348. Evaluation of Directly Observed Treatment Providers in the Revised National Tuberculosis Control Programme

C Nirupa, G Sudha, T Santha, C Ponnuraja, R Fathima, V Chandrasekaran, K Jaggarajamma, A Thomas, PG Gopi and PR Narayanan; Tuberculosis Research Center, Mayor V R Ramanathan Road, Chetput, Chennai – 6000 031: Indian J Tuberc 2005, 52, 73-77

Non-governmental personnel such as Anganwadi workers and community volunteers have been used as Directly Observed Treatment (DOT) providers in the Revised National Tuberculosis Control Programme (RNTCP), but their effectiveness has not been documented. To assess the treatment outcome and problems encountered by patients managed by different DOT providers in the RNTCP. In this article patients diagnosed with tuberculosis at 17 Primary Health Institutions (PHIs) in Tiruvallur District during a 3year period received DOT from one of the four types of trained DOT providers (PHI staff, governmental outreach workers, Anganwadi workers, community volunteers), and their treatment outcomes were compared. Of the 1131 new smear-positive patients treated between May 1999 to June 2002, 199 (18%) received DOT from PHI staff, 238 (21%) from outreach workers, 496 (44%) from Anganwadi workers, and 170 (15%) from community volunteers. Twenty-eight patients (2%) collected drugs for self-administration. The results revealed that treatment success rates among patients treated by different DOT providers, Anganwadi workers (80%), governmental outreach workers (81%) community volunteers (76%), were statistically similar. Patients who received drugs for self-administration were significantly more likely to fail to treatment or die than patients who were treated by a DOT providers (5/28 versus 84/1103; odds ratio=4.1; 95% confidence interval=1.2-12.6; p=0.02). The author has concluded that in addition to governmental staff, Anganwadi workers and community volunteers can be effectively utilized as DOT providers.

349. Gender and literacy: factors related to diagnostic delay and unsuccessful treatment of tuberculosis in the mountainous area of Yemen

J Date and K Okita; Graduate school of Medicine, Yamaguchi University, Ube, Yamaguchi, Japan: Int J Tuberc Lung Dis 2005, 9/6, 680-686

The study was conducted among community people in the mountainous area of Yemen, who, having maintained their traditional lifestyle, generally believe that uneducated women are unsuccessful in using modern medical care. The present article examines whether this belief applies to tuberculosis (TB) diagnosis and treatment has not been researched in Yemen. The questions considered were 1) Do sex and literacy factors limit opportunity to obtain proper treatment ? And 2) do traditional beliefs and customs affect patient's actions?. The methodology adopted was individual interviews and data collection were conducted for 74 smear-positive pulmonary TB patients visiting the National Tuberculosis Institute in Sana's from December 2001 to March 2002. The treatment outcome for each patient was checked from September 2002 to March 2003. The results of the study highlights that illiterate patients had a longer diagnostic delay than literate patients (P=0.006, univariate logistic regression analysis). They also maintained their traditional view of illness, not the illness 'TB'. More females than males completed treatment (P=0.046, univariate logistic regression analysis). Supervision by male relatives contributed to completion of treatment among female patients. The article concludes that lack of education does not hinder women from receiving TB diagnosis and treatment. The concept of traditional illness, however, causes a longer diagnostic delay among illiterate patients and the role of male relatives positively influence treatment outcomes for female patients.

350. Analysis of factors affecting the epidemiology of tuberculosis in China

JJ Liu, HY Yao & EY Liu; National Center for Tuberculosis Control and Prevention (NCTB), Beijing, China: Int J Tuberc Lung Dis 2005, 9/4, 450-454

The tuberculosis (TB) epidemic situation is both a public health problem and a socioeconomic issue in China. This study attempts to examine the effects of socioeconomic development of the TB control strategy on the TB epidemic in China. The data on prevalence of smear-positive TB from four National Epidemiological Surveys of TB conducted in 1979,1984/85, 1990 and 2000 was used for analysis and correlation co-efficiency was used to study the relationship between changes in the TB epidemic situations, the socioeconomic level and the Health TB control project. It was found that the prevalence of smear-positive TB had significant medium correlation with the per capita net income of the rural population, the consumption level of urban population, the per capita GDP, the population density, and the proportion of rural to total population, among which the correlation with the first four was negative and with the last was positive. The decline in prevalence in the project areas was much greater than in the non-project areas (44.4% vs 12.3 %), while their GDP increases were similar. The article emphasizes that with socioeconomic development, correlation between the socioeconomic indices and the TB epidemic becomes more significant. The TB control project is vital to reduce the prevalence of TB in China.

351. A method to determine the utility of the third diagnostic and the second follow-up sputum smear examinations to diagnose tuberculosis cases and failures

HL Rieder, CY Chiang, ID Rusen: Tuberculosis Division, International Union Against Tuberculosis and Lung Disease, Paris, France; Int J Tuberc Lung Dis 2005, 9/4, 384-391

The study was conducted in forty-two laboratories in four countries to determine the number of sputum smear examinations required to identify one additional case of tuberculosis from a third serial diagnostic smear or one additional treatment failure from a second serial follow-up smear. Country-specific prevalence of new cases and failures among 59665 examinees were determined, as well as the incremental yield from serial smears. The reciprocal value of the product of the prevalence of cases or failures and the respective incremental yield from the last serial smear provided the number of slides that have to be examined to identify one additional case or failure. The analysis found that the expected prevalence of cases among suspects ranged from 5.4% to 32.8%; the incremental yield from a third serial smear ranged from 0.7% to 7.2%. Between 122.7 and 796.3 smears were required to identify one additional case with the third serial smear. The prevalence of failures among follow-up examinees ranged from 1.0% to 2.5%; the incremental yield from the second follow-up serial smear ranged from 4.5% to 26.9%. Between 164.8 and 2133.4 slides were required to identify one additional failure with the second serial smear. The study provides a framework for how each country can asses rationally how many serial smears it will require in the diagnosis of both new cases and treatment failures. It advocates that serial smears can be rationally determined by careful review of program data and it should be country specific.

352. Application of lot sampling of sputum AFB smears for the assessment of microscopy centres

N Selvakumar, E Prabhakaran, B N Murthy, S Sivagamasundari, S Vasanthan, R Govindaraju, M Perumal, F Wares, L.S Chauhan, T Santha,and PR Narayanan; Tuberculosis Research Centre, Indian Council of Medical Research, Chennai; **Int J Tuberc Lung Dis 2005, 9/4, 384-391**

The study documents the experiences gained by using lot sampling of sputum acid-fast bacilli (AFB) smears in a tuberculosis unit in Tiruvallur district, Tamil Nadu state, India, during the period May 2002 to April 2003. The study included Designated microscopy centres (DMC) and additional microscopy centres (AMC) performing sputum (AFB) microscopy, the District TB Centre (DTC) and a reference laboratory (RL). The objective of the study was to ascertain the feasibility of adopting lot sampling of AFB smears and to assess the performance of MCs employing Senior Tuberculosis Laboratory Supervisors (STLS) with no knowledge about the principles of quality assurance of AFB microscopy and RLbased laboratory technicians with training on quality assurance for blinded checking of AFB smears. The methodology adopted was, slides from MCs were transported to the DTC and the RL; 20 smears per month per MC were selected systematically; 1547 slides from DMCs and 726 from AMCs were checked, respectively, by STLSs at the DTC and the RL laboratory technicians, Discrepancies were resolved by reference. The results of the study indicated a discrepancy between MC laboratory technicians and STLSs at the DTC was 4.7%, compared to 1% at the RL. The STLSs and RL-based laboratory technicians had 70 and 2 errors, respectively. The study finds that Lot sampling of AFB smears is feasible under field conditions. Assessment of MCs was more valid with RL-based technicians trained in principles of quality assurance of sputum AFB

microscopy than with STLSs with no such training and working in the field.

MS Subramanya Rao Statistical Officer NTI, Bangalore

353. A double-blind study of oral salbutamol supplement and repeat sputum smear microscopy in enhancing diagnosis of smear negative pulmonary tuberculosis in South India

Balasubramaniam R, Rajeswari R and Naik A.C., et al; Tuberculosis Research Center, Mayor V. R. Ramanathan Road, Chetput, Chennai – 6000 031: **Indian J Tuberc; 2004; 51; 191 – 198.**

Direct microscopic examination of sputum for acid-fast bacilli [AFB] remains a corner stone for the diagnosis of tuberculosis in both low income and industrialized countries. Even though the identification of AFB in a sputum specimen is highly specific for the diagnosis, it is estimated that in most developing and technically advanced countries, at least half the diagnosed cases of pulmonary tuberculosis are likely to be smear negative. These patients constitute a substantial case load. Accuracy of the diagnosis of smear negative pulmonary tuberculosis [PTB] in resource-poor countries in the absence of culture facilities, particularly under programme conditions, is challenging as this group of tuberculosis suspects is likely to include persons suffering from both tuberculosis and non-tuberculosis respiratory infections. Secondly, their diagnosis is essentially made based on the presence of clinical symptoms supplemented by chest radiography. This practice might lead to over or under diagnosis.

In a double blind placebo controlled study, the role of repeat sputum microscopy after antibiotics and oral Salbutamol supplement in improving the diagnosis of smear negative TB suspects was investigated in an urban TB clinic. Culture examinations for all study patients were done to find out proportions of TB cases in this series. A total of 230 smear negative suspects were enrolled in the study in one year 2001. Of these, 24 were excluded for various reasons: 13 failed to complete the exercise and 11 had previous history of hypersensitivity to salbutamol. Of the remaining 206, [101 salbutamol(s), 105 placebo (p) groups] 26 were positive by repeat sputum smear examinations. In all, 40 (s 23, p 17) including 26 smear positives were culture – positive for *Mycobacterium tuberculosis*.

The authors opine that the study has shown that in resource poor settings, repeat sputum smear microscopy after a trial of antibiotics, could improve the diagnostic accuracy of smear – negative PTB patients. On the other hand, oral salbutamol supplement was not beneficial in improving the diagnosis of smear negative PTB. Therefore, the authors recommend repeat sputum examinations as a routine procedure to be included in the diagnostic algorithm, especially for developing countries like India where culture facilities are not available in the programme. It has the advantage of both confirming the disease, helping in proper categorizations and also inpatients getting appropriate treatments.

354. Treatment of tuberculous pleural effusion patients and with their satisfaction with DOTS – 1 $\frac{1}{2}$ year follow up.

Dhingra V. K, Rajpal S and Aggarwal N. et all; New Delhi TB Centre, Jawaharlal Nehru Marg, New Delhi – 110 002: Indian J Tuberc 2004; 51; 209 – 212.

Under the WHO recommended DOTS strategy, patients who are smear negative after 3 smear examinations are subjected to radiological examination after they fail to respond to a course of antibiotics for a period of two weeks. Those showing radiological evidence of pleural effusion are examined physically and investigated further by tuberculin testing and diagnostic aspiration. Those confirmed to be suffering from tuberculous pleural effusion by naked eye examination; biochemical tests and cytology of pleural fluid are given a fixed schedule of drugs. The treatment is stopped after 6-8 months as per category and out come is reported as "Treatment completed". Many a time, patients question the validity of stopping treatment without radiological examinations. Physicians treating are also at times not confident themselves and often fail to reassure such patients. Presence of residual symptoms in such patients before stopping treatments creates further uneasiness among the treating physicians.

Of the total 58 patients of tuberculous pleural included in the study, only 36 of them could be followed up for a period of 1 ½ years. The study revealed that 63.9% of them were satisfied with the DOTS policy of stopping treatment without X-ray at the end of treatment whereas 36.1% expressed dissatisfaction with this policy. As many as 16.7% even got their x-rays done elsewhere, before stopping the treatment for their own satisfaction. The 1 ½ year follow up revealed only one case of relapse.

The authors feel that in cases of pleural effusion it would be more prudent to leave the decision of repeat radiological examination to the discretion of treating physicians especially in urban TB clinics which are being managed by trained TB specialists. The authors opine such an approach would reduce the extent of dissatisfaction and might further improve the participation of patients in the programme.

355. Predictors of relapse among pulmonary tuberculosis patients treated in a DOTS programme in South India.

Thomas A, Gopi PG and Santha T, et al; Tuberculosis Research Centre [ICMR], Chennai, India: **Int J Tuberc Lung Dis, 2005,9/5, 556 -561** In the Revised National Tuberculosis Control Programme of India, based on the DOTS strategy, patients are treated with an intermittent shortcourse regimen with drugs administered thrice weekly on alternate days under controlled clinical trial conditions similar short course treatment regimens have been found to be highly successful with reported end of treatment cure rates of 95 – 100% and relapse rates of 3-8% over a 2 year follow up period.

A prospective study was conducted to measure the rate of relapse among patients who successfully completed treatment and were declared cured under the programme and to identify the risk factors for relapse. Sputum samples were collected from a cohort of TB patients registered between Apr. 2000 and Dec. 2001 were examined by fluorescence microscopy for acid-fast bacilli and by culture for Mycobacterium tuberculosis at 6, 12 and 18 months after treatment completion. Of the 534 cured patients, 503 (94%) were followed up for 18 months after treatment completion. Of these, 62 (12%) relapsed during the first 6 months of follow up. Patients who took treatment irregularly were twice more likely to have a relapse than adherent patients (20% Vs. 9%; adjusted odds ratio [aOR] 2.5; 95\5 CI 1.4 - 4.6). Other independent predictors of relapse were initial drug resistance to isoniazid and for rifampicin (aOR 4.8; 95% CI 2.0 - 11.6) and smoking (aOR 3.1; 95% CI 1.6 -6.0). The relapse rate among non-smoking treatment adherent patients with drug-sensitive organisms was 4.8%.

The authors feel that there is a need to take a proper history prior to starting anti- tuberculosis treatment. It should be emphasized to the medical officers for correct categorization of treatment. Ensuring that patients take their treatment regularly and are counselled effectively about quitting smoking can reduce the relapse rate under the RNTCP. There is a need to develop effective communication strategies with effective health education materials, which in turn will have farreaching effects on the health of the population. Further research is needed to develop and test local communication strategies to help smokers quit smoking and document this impact on the cure of tuberculosis.

356. Every provider counts: effect of a comprehensive public-private mix approach for TB control in a large metropolitan area in India.

Ambe G, Lonnroth K and Dholakia Y, et al: Mumbai Municipal Corporation, Mumbai, India; **Int J Tuberc Lung Dis 2005, 9/5, 562 – 568**

In many countries, including India, the existing public-private mix (PPM) of health care providers has not been optimally utilized for DOTS expansion. The for-profit private sector is often poorly regulated and controlled by the health authorities and is therefore perceived as being out of reach of public health programme planning and implementation. However, it seems that many public sector providers are also out of reach of public health programme implementation, often due to a lack of coordination and joint central planning between different Ministry of Health (MoH) departments as well as between the MoH and other ministries responsible for health care provision in a variety of sectors, such as the prison system, the armed forces educational systems and employee health insurance schemes.

The study was conducted to assess the impact on case notification and treatment outcome of a public- private mix approach for tuberculosis (TB) control involving private providers, non-government organization (NGOs) and public providers not previously involved in the Revised National TB Control Programme (RNTCP). Under the stewardship of the RNTCP, providers were allocated different roles in referral, diagnosis, treatment initiation, directly observed treatment

(DOT) provision, training and supervision. Referral forms were introduced and RNTCP registers were adapted to enable monitoring of case notification by different providers and cohort analysis disaggregated by provider type. A fraction of all non-RNTCP providers had become actively involved by the end of 2003. These providers contributed 2145 new smear-positive cases in 2003, and increment of 40% above the 5397 cases detected in RNTCP facilities. The treatment success rate for new smear-positive cohorts for 2002 was 85% in RNTCP facilities, 81% in private clinics, 88% in medical colleges, 91% in NGOs and 73% in the TB hospital (where the death rate was 16%).

The authors feel that active involvement of some key public and private providers can increase case notification substantially while maintaining acceptable treatment outcomes. The impact can be expected to be even larger when all health providers have been involved.

> SR Kusuma Laboratory Technician NTI, Bangalore