smear-positive (table 3). The difference in the proportions is not statistically significant (X^2 = 1.7 422; df = 1; P > 0.05).

Table 3 AFB Smear Status at the End of the Study

Smear Status	Study Group	Control Group	Total
Positive	232	218	450
Negative	68	82	150
Total	300	300	600

X^2 = 1.7422; P > 0.05

Treatment Completion Rate

At the end of the study, 276 (92%) of the study group completed treatment and 24 (8%) did not while 270 (90%) of the control group completed treatment and 30 (10%) did not. As could be seen in table 4 the difference in these proportions is not statistically significant (X^2 =0.7326; P > 0.05).

Table 4 Treatment Completion Rate Status at the End of the Study

Status	Study Group	Control Group	Total
Completed Treatment	276	270	546
Did Not Complete Treatment	24	30	54
Total	300	300	600

X^2 = 0.7326; P > 0.05

DISCUSSION

The study was designed to investigate the feasibility of using trained lay supervisors to supervise the intensive phase of DOTS at patients' homes, and to compare the primary

outcome measures (treatment completion and sputum conversion rates) between patients supervised by trained lay supervisors and those supervised by clinic nurses. The results show that lay people can be trained and used to supervise DOTS at home.

The trained lay supervisors achieved a higher treatment completion rate (92%) than the clinic nurses (90%), though the difference is not statistically significant. This result is in keeping with the findings of similar studies[19-21]. This better treatment completion rate could be as a result of reduced travel time incurred by the patients as it has been shown that patients who traveled for more than one hour to receive service are more likely to default treatment [22].

The study also showed that the trained lay supervisors also achieved a slightly better sputum conversion rate (77.3%) than those supervised by clinic nurses (72.7%), though this difference again is not statistically significant. For all smear positive pulmonary tuberculosis patients on treatment, sputum conversion at the end of the intensive phase is the most important prognostic sign. It therefore means that using lay people to supervise DOTS at home placed the patients at no higher risk than the patients supervised in the clinic by health workers.

Direct observation of therapy is labour intensive. In populations characterized by low facility coverage and increasing TB caseload occasioned by the HIV/AIDS pandemic as typified by Nigeria, DOTS implementation would require additional manpower resources. This study demonstrates that this additional resource can be recruited from outside the formal health sector as family members have proven to be effective surrogates. This is significant judging from the findings of Ngamvithayapong et al [23] who showed that health workers feel that direct observation of treatment is impractical, and home based DOTS not feasible. Our study demonstrates that home based DOTS is feasible and effective using trained lay supervisors. We therefore agree with Wilkinon and Davies[19] that high Tuberculosis treatment completion and sputum conversion rates are achievable and sustainable even in resource poor countries if community resources are harnessed and that patients may be more effectively supervised by these lay people than by health workers without being placed at increased risk.

CONCLUSION AND POLICY IMPLICATION

We therefore conclude that trained lay people were able to supervise DOTS at home and even achieved slightly better treatment completion and sputum conversion rates than those supervised by clinic nurses, though the differences were not statistically significant. Consequently we recommend that home based DOTS using trained lay supervisors be incorporated into the National Tuberculosis and Leprosy Control Programme in Nigeria.

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