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# OPERATIONAL RESEARCH STUDIES IN TUBERCULOSIS CONTROL CONTRIBUTIONS IN THE LAST TWO DECADES FROM TUBERCULOSIS RESEARCH CENTRE, SOUTH INDIA

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Operational research (OR) provides a scientific and methodical approach that would help to better monitor the TB control programme in addition to routine reporting system in existence. OR should always be closely connected with disease control activities. OR in TB is a public health imperative in this millennium in the wake of multi-drug resistance and HIV in many parts of the world.

India has been a pioneer in undertaking innovative investigations in the field of TB. Tuberculosis Research Centre (TRC), Chennai has a big share in contributing towards evolution of effective chemotherapeutic regimens for both pulmonary and extra-pulmonary TB and on important operational aspects of programme<sup>1</sup>. Findings of various TRC studies revolutionized the TB control practices in India and around the world (Table 1).

**Table1.** Landmarks in tuberculosis research from TRC / ICMR

Year	Research findings
1955	National Sample Survey to estimate the burden of tuberculosis
1956	Effectiveness of domiciliary treatment
1958	Need for direct observation of treatment
1964	Effectiveness of intermittent chemotherapy
1974	Lack of effectiveness of BCG vaccine in preventing adult TB
1974	Evolved effective short-course chemotherapeutic regimens
1983-2002	Various operational research studies

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Similarly National TB institute (NTI) Bangalore contributed by voluminous research towards understanding of TB control in 1960s and 70s<sup>2</sup>. The National Tuberculosis Programme, launched in 1962, was based on path-breaking epidemiological and sociological studies by NTI Bangalore and indeed, became a blue print for the control of tuberculosis in other developing countries of the world also<sup>3</sup>. In National Tuberculosis Programme (NTP) TB services were integrated into the general health services. ICMR Expert Committee evaluated NTP in 1975 and highlighted poor case-finding activity, poor defaulter retrieval system, non-availability of sufficient trained staff and inadequate supervisory activities<sup>4</sup>. According to a mathematical model with the case finding, case holding and chemotherapy efficiency of 30%, 35% and 75% respectively, it was estimated that less than 8% of patients were successfully treated under NTP<sup>5</sup>. The scenario did not change even after introduction of almost 100% effective Short-course chemotherapeutic regimens in the programme. In 1993, a review by Government of India / WHO / SIDA highlighted the operational constraints faced by NTP. RNTCP was built upon some of these lessons<sup>6</sup>. The challenge in implementation of RNTCP is to achieve sustainable programme objectives. Thus there is a need to study interventions that would enhance effectiveness of TB control measures.

TRC for more than 2 decades has been working on many aspects of the programme to identify or develop appropriate strategies for successful implementation of the programme. The issues addressed are listed in Table 2. A bird's eye view of these studies is given in this report.

**Table 2.** Areas investigated under Operational Research

<p><b>a. Estimating the burden of illness</b></p> <ol style="list-style-type: none"> <li>1. Prevalence of disease and infection during 15 years</li> <li>2. Surveillance of drug resistance in TB in Tamil Nadu state</li> <li>3. Socio-economic impact of tuberculosis on patients and their families</li> <li>4. Socio-economic impact of parental TB on children</li> <li>5. Usefulness of community surveys</li> <li>6. Molecular epidemiology of TB in a rural area</li> </ol> <p><b>b. Methods to improve case-finding and case –holding</b></p> <ol style="list-style-type: none"> <li>1. Identification of task forces for TB case-finding in rural, tribal and urban areas</li> <li>2. Influence of initial and repeated motivation on treatment compliance</li> <li>3. Assessment of address card system acceptability and efficiency</li> </ol> <p><b>c. Behavioral studies</b></p> <ol style="list-style-type: none"> <li>1. Sample survey of awareness of tuberculosis and action taking behaviour of tuberculosis suspects in the community</li> <li>2. Care seeking behaviour of tuberculosis suspects in the community</li> <li>3. Sample survey to assess the knowledge of TB in a rural community initially and after health education</li> <li>4. Assessment of knowledge of TB among educated public</li> <li>5. Health seeking behaviour of tribals</li> <li>6. Factors for delay by patients &amp; at the level of the health system in the diagnosis of TB</li> <li>7. Identification of reasons for "lost" cases in two districts in NTP</li> <li>8. Association of tobacco smoking and TB</li> </ol> <p><b>d. Evaluation of programme</b></p> <ol style="list-style-type: none"> <li>1. Feasibility of introducing SCC under the existing NTP in 18 districts in India</li> <li>2. Evaluation of different DOT providers in RNTCP</li> <li>3. Status of patients started on treatment in the programme in the follow up period after completing chemotherapy</li> </ol>
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## STUDIES ON ESTIMATING THE BURDEN OF ILLNESS

Measurement of the burden of illness included estimating the prevalence of the disease, prevalence of infection, surveillance of drug resistance, assessment of socio-economic burden, and utilization of molecular epidemiological tools to obtain information on the mechanism of transmission of disease in the community. Information on epidemiological trends

in TB is of great importance for planning, monitoring and evaluation of TB programme. Reliable data on the subject are few in developing countries with heavy burden of disease.

## Trends in the prevalence and incidence of tuberculosis in South India

The burden of illness was measured with respect to trends in prevalence and incidence of disease and annual risk of TB infection (ARTI) during 15 years (1969-1985)<sup>7</sup>, The trends in the prevalence and incidence of tuberculosis in this part of South India has shown that the prevalence of tuberculosis and annual risk of TB infection (2%) showed little or no decrease during 15 years; prevalence of culture positive TB was highest in 1973-1975 survey , 890 / 100,000 and showed a significant steady decline by 2.3% per annum and was 694 / 100,000 in 1984-1986. But with reference to smear positive TB there was no consistent pattern; it was highest 511 / 100,000 in 1973-1975 and it was 428 / 100,000 in 1984-1986. Similar findings have been reported earlier from 3 epidemiological studies from India. The largest initiated in a rural population of 60,000 in 1961 in Bangalore district

showed no change in prevalence of disease over a 5-year period<sup>8</sup>. Another study in 20-25 thousands rural populations in Tumkur district showed no change in prevalence of infection or disease over a 12-year period in 1961-1973<sup>9</sup>. A recent study from New Delhi showed no change in prevalence in 30,000 population over 30 year period<sup>10</sup> (1962-1991) and no change in incidence over 15 year period (1962-1977)<sup>11</sup>. Epidemiological trends are essential for evaluation of the performance of the programme

Reliable information on the levels of drug resistance at periodic intervals is essential to formulate treatment policy for the nation. However National surveys of drug resistance are prohibitively expensive and logistically difficult considering the many constraints faced, including the large size of the country. The levels of drug resistance provide an epidemiological indicator to assess the extent of resistant bacterial transmission in the community. This also serves as a useful parameter in the evaluation of current and past chemotherapy programmes.

#### **Surveillance of drug resistance in tuberculosis in the state of Tamil Nadu**

Surveillance of drug resistance in an entire state of Tamil Nadu was undertaken using internationally accepted standardized methodology<sup>12</sup>. Drug resistance surveillance has shown gradual increase in initial drug resistance over the years in Tamil Nadu; the proportions of resistance to H, R and HR were 15.4%, 4.4% and 3.4% respectively in newly detected patients.

#### **Surveillance of drug resistance in tuberculosis in two districts of South India**

Drug resistance surveillance undertaken in North Arcot district had shown that the proportion of MDR TB in newly diagnosed patients had marginally increased over the last 10–15 years (2.5–2.8%)<sup>13</sup>. Also NTI reported that HR resistance was 1.36% in urban DTC and 3.42% in rural PHI<sup>14</sup>. These findings suggest that drug resistance needs to be monitored continuously in the programme. The only way to prevent emergence of resistance to rifampicin and isoniazid is to adhere to direct observation of treatment strictly in the programme.

#### **Socio economic impact of tuberculosis on patients and family in India**

TB affects the most productive age group and the resultant economic cost for society is high. We tried to document the economic impact (out of pocket expenses) of TB on patients and their families<sup>15</sup>. The findings were that the average total cost was Rs 5986 per patient amounting to about 13,000 crores a year for the Country, even though the treatment and diagnosis were offered free of cost to patients.

#### **Socio economic impact of parental tuberculosis on children**

In addition 11% of children dropped out of school on account of parental illness and 20% of the children had to take up jobs in order to supplement income especially if the father had TB<sup>16</sup>. Thus TB has the potential to impede the development of both individuals and society. These findings may help policy makers, potential donors and health planners to develop new approaches for effective promotion of TB control.

The DOTS strategy recommends screening of TB suspects at the health facilities as the primary mechanism for detecting TB. Recently there has been a renewed interest in active case detection as a part of expansion of DOTS strategy in high prevalent areas<sup>17</sup>.

#### **Role of community surveys to detect tuberculosis patients in high prevalence areas**

A unique opportunity was available to examine the value of active case finding in a rural area where cases were also detected at the health facilities. We tried to ascertain the usefulness of active case-finding for TB by community surveys<sup>18</sup>. The

study findings were that Community surveys were of little help in reducing the spread of tuberculosis even in high prevalence settings, as they identify cases, which were less symptomatic and less infectious and also 80% of these cases had already consulted a governmental or private health-care provider for seeking relief of symptoms. Considerable resources were required by community surveys in: identifying new cases; motivating less symptomatic patients to start treatment; and persuading non-adherent patients to resume treatment. A community survey also has the potential to increase the risk of emergence of drug resistance by adding to the number of incompletely treated cases. Even without changing patient behaviour or additional resources for prohibitively expensive community surveys, case detection rates above 70% can be achieved by active and effective screening of patients with chest symptoms who voluntarily seek medical care. Hence active case finding is not necessary for TB control.

### **Molecular Epidemiology of TB in a rural area**

A novel study on molecular epidemiology; restriction fragment length polymorphism analysis was undertaken on clinical isolates from TB patients treated under DOTS strategy has shown that majority of these patients were due to reactivation<sup>19</sup>. Therefore sustained TB control measures are needed to reduce the bacillary load in the community.

### **STRATEGIES TO AUGMENT CASE-FINDING AND CASE HOLDING COMPONENTS**

#### **Utilization of**

- a) traditional birth attendants (DAIS) in rural area,

- b) literate tribal youth volunteers in tribal area &
- c) male student volunteers in an urban area for TB case –finding and drug delivery/ defaulter retrieval (motivation) of TB patients.

In order to augment case-finding and case-holding components of the programme, different task forces were utilized in various geographical areas; traditional birth attendants (DAIS) in rural areas<sup>20</sup>, tribal literate youth volunteers in tribal area<sup>21</sup> and male student volunteers in city<sup>22</sup>.

### **Role and acceptability of DAIS in a rural community**

These task forces were chosen depending on the strength, availability and acceptability by the community<sup>23</sup>. All these task forces were found to be very efficient in detection of TB cases in the community, transportation of sputum specimens with proper labeling and also in anti-tuberculous drug supply after a short period of training. This finding is in conformity with that reported by Jagota et al on utilization of traditional birth attendants for administering drugs under direct supervision for the entire 6 months in the PHI and the treatment completion rates, conversion rates and cure rates improved significantly<sup>24</sup>. These task forces can be effectively utilized as DOT providers in respective areas. These task forces serve as excellent models of community participation.

### **Influence of initial and repeated motivation of patients on treatment adherence**

Treatment default and premature discontinuation of treatment continue to be major constraints for the successful implementation of the NTP and

has always been an important topic for research. In order to assess the influence of motivation in improving patient compliance, a study was conducted at three taluka hospitals, in Tamil Nadu<sup>25</sup>. Results have shown that treatment completion rate improved among patients who had initial and repeated motivation. These findings are similar to that reported from NTI, Nepal and an NGO from Bombay<sup>26-28</sup>. This study has highlighted the importance of initial counseling and motivation of patients in improving treatment adherence in programme.

### **Feasibility of an address card system for obtaining accurate address in programme**

There are inherent problems in keeping track of TB patients till they complete treatment, as the period is 6-8 months. In addition, recording of addresses incorrectly is common in the programme. Obtaining accurate address of patients is crucial for retrieval of defaulters during treatment. A novel method of feasibility of utilizing address card system for obtaining accurate address of rural patients under programme conditions was examined<sup>29</sup>. An address-card on which patient's home address is asked to be recorded by a person knowing for sure the patient's address, was investigated for acceptability and efficiency. This system was acceptable and found to be useful. This finding is similar to that reported by Radhakrishna et al where the acceptability was 96% and accuracy was 85% among urban patients<sup>30</sup>. This system can be easily introduced in the programme.

## **BEHAVIOURAL STUDIES**

### **TB Awareness studies in community, among educated public and tribal community and action taking behaviour of TB suspects in community**

DOTS strategy recommends passive case finding at the health facilities as the primary mechanism of case finding in the programme. This is based on scientific evidence that TB suspects would seek care on their own for relief of their symptoms in the community. For this, the community should be aware of TB and its symptoms. Studies on the awareness on TB and action taking behaviour of TB suspects provide important clues for the planning of TB control programme. Hence care seeking behaviour of TB suspects and their awareness of symptoms were investigated on two occasions with an interval of about 10 years<sup>31-32</sup>. A sample survey in rural, urban and metropolitan areas was undertaken to identify the tuberculosis suspects and collect data on their action taking behaviour. The salient findings of the first study were that more than 80% of the symptomatics were aware, and more than 90% had contacted health facilities of which one half were governmental. The second study findings were that 80% of urban participants and 63% of rural participants had sought care, 93% within one month of onset of symptoms. Fifty percent of the participants who did not seek care felt that their symptoms were not severe. There has been no appreciable change in the behaviour of TB suspects over a period of 10 years. Earlier studies from NTI had reported that 95% of patients were aware, 74% were symptomatic and 49.5% of bacillary TB patients sought care and many of them at multiple agencies<sup>33-34</sup>.

Awareness of TB among educated public (college students, teachers, Bank employees, Clerical staff) was undertaken to find out whether awareness would be different from that of community<sup>35</sup>. The educated were aware of the cause and symptoms and diagnostic tools of TB but unaware of sputum disposal and the duration of treatment. Hence health education on all

aspects TB is essential even for educated community.

This finding is substantiated by the findings of another study of assessment of knowledge about TB among nurses by Neeta Singla et al; only 41% of nurses working in the TB ward and 11% of the general hospital nurses had a satisfactory level of awareness<sup>36</sup>. Paramedics and especially nurses are an integral part of any health care system. TB treatment is domiciliary for majority of patients but a few patients may require hospital admission. The nurses in the hospital are not only involved in management of patients and administration of the wards but they are also responsible for providing health education and also for clarification of doubts to patients and their families. Hence the programme managers should plan to train nurses on all aspects of TB. Poor knowledge of nurses may be a big hindrance in running the programme.

Tribal communities are quite different in all aspects from other communities due to their traditional and cultural background. A study was undertaken to assess the health seeking behaviour, preference of health facilities and awareness of TB among tribals of Andrapradesh<sup>37</sup>. Only 44% of 429 tribals had heard of TB. The available government health facilities were acceptable to the tribals. They were in favour of modern medicine compared to native medicines.

Findings from the above awareness studies confirm that TB suspects are aware of TB and majority seek care either at governmental facilities or private health system within one month.

### **Role of health education methods in improving awareness on TB**

The role of health education in improving awareness of TB has also been studied.

Knowledge of TB in a south Indian population initially and after health education was assessed in a rural area<sup>38</sup>. After obtaining knowledge about TB, the community was educated about important aspects of TB by pamphlets, film shows, exhibitions, role-plays, group activities and public meetings. After 2 years, interview of the original respondents had shown that their knowledge on various aspects of TB had improved. This study highlights the efficiency of various health education methods used.

### **Risk factors for “patient delay” and “health system delay” in the diagnosis of TB**

Delay in diagnosis of TB causes spread of infection in the community and is associated with a higher risk of mortality. TB diagnosis can be delayed when patients postpone seeking care until much after the onset of symptoms (patient delay) or when health providers take more time than required to diagnose patients seeking care (health system delay). Studies were undertaken to identify factors for patient and health system delays<sup>39</sup>. The patient delay was greater if the patient had initially consulted a government provider, resided at a distance >2 km from a health facility and was an alcoholic. Factors associated with health system delay were: first consultation with a private provider, alcoholism and patients residence >2 km from a health facility. Studies conducted elsewhere have reported other factors like education lasting <9 years and lack of knowledge about tuberculosis associated with longer patient delays<sup>40-41</sup>. Culturally appropriate messages should be developed to increase public awareness about chest symptoms and availability and location of free TB diagnostic services. Effective partnership with private providers and their active involvement in the programme is mandatory.

These studies highlight that the behaviour of the TB suspects and patients does not need to be changed but the health system's response to this behaviour must change suggesting that the responsibility is that of the health providers to "think TB" and diagnose them promptly.

### **Analysis of reasons for getting "lost" from programme**

Reasons for stopping treatment prematurely and getting lost to the programme were investigated in two districts in Tamil Nadu and Karnataka<sup>42</sup>. The main reasons for stopping treatment or getting "lost" from Short-course chemotherapy (SCC) were abatement of symptoms (19%, 35%), adverse reactions 13-22% and lack of faith in diagnosis and treatment 10-27%. About 50% of patients who were "lost" had done so within 2 months. Hopewell from Peru had reported that 60% of patients were lost within 3 months<sup>43</sup>. Seetha et al had also stated that about half the "lost" patients discontinued treatment at the second or third collection<sup>44</sup>. The programme should include initial counselling and repeated motivation covering all these issues.

### **Association between smoking and TB**

In almost all the countries, the TB notification rates were higher among males compared to females. In this context the association between smoking and TB was examined by a case control study<sup>45</sup>. There appears to be a positive dose-response relationship between tobacco smoking and bacillary TB (OR 2.5). These findings reinforce that these issues should be addressed in health education programmes in the community. IEC activities need to be strengthened in programme.

## **EVALUATION OF PROGRAMME**

### **Seven-year findings of SCC in 18 districts in India under NTP**

Public health programme needs continuous monitoring and periodical evaluation to assess the programme performance, identify lacunae and to take appropriate corrective measures. We undertook 3 important studies to evaluate the programme performance. A feasibility and acceptability study of introducing SCC in 18 districts with a population of 40 million under the existing NTP in India was undertaken<sup>46</sup>. Cohort analyses had shown that the treatment completion rate was 51%-55% for Short-Course Chemotherapy. Even though it was feasible to introduce SCC, additional efforts have to be made for further improvement of case finding and case holding. A report published from NTI on the impact of SCC on the operational efficiency of programme had shown that PHIs showed increased efficiency in new sputum examination performance, number of TB patients diagnosed and number of bacillary cases detected<sup>47</sup>. These findings suggest that decentralisation has happened. This is an encouraging finding.

### **Risk factors for default, failure, & death among TB patients in a DOTS programme**

The second study was analysis of the risk factors associated with default, failure, and death, among tuberculosis patients treated in DOTS programme in South India<sup>48</sup>. Higher default rates were associated with irregular treatment, being male, history of previous treatment, alcoholism, diagnosis by community survey and age  $\geq 45$  years. Multi-drug resistant tuberculosis patients were more likely to fail treatment. Higher death rates were independently associated with weight  $< 35$  kg and history of previous treatment. To



prevent default, directly observed treatment should be made more convenient for patients. Community volunteers can be utilized for DOT closer to the residence of patients. Alcoholism has been reported as a risk factor for default in other studies as well. Better supervision, home visits and health education have been successfully used as interventions to reduce default<sup>49-54</sup>. To reduce mortality, the possible role of nutritional interventions should be explored among underweight patients.

### **Critical assessment of smear – positive PTB patients after chemotherapy in NTP**

The third one was critical one time assessment of smear – positive pulmonary tuberculosis patients after chemotherapy in programme<sup>55</sup>. The salient findings were that even among those who had taken less than 50% of their treatment, 56% were bacteriologically negative. However, inadequate or irregular chemotherapy resulted in over four times the mortality and about twice the rate of smear positivity as compared with those who had taken adequate chemotherapy. These findings strongly suggest that the community should be educated about the dangers of inadequate and irregular chemotherapy.

### **ASSESSMENT OF TREATMENT AND DIAGNOSTIC PRACTICES OF PRIVATE MEDICAL SECTOR**

In India, the private health sector has outgrown the public health sector and 80% of the qualified medical personnel in the country are in private sector<sup>56</sup>. More than half of TB patients initially approached private practitioners (PPs) for treatment. Still PPs did not have a strong presence or defined role in NTP. Few studies have investigated the TB management practices of

private medical practitioners. There was a need to conduct similar studies in other parts of the country. Hence a study was conducted to find out the prescription practices for TB of medical practitioners including chest specialists and practitioners working in government programmes from all over India<sup>57</sup>. This study was repeated after 5 years to find out the change in the prescribing patterns. The salient findings were that initially only 36% of practitioners prescribed proper SCC regimens in 1991. These findings are similar to that reported earlier from Bombay that PPs did not have adequate knowledge of proper treatment regimens for TB<sup>58</sup>. However this proportions increased to 81% when the study was repeated after 5 years in 1996 and the encouraging finding is that only SCC regimens were being prescribed. The main source of information was from books, journals, WHO periodicals & TB institutes.

Subsequently TB diagnostic and treatment practices of rural and urban private for-profit providers (allopaths) were investigated. Both rural and urban practitioners relied on chest radiographs for diagnosis, as they do not have reliable laboratories to perform sputum microscopy. Patients are treated with various regimens tailored to the patient needs. They prescribe but have no mechanism to monitor treatment adherence, defaulter retrieval and details regarding patients completing treatment. The heartening element of the study was that majority were willing to participate in the programme (TRC, unpublished).

A similar study was done at New Delhi among private practitioners from the area where RNTCP was field-tested<sup>59</sup>. About 12% of the PPs advised sputum examination for the diagnosis. Only 20% of doctors emphasized the importance of regular treatment.

Findings from the above studies suggest that PPs need to be trained in RNTCP. Programme managers should collaborate with the PPs and develop a sustainable public-private model for the control of TB.

### **Role of private pharmacies in TB programme**

In an other study dispensing practices of the pharmacies were studied. In most settings in India, private pharmacies dispense prescriptions for anti tuberculosis drugs, given by private practitioners. We assessed the dispensing practices for tuberculosis and knowledge on tuberculosis programme of 300 pharmacies<sup>60</sup>. Doctors' prescriptions were for months but half the patients bought drugs one dose at a time, due to lack of funds, for self-administration. This practice might promote drug resistance. Majorities were willing to learn and contribute towards tuberculosis control. This study has shown that there is potential and a need to involve private pharmacies in tuberculosis control.

### **DESIGNING BETTER DIAGNOSTIC TOOLS**

It is well known that the sputum smear microscopy has varying sensitivity for the diagnosis of acid-fast bacilli. Few attempts were made to refine the Ziehl-Neelson (ZN) staining procedure. All these procedures were double blind and used culture results as the "gold standard".

The sensitivity and specificity of 0.3% carbol fuchsin staining method for AFB was compared with that of the standard ZN staining method<sup>61</sup>. The sensitivity of the 0.3% ZN staining method was significantly lower than that of the standard method. The World Health Organisation's recommendation of 0.3% carbol fuchsin in the ZN staining needs to be reconsidered.

Secondly the sensitivity and specificity of the phenol ammonium sulfate (PhAS) sediment smear microscopy method was examined<sup>62</sup>. The sensitivity and specificity of the PhAS was comparable to the direct method. The PhAS method was better accepted by the laboratory technicians and safer but necessitates an overnight sedimentation, which delays reporting of results until 1 day after sputum collection.

A two – reagent cold staining method for detection of acid fast bacilli in sputum smears was also found to be as sensitive and specific as the Z-N method<sup>63</sup>. However, large-scale multi centric studies in different climatic conditions need to be conducted to assess its efficacy in the diagnosis of pulmonary tuberculosis.

Washing of microscopic glass slides in dichromate solution has not been found to be beneficial<sup>64</sup>.

Similarly processing of sputum samples in a refrigerated centrifuge does not improve the rate of isolation but resulted in rapid isolation of *M. Tuberculosis*<sup>65</sup>.

### **CONCLUSIONS**

All these studies have given an insight into the functioning and effectiveness of the programme. Some of the studies need to be repeated to draw firm conclusions. Policy makers, potential donors and Health planners may use the findings of these studies to develop new approaches towards more effective TB control. Even though the programme is based on scientific principles, the tools need to be evaluated periodically and refined in order to make them user friendly and also to optimise the available resources. Operational research studies are essential to develop sustainable strategies. This will enhance the success of the programme and make TB control a reality.

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# TUBERCULOSIS CONTROL PROGRAMME – IS IT PRO POOR?

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## ABSTRACT

**Background:** TB is a complex socio economic problem that impedes human development and traps the poorest and most marginalized in a vicious circle of disease and poverty. India accounts for 30% of all TB cases in the world.

**Objective:** This paper is focusing on whether the TB programme is outreaching the poorer segment of the community. We did a prospective study to assess the economic indices (SLI) of TB patients registered under government TB control programme of Tamil Nadu. This data was compared with that of the National Family Health Survey (NFHS) data of the community.

**Methods:** A semi-structured and pre-tested schedule was used for data collection. Information elicited through the interview included demographic and socio-economic characteristics such as employment, income, assets of the patient and family. Based on the information collected, standard of living index (SLI) was measured using the NFHS definition and classified as High, medium or low SLI.

**Results:** A total of 980 TB patients were registered during the study period of which 896 (91%) patients were interviewed for this study. The economic status and SLI of the community compared with that of TB patients registered under the programme was as follows: people owning assets in the form of agriculture land 40%, 15%, owning a house 92%, 74% and livestock 36%, 14% no of persons sharing a room more than 5 persons per room 9%, 28%. The distribution of SLI in the community was low in 51%, medium in 40% and high in 8% as compared to the distribution of SLI of TB patients where low SLI was observed in 64%, medium in 32% and high in 4%.

**Conclusion:** This study clearly shows that two thirds of TB patients who have access to the TB programme were poor and meets the health need of the most vulnerable segment of the population.

"Even when an economy is poor, major health improvements can be achieved though using the available resources in socially productive ways..." Prof Amartya Sen, Nobel Laureate

**Keywords:** Tuberculosis, poverty, Standard of living index (SLI), pro poor

## BACKGROUND

Tuberculosis (TB) is a serious public health challenge, not only because of its perennial toll of death and disease, but also because of its clear links with poverty.<sup>1-5</sup> Globally, the highest burden of TB is found in poor countries,<sup>6-9</sup> making it a

disease of the poor. In India, the Revised National Tuberculosis Control Programme (RNTCP), based on the DOTS (Directly Observed Treatment Short course) strategy was introduced in 1993 to address the increasing burden of tuberculosis. RNTCP provides free diagnostic and treatment services to all the patients registered under it. But at present there is no information whether the programme meets the health needs of the most vulnerable segment of its population and about the standard of living (SLI) of patients

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registered under TB control programme. This will also throw light on utilization of government health services by poor TB patients.

We did a prospective study to assess the economic indices of TB patients registered under government TB control programme of Tamil Nadu and compared the same with that of the community. This will point to whether the programme is outreaching the poorer segment of the community.

## METHODS

This study was conducted in Tiruvallur district of Tamil Nadu, south India. Patients diagnosed with TB and registered for treatment under the National Tuberculosis Control Programme during the 6-month period from July to December 2000, were interviewed. A semi-structured and pre-tested schedule was used for data collection. Care was taken to establish a rapport with patients before interviewing them. Information elicited through the interview included demographic and socio-economic characteristics such as employment, income, assets of the patient and family. Based on the information collected, standard of living index (SLI) was measured using the NFHS definition.

International Institute for Population Sciences, Mumbai, India conducted the National Family Health Survey (NFHS-2)<sup>10</sup> in 1998–99. The NFHS was a nationally representative sample survey of 88 562 households and more than 500 000 residents. The NFHS had a systematic, multistage, stratified sample design. It had assessed the standard of living (SLI) in Tamil Nadu and had broadly classified the people living in the community in to three groups (low 51%, medium 40%, high 8%) based on their living conditions.

Definition of Standard of Living Index (SLI): The SLI is calculated by adding the following scores:

House type: 4 for *pucca*, 2 for *semi pucca*, 0 for *kachha*; Toilet facility: 4 for own, 2 for public, 0 for no facility; Main fuel for cooking: 2 for liquid petroleum gas, 1 for kerosene, 0 for wood; Source of drinking water: 2 for pipe, hand pump or well, 1 for public tap, 0 for others; Separate room for cooking: 1 for yes, 0 for no; Ownership of house: 2 for yes, 0 for no; Ownership of land: 2 for yes, 0 for no; Ownership of livestock: 2 if owns livestock, 0 if does not own livestock; Ownership for durable goods: 4 each for a car or tractor, 3 each for a moped / scooter/motorcycle, telephone, refrigerator, or colour television, 2 each for a bicycle, electric fan, radio/transistor, sewing machine, black and white television, water pump, bullock cart, or thresher, 0 for no.

Index scores range from 0-14 for a low SLI, 15-24 for a medium SLI and more than 25 for a high SLI. In this paper, SLI of TB patients has been compared with the SLI of the community, as described in the survey conducted by NFHS-2.

## RESULTS

The profile of the patients registered in TB control programme and their economic status are summarized in Table 1. A total of 980 patients were registered during the study period of which 896 (91%) patients were interviewed for this study. Seventy percent of the patients were males and in more than two thirds of the patients the family size was more than 4. Thirty seven percent of the patients were illiterates and 27% of patients were not working. Patients' standard of living as shown by the SLI was low in 64%, medium in 32% and high in 4%.

Table 2 compares the economic status and SLI of the community with that of TB patients



registered under the programme. The percentage of people owning assets in the form of agriculture land (40%, 15%), house (92%, 74%) and livestock (36%, 14%) were high in the community compared to the TB patients. More than 5 persons per room were observed in 9% of the community as against 28% among TB patients.

Figure 1 compares the distribution of SLI of the community with that of TB patients. The distribution of SLI in the community was low in 51%, medium in 40% and high in 8% as compared to the distribution of SLI of TB patients where low SLI was observed in 64%, medium in 32% and high in 4%.

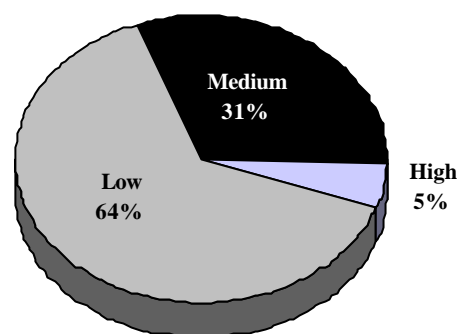
**Table 1.** Profile of the TB patients registered for treatment under government health facilities

	No	%
<b>Age (years)</b>		
15-54	664	74
55+	232	26
<b>Sex</b>		
Male	627	70
<b>Family size</b>		
4+	619	69
<b>Education</b>		
Illiterate	335	37
<b>Occupation</b>		
Not working	240	27
<b>Standard of living</b>		
Low	403	64
Medium	368	32
High	125	4
<b>Total</b>	<b>896</b>	<b>100</b>

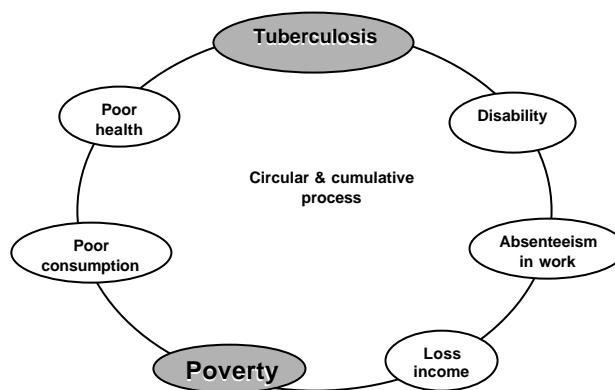
**Table 2.** Profile of the TB patients registered for treatment under government health facilities

	Community Tamil Nadu n=22086 (%)	TB patients Tamil Nadu n=896 (%)
<b>Assets</b>		
Owning agricultural land	40	15
Owning a house	92	74
Owning livestock	36	14
Bicycle	47	42
Telephone	3	3
Moped/Scooter/Motorcycle	9	6
Bullock Cart	2	2
Tractor	1	1
<b>Person per room</b>		
More than 5 person per room	9	28
<b>Source of drinking water</b>		
Piped	65	72
Hand pump	18	9
Well	13	19
<b>Standard of living</b>		
Low	51	64
Medium	40	32
High	8	4
Missing	1	-

**Fig 1.** Utilisation of TB programme in different economic strata



**Fig 2.** Vicious cycle of poverty



## DISCUSSION

Findings of our study undoubtedly bring out that the living status of two thirds of the TB patients registered under TB control programme was low. This was much higher than that reported in general community, as per NFHS of Tamil Nadu, where about 51% of the households had low living index. This finding substantiates that the programme is outreaching the poor. In the present study the tool used for measuring poverty was SLI, which is a widely used tool to assess the economic status of the community by World Bank and National Family Health Surveys. This is the first time poverty is quantified among TB patients in terms of living index assessment and compared with SLI of the community.

Poverty is of multidimensional nature and to assess levels of poverty, earlier studies have used direct indices based on income, food consumption etc or proxy indices like literacy. The following studies had measured poverty related to TB using these tools and similar findings have been observed. In mid-1950s, in Calcutta, TB prevalence rates were over 50 per 1000 in the poorest areas as against 2.48 per 1000 in comparatively affluent areas.<sup>11</sup> Using income as a tool, Nayyar reported that the prevalence of TB among those with income less than US\$ 7 per month was twice higher compared to that of those with a monthly income greater than US\$ 20 in 1989. Similarly, a study from an urban area reported that the prevalence of TB was four times higher among those with no schooling compared to graduates.<sup>12-13</sup>

This study clearly shows that two thirds of TB patients who have access to the TB programme were poor. Considering the benefits of the current TB programme, in India, more than 600 million people in over 300 districts have access to DOTS strategy. Each month more than 50000 patients are being initiated on DOTS. Of them more than 8 of 10 patients are successfully treated and the mortality is reported to be less than 1%.<sup>14</sup> Therefore poor TB patients are immensely benefited.

In the earlier studies it was shown that work absenteeism is significantly reduced among patients treated under DOTS strategy.<sup>15</sup> Thus the programme has the potential to reduce the economic burden of these poor patients and their households by reducing cost and more importantly, enabling them to return to work early.

In the current series it was observed that more than 5 persons shared one room in 28% of the

TB patients where as in the community more than 5 persons shared one room in 9%. This finding substantiates that over crowding is an important risk factor for TB.

TB has a severe impact on the impoverishment of the patients and their households. The major factors, which lead to impoverishment, are inability to work due to illness and cost for diagnosis and treatment. The costs are higher for poor patients and the impact of poverty will be felt by the generations to follow.

## CONCLUSIONS

Public health interventions in TB case detection and treatment could represent an effective part of an anti poverty approach to development in developing countries.<sup>16-19</sup> It has saved TB patients lives and billions of dollars to countries through curing TB patients and by their continued productivity. In India and elsewhere, effective TB control facilitates to break the cycle of poverty and disease (Fig 2). Revised National TB Control Programme (RNTCP) has been acknowledged to be a cost effective health intervention, in curing people and making them return early to work, which in turn benefits their families and in the broader perspective contributes to the overall economic and social development of their country and may help in alleviation of poverty.

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# PRIMARY DRUG RESISTANCE TO ANTI-TUBERCULOSIS DRUGS IN KARACHI, PAKISTAN

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## ABSTRACT

**Background:** Primary drug resistance to anti TB drugs is a universal phenomenon. It is a major threat to TB control programs. Pakistan faces the same threat. It had not participated in the Global Project on Anti TB Drug Resistance Surveillance.

**Objective:** To know the prevalence of primary drug resistance in Karachi, Pakistan.

**Methods:** It was hospital based prevalence study done on new pulmonary TB patients in year 2000 at outdoor facility of the department of Thoracic Medicine, Jinnah Postgraduate Medical Center Karachi.

**Results:** Out of 100 culture positive new pulmonary TB patients 24% Showed resistance to one or more Anti TB drugs. Primary MDR was 1%. INH and Rifampicin resistant were 16 and 7% respectively.

**Conclusion:** Primary drug resistance occurs in high proportion of cases in Karachi. It falls within the range of high prevalence countries. Country wide systemic survey of primary drug resistance is urgently needed to know the magnitude of problem in depth.

**Key Words:** Prevalence Study, Primary Drug Resistance, Pulmonary Tuberculosis, Pakistan.

## Introduction

Drug resistance to anti tuberculosis drugs is a global problem (1). It has been recognized soon after the introduction of effective anti TB drugs (2). It has emerged as a major public health threat to TB control programs both in developing and developed countries (3, 4, 6).

Drug resistance in tuberculosis is broadly classified as primary and acquired (5). Acquired resistance is a man made problem, developed due to erratic management of TB patients, while

primary resistance means presence of resistance strains of Mycobacterium Tuberculosis in patients who either received no anti TB treatment or received it for less than one month. Accurate distinction between primary and acquired resistance is not always possible. In the absence of tuberculosis registries, this distinction depends on a patients report and on the training of clinicians in obtaining reliable histories (2, 6).

There is much variation in anti TB drug resistance between different countries, even in various parts of the same country. The global project on Anti TB drug Resistance Surveillance provides standard overview of the prevalence of drug resistance in many countries around the world (7).

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Pakistan had not participated in this global project (2). It has considerably higher incidence of TB and its revised TB control program is still at its primitive stage of implementation (8). It is yet to be launched in Karachi. There is dearth of knowledge about the prevalence of primary drug resistance in the country. This study was done to know the primary drug resistance to first line anti TB drugs in Karachi, Pakistan.

## **Methodology**

This was a hospital based prevalence study done on pulmonary TB patients who had visited outdoor facility of the department of Thoracic Medicine, Jinnah Postgraduate Medical Center Karachi during year 2000.

Jinnah Postgraduate Medical Center Karachi is one of the largest government run tertiary care hospital of the country. Its department of Thoracic Medicine is one of the main facilities of the city catering the need of TB patients. Here anti TB drugs are provided free of cost. Majority of the patients entertained at this department belongs to lower middle to lower class social strata.

Initially those pulmonary TB patients were recruited, who in response to direct questioning denied having had anti TB treatment before. After informed consent, three sputum samples of each patient were examined under microscopy using the Ziehl Neelsen method, two at the laboratory of Medical Unit I, Jinnah Postgraduate Medical Center and one at Aga Khan University Hospital laboratory. The same sample was applied for Mycobacterial culture and susceptibility testing on Bactec Radiometric system at Aga Khan University Hospital Laboratory. Subsequently those patients who were found to be culture positive considered as study cases.

The sample size was estimated as per estimated incidence of TB in Karachi for year 2000 at the estimated population of the same year. According to 1998 census the population of Karachi was 9.27 million. It was growing at the rate of 3.45 annually (9). The estimated population for the year 2000 was 9.92 million and the expected number of new TB patients was around 18000 calculated at the incidence rate of 181 per 100,000 (8).

The expected primary resistance to one more anti TB drug was around 17%, as same was reported by Khan J et al in 1993 and the worst acceptable figure was around 9.8%, as the same figure was reported in year 1998 from neighboring country Nepal who participated in the Global Surveillance Project for Anti TB Drug Resistance (2, 10).

Based on these assumptions, the sample size was calculated with the help of Epi Info 2000 software program. At 95% confidence level, minimum 104 patients were required to detect the potential primary drug resistance to anti TB drugs. By adjusting non-response at a rate of 10%, a required final sample size was 114.

Finally we succeeded in registering 100 culture positive pulmonary TB patients in one calendar year. We achieved 96% of target hence the chances of bias were less.

The data was entered in Epi Info 2000 software program and analyzed.

## **Results**

Out of 126 provisionally selected pulmonary TB patients, 100 patients were found to be sputum culture positive for mycobacterium tuberculosis. The yield of single sputum culture was 79.3%. Among them 81% were smear positive. The mean age was 35.6 years with standard deviation of 15.3 and range was 18-70 years. Sixty one were male

and 39 were female. Their susceptibility pattern is shown in Table I and II.

**Table 1.** Summary of patterns of Primary Resistance to First Line Anti Tuberculosis Drugs.

	No (%)
Total Tested	100 (100)
*Fully Sensitive	76 (76)
**Any Resistance	24 (24)
+Mono Resistance	20
++Poly Resistance	04
Resistance to two drugs	04
^MDR ( Including Resistance to R & H)	01
^^Non RH MDR	03
Resistance to HE	01
Resistance to HS	01
Resistance to RS	01
Resistance to three drugs	00
Resistance to four drugs	00

\*Sensitive to four first line anti TB drugs (Rifampicin, Isoniazid, Ethambutal & Streptomycin)

\*\*Resistance to one or more of four first line anti TB drugs (Rifampicin, Isoniazid, Ethambutal & Streptomycin)

+Resistance to one drug

++ Resistance to two or more drugs

^Multi drug resistance (resistance at least to both Rifampicin and INH)

^^Multi drug resistance (excludes either Rifampicin or INH)

R=Rifampicin, H=INH (Isoniazid), E=Ethambutal and S=Streptomycin

**Table 2.** Summary of Mono Resistance.

Drug	No	%
Rifampicin	07	( 7 )
INH (Isoniazid)	16	( 16 )
Ethambutal	02	( 2 )
Streptomycin	03	( 3 )

## Discussion and conclusion

Recent investigation shows that the global prevalence of primary resistance to any of the four anti TB drugs (rifampicin, INH, Ethambutal and Streptomycin) tested ranged from 2.0 percent in the Czech Republic to 40.6 percent in the Dominicans Republic (2). This study shows the prevalence of 24 percent which falls within the

range of high prevalence countries like Bolivia, Dominicans Republic, Estonia, Latvia, Russia, Thailand and Vietnam (2). It is higher than the early reported figure of 17 percent by Khan J et al in 1993 in their study conducted at Aga Khan University Hospital Karachi, where majority of the patients treated belongs to upper middle to upper class social strata (10). The likely possibilities of this difference could be the limitation of this study and reflection of the overall TB control activities carried out in the Metropolitan.

This study reports the prevalence of primary MDR as 1 percent, which is within the range of low prevalence countries like Brazil, New Zealand and Nepal and is largely un-explained but may be due to vivo and vitro differences (2).

This study documents INH resistance of 16 percent which is between 11 and 29 percent reported by Khan J et al in 1993 from Karachi and Shamshad Rasul et al in 1995 from Lahore respectively (10, 11). This could be explained on the basis of variations in resistance in different countries, even in the parts of same country and over a period of time.

This study also demonstrates the high prevalence of rifampicin resistance i.e. seven percent. The reason could be easy availability and erratic use of drug over a long period of time (2).

This study is limited by being done at a tertiary care hospital and serial selection of the patients who on detailed enquiry denied of having had anti TB treatment in the past. There exists a great need for a systemic survey of primary drug resistance data from adequate samples of representative population reflecting the distribution of tuberculosis in Karachi and country as a whole.

Furthermore, continuous monitoring of primary drug resistance in Pakistan is badly needed as it

measures the effectiveness of TB control program in the community and largely results from the transmission of infection from the pool of patients with acquired drug resistance over a number of years (12).

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# THE RELATIONSHIP BETWEEN SOCIAL SUPPORT AND PATIENT COMPLIANCE WITH DOTS IN KATHMANDU URBAN AREAS, NEPAL

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**OBJECTIVES:** *To identify the relationship between social support and patient compliance with DOTS.*

**METHODOLOGY:** *A descriptive cross sectional study was carried out on a representative sample of new smear positive tuberculosis patients registered between 1st May to 30th November 2002 in the 22 DOTS centres established in government, private, Metropolitan and NGOs sectors of Kathmandu. Structured face to face questionnaire was administered to random sample of 571 new smear- positive TB patients currently under treatment or defaulted. Analysis of non-compliant (missed > 7 consecutive treatment days) versus compliant was done using SPSS.10 data analysis package.*

**RESULT:** *The overall scores of social support from family and friends were significantly different between the two groups ( $p < 0.05$ ). The result shows increased levels of social support from family and friends in complaint patients but the difference is not demonstrated in perceived support from health workers.*

**CONCLUSION:** *It was found that compliance behavior is closely associated with the social support from family and friends. Control programmes that take these factors into consideration must be successful in reducing non-compliant.*

**KEY WORDS:** *Compliance, social-support, tuberculosis, Nepal*

Tuberculosis is one of the major public health problems in Nepal. Data from the National Tuberculosis Programme of Nepal shows that there are about 20,000 new infectious cases and 8000-11,000 deaths due to TB every year<sup>1</sup>. The reported

incidence of tuberculosis amongst the general population was 122 per 100,000 in 2001.<sup>2</sup>

A number of tuberculin surveys have been undertaken in various districts of Nepal. Estimated average annual risk of TB infection (ARTI) from these surveys varies from less than 1% in the mountain areas, 1.5% in the hills, 2.5% in the plains and 4% (Kathmandu area) in the urban areas<sup>1</sup>. Directly Observed Treatment Short

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Course (DOTS) was introduced in 1996. This consists of 2 months of intensive phase treatment with Isoniazid, Rifampicin, Ethambutol and pyrazinamide under the direct observation of health worker, followed by 6 months of treatment with Isoniazid and Ethambutol to be collected weekly from the health facilities.<sup>1</sup> The initial pilot cohort consisted of 289 new smear positive cases covering 1.7% of the population. About 90% treatment success rate was found in the cohort analysis of this group in 1997.<sup>2</sup> Since then, DOTS has been gradually expanded throughout the country. By 2001 DOTS had nationwide coverage with services available in all 75 districts of Nepal.<sup>2</sup>

The Kathmandu urban area has a population of around one million with the highest rate of TB transmission with an estimated annual risk of TB infection of 4%. It is estimated that in the city around 4,000 people develop Tuberculosis every year. About 2100 TB cases were registered under the NTP from July 2000 to July 2001. Amongst these nearly 50% were infectious pulmonary TB cases. The overall cure rate of both DOTS and None-DOTS was 77% and treatment success (cured plus completed) rate was 82% and the defaulter rate was nearly 10% among the new smear positive patients registered during the year 1999–2000.<sup>2</sup> Although these results shows improvement from the situation prior to the introduction of DOTS, we estimate that up to 200 people default from treatment in Kathmandu every year. Defaulting and poor compliance with treatment regimens has been recognized as a major threat for tuberculosis (TB) control programs.<sup>3</sup> Partially treated patients are sources of MDR TB. Studies from urban areas of other countries have studied socio economic factors; behavioral factors have also been addressed in more recent research. The studies in other urban settings have identified many constraints to

treatment but this has yet not been studied in Kathmandu.

This study was conducted in Kathmandu to identify behavioral factors affecting patients' compliance with DOTS, and to make recommendations to the NTP regarding those factors that might be amenable to intervention.

## STUDY METHODS

### Study design and setting

Kathmandu is the capital city of Nepal. Its population, projected for the year 2000/2001, was about 1 million and annual risk of TB infection is 4%, which is the highest of the country.<sup>1</sup> Because of the magnitude of the problems, an urban DOTS partnership program was started in 1999 involving Kathmandu Metropolitan City, Central Hospital, NGOs, private sector, Jail and other public sector health facilities. This descriptive cross sectional study was carried out on a representative sample of new smear positive tuberculosis patients registered in the 22 DOTS centres established in government, private, Metropolitan and NGOs sectors of Kathmandu, by means of face to face interviews using a structured questionnaire.

### Sample size calculation:

The sample size was chosen to detect a 82% awareness outcome (p) with absolute precision (d) of 0.05 with SND ( $z^2\alpha$ ) set at 1.96.

$$n = \frac{z^2\alpha/2p(1-p)}{d^2}$$

This requires a sample size of  $n = 226$  as per above mentioned formula.<sup>4</sup>

In addition for Compliant and Non-compliant subgroups in this sample (estimated to be in a ratio of 2:1) sample size calculation was carried out using Epi INFO 6.04c.<sup>5</sup>

To detect a difference of 20% in the non-compliant sub group using expected frequency of 50% awareness outcome in the compliant subgroup, with power of 80% and C.I. of 95% requires a total sample size of 228.

We obtained a sample of 234 patients, which were interviewed over a three-week period.

### **Inclusion criteria and exclusion criteria**

Included were all-new sputum smear positive patients aged  $\geq 15$  years registered and still due for i.e. started on DOTS treatment between the 1st May and 30<sup>th</sup> November 2002, who had completed at least 30 doses of anti TB drugs

Excluded were smear negative pulmonary, extra-pulmonary, and re-treatment cases and those aged below 15 years.

### **Study team and questionnaire administration**

The principle investigator trained four interviewers on the structured questionnaire. The principal author acted as an observer during initial interviews of all four interviewers. Patient face-to-face interviews with trained interviewers were carried out in December 2002 either at the DOTS treatment centre or at the homes of those who had defaulted.

The questionnaire was pre-tested on patients in a District Health Office clinic in a neighboring urban district.

Oral consent from participating patients in the study was obtained at the start of interviews. Confidentiality was considered throughout the study period with questionnaires and results being only available for the purpose of this study.

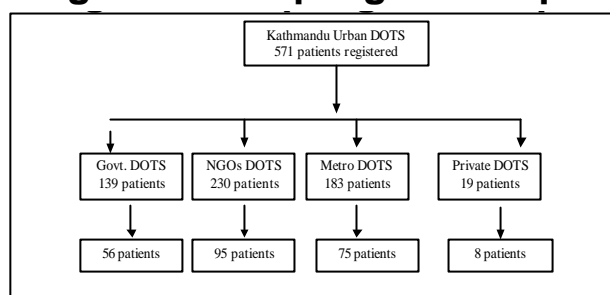
### **Stratification and randomization:**

There were 571 patients matching the inclusion criteria registered during the previous 7 months

i.e. between 1st May to November 30th 2002. All of these were listed.

There were 4 types of DOTS facilities. Of the 22 DOTS treatment centres there were 4 private, 4 NGOs, 8 Metro and 6 government clinics, and we decided to obtain 40% samples from each proportional to their contribution to the total 571 patient numbers. (See figure 1)

**Figure 1: Sampling Technique**



For patients within each of the four types of DOTS facilities, randomization was carried out in the following way. Registration numbers of all the new TB patients that matched the inclusion criteria, were put into a hat, mixed up and then randomly selected by the principal investigator. The selected patients were categorized by the principle investigation as either being compliant or non-compliant by review of treatment cards using the following criteria: patients were deemed to be non-compliant when they had missed more than 7 consecutive days of treatment. The principal investigator then entered the available patient details on the questionnaire and then gave these to the 4 interviewers to trace the patients and carry out the interviews.

### **Design of Questionnaire: tool**

A structured questionnaire was designed to assess social support to both groups of patients. The questionnaire was prepared in English and translated into Nepali. It was pre-tested in a District Health Office clinic in a neighboring urban district. The same questionnaire was used for all patients whether treatment compliant or not.

## **Social Support**

Questions were asked about emotional, informational and, logistical support received from family members, friends and health workers. Again two positive and two negative statements were asked in each category, based on the method.

### **Data entry and analysis**

Data were computerized and analyzed using EPI-Info,<sup>5</sup> and SPSS.10 (SPSS for Windows, SPSS Inc. Chicago, IL, USA) systems. Numbers and percentages were used for description.

To measure the social support patients received during the treatment, each positive item was scored 1 corresponding to yes, and 0 for no. Each negative statement was scored as no for 1, and yes for 0. Level of social support was then categorized based on total score (>80% = high, 60%-80% = moderate and <60% = low).

Average scores in compliant and non compliant groups were compared using the student t-test. A P value of less than 0.05 was considered statistically significant.

## **RESULTS**

There were 238 patients eligible for interview. Of these 4 refused to take part. All of these patients were currently compliant with treatment. Of the 234 patients who took part in the study, 175 patients were in the compliant group and 59 in the non compliant group with 18 current defaulters from treatment and 41 patients who had missed at least 7 consecutive doses of treatment but had returned for treatment (late patients).

### **Social support from family members (Table 1)**

*Emotional support:* Majority (97%) of respondents had good relationship with their family, more than three quarters (76.5%) of

respondents were not isolated and 96.1% of the respondents had been receiving better care from family. 95.3% of respondents had the friendly talk with the family members.

*Informational support:* Majority (94.9%) of the respondents were informed for daily treatment at the health centre. Almost all (97%) respondents had been informed for sufficient foods and majorities (94.9%) of respondents were reminded to take the medicines daily. Two third (67.5%) of respondent had got the information that TB is caused by bacteria.

*Logistical support:* Almost all (99.6%) respondents had the support with sufficient foods, 90.6% of respondents had the good financial support, majority (93.6%) of the respondents' family member became happy to go with them to DOTS centre and 93.6% of respondents had the support of sufficient cloths and lodging materials from the family members.

### **The social support from friends (Table 1)**

*Emotional support:* Almost all (95.7%) of respondents had got the frequent visits from their friends. Majorities (88%) of respondents were encouraged that they would be cured with DOTS.

*Informational support:* Most (83.8%) of the respondents were informed to visit the DOTS centre by their friends at the beginning stage of TB suspecting. It was found that majority of the respondents were informed about the benefit of DOTS and impact of irregular treatment.

*Logistical support:* Majority (88.5%) of the respondents were got the financial support as per their request from their friends and 85% of respondents' friends were happy to accompany with them to DOTS centres.

## Social support from health workers (Table 1)

*Emotional support:* It was found that 95.3% of the respondents were asked about their health improvements regularly where as similar proportion of the respondents responded that health workers did not provide them enough time to listen their problems. Almost all (97%) of respondents were encouraged to take medicines daily with DOTS. Majority (94%) of respondents were received the solution for solving the problem from the health workers.

*Informational support:* Almost all (97%) respondents were informed about the side effect of TB drugs and its management. Majority of the respondents had got the sufficient information about the benefits of the DOTS.

*Logistical support:* All the respondents had got the prescribed medicines. Only 53.2% of the respondents were benefited with health education materials from the health workers.

**Table 1 : Percentage of respondents classified by social support item with sources**

Social support statement		% (n=234)	
		Yes	No
<b>From family member</b>			
<b>Emotional support</b>			
1	After getting TB disease, your family have as good as relationship with you as before	97.0	3.0
2	You are isolated from your family member since you got TB disease	23.5	76.5
3	You are getting better care from family since diagnosis	96.1	3.9
4	You have not had a good talk even your closest family member	4.7	95.3
<b>Informational support</b>			
5	You are informed to go to DOTS centre at right time by your family members	94.9	5.1
6	After getting TB disease, no body inform you to have the sufficient foods	3.0	97.0
7	You are reminded to take the medicines daily by the family members	94.9	5.1
8	You are not informed that TB is caused by spirit, it is not caused by bacteria	32.5	67.5
<b>Logistical support</b>			
9	You are getting the sufficient foods from the family	99.6	0.4
10	You are not getting the enough money from the family member after getting the disease.	9.4	90.6
11	Your family member become happy to go with you to DOTS Centre	93.6	6.4
12	You do not have sufficient cloths, lodging material after getting TB disease	6.4	93.6
<b>From friends</b>			
<b>Emotional support</b>			
13	Your friends visit you time to time	95.7	4.3
14	Your friends do not encourage you will be cured with DOTS	11.9	88.1
15	Your friends listen your problems carefully	90.2	9.8
16	Your friend don't like to come to close you	20.1	79.9
<b>Informational support</b>			
17	At the beginning time of TB suspecting, you are informed to visit the DOTS Centre by your friends	83.7	16.3
18	You are not getting any health information from your friends	21.8	78.2
19	You are informed time to time that if you get cured, it means you will save to others	89.3	10.7
20	Your friends never talk with you that the irregular treatment may cause the death	9.8	90.2
<b>Logistical support</b>			
21	Your friends provide you sufficient health education materials	48.3	51.7
22	Your friends do not lend you money when you request	11.5	88.5
23	Your friends accompany with you to DOTS centre	85.0	15.0
24	Your friends do not trace you when you are late in treatment	19.7	80.3
<b>From Health workers</b>			
<b>Emotional Support</b>			
25	Health worker ask you about your health regularly	95.3	4.7
26	Health workers do not provide you enough time to listen your problem	6.8	93.1
27	Health workers encourage you to take medicine daily with DOTS	97.0	3.0
28	Health workers do not give you the solution to solve your problems	6.0	94.0
<b>Informational support</b>			
29	Health worker always ask about the side effects of TB drugs	97.0	3.0
30	When you ask for TB information, the health worker provide you with little information	4.7	95.3
31	Health workers always encourage to have a sufficient foods	98.3	1.7
32	You are not informed smoking and drinking alcohol is not good during treatment	3.9	96.1
<b>Logistical support</b>			
33	Health workers provide you medicines as prescribed	100	0.0
34	Health workers do not provide the sufficient drinking water when taking TB drugs	5.6	94.4
35	Health workers provide you sufficient health education materials	53.2	46.8
36	You do not get health workers easily when you visit DOTS centre for treatment	3.0	97.0

### Level of Social support from different sources

Table 2 showed that majority (85.9%) of respondents were receiving high levels of family

support, more than two third (70.1%) of respondents had high level of social support from friends and majorities (93%) were benefited having high level support from health workers.

**Table 2 Number and Percentage of respondents classified by level of social support from family, friends and health workers**

Level of social support	Number (n=234)	Percentage
<b>From Family members</b>		
High (10-12)	201	85.9
Moderate (7-9)	33	14.1
Mean±SD =10.855±1.262, Min =7, Max =12		
<b>From Friends</b>		
High (10-12)	164	70.1
Moderate (7-9)	49	20.9
Low (<7)	21	9.0
Mean±SD = 9.970±2.219, Min =0, Max =12		
<b>From Health workers</b>		
High (>10-12)	216	92.7
Moderate (7-9)	16	6.9
Low (<7)	1	0.4
Mean±SD =11.107±1.087, Min = 4, Max = 12		

Table 3 presents the support from family and friends was significantly higher in compliant than in non-compliant groups. Support from family members compliant group score (91.5%) 10.97±1.15, vs non-compliance group 10.53 (87.7%) ±1.50.(t-

test=2.34 (232), p = 0.02, Support from Friends compliant group score (84.7%) 10.17±2.04, vs non-compliance group (78%) 9.37 ± 2.61.(t-test=2.42 (232), p = 0.016, Support from health workers did not seem to affect compliance ratios.

**Table 3 Comparison of social support score from family, friends and health workers between compliance and non-compliance group**

Group	Number (n=234)	$\bar{x} \pm SD$	t-test (df)	p-value
<b>Family Members</b>				
Compliance	175	10.97±1.15	2.34(232)	0.020
Non-compliance	59	10.53±1.50		
<b>Friends</b>				
Compliance	175	10.17±2.04	2.42(232)	0.016
Non-compliance	59	9.37±2.61		
<b>Health Workers</b>				
Compliance	174	11.13±1.12	0.46 231)	0.645
Non-compliance	59	11.05±0.99		

## Discussion

Social support systems are important for the TB patients directing to compliance. It has been shown in Sialkot, Pakistan, that the direct and indirect (productive hours lost and loss of income) cost of treatment and medication are of major concern among TB patients.<sup>7</sup> A study carried out by Lee RP and Chiou YF showed that financial support of the family became important in the continuation phase and patients who had no financial support had thrice the risk of defaulting. Material assistance from the social network such as regular visits from family and friends, assistance with the care of children, in the home, with the job or studies, contributed to compliance.<sup>8</sup> A study conducted by Morankar S. presented that those females who received a high level of support from spouses are found to be more optimistic about cure and are also more mentally stable.<sup>9</sup> The finding of this study showed significant protective effect of family support. It was found that the risk of being a non-compliant was lower in those with family support. Our study also suggests that increased level of social support in terms of emotional, informational and logistical from family in compliant patients. It is reasonable that family support can alleviate patients' economic and social problems. Family members can also observe patients taking their medications, provide encouragement and remind them to go to the DOTS centre. A study done in Pakistan has also highlighted the role of family members in the implementation of DOTS.<sup>10</sup>

This study presented that social support from friends is closely associated with the treatment compliance. This study also showed that adequate regular visits during the treatment,

financial assistance, and informational support regarding the benefits of DOTS in compliant patients. Other studies have shown that low levels of social support from friends are also associated with lower treatment compliance.<sup>8,11</sup>

An intervention study in Port Elizabeth Municipality in South Africa has shown that community based support increased compliance from 67% to 84%.<sup>12</sup> and a further study demonstrated improved compliance 57% to 77% with health worker initiated reminders to take medicines.<sup>13</sup> This study suggests increased levels of social support from family and friends in complaint patients but this difference is not demonstrated in perceived support from health workers. This might be due to information bias as interviews were done at the DOTS centres.

## Conclusion

It was found that compliance behavior is closely associated with the social support from family and friends in the Kathmandu Urban areas of Nepal. We recommend that this aspect of DOTS treatment needs to be examined in detail and strengthened with emphasis of social support for full course compliance.

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## TUBERCULOSIS AND HIV CO-INFECTION STATUS IN UNITED MISSION HOSPITAL, TANSEN - WESTERN NEPAL

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### ABSTRACT

*A prospective study was conducted by Central Department of Microbiology, Tribhuvan University, National Tuberculosis Centre (NTC) and United Mission Hospital, Tansen (UMHT), during July 2001-June 2002 with an objective to find out the prevalence of TB/HIV Co-infection in patients visiting UMHT, Palpa. Among the 8510 out patient Department (OPD) attending patients 260(3%) suspected of either Tuberculosis (TB) or HIV were investigated for both TB and HIV. Eighty-one cases of HIV could be recorded during the study period. HIV cases were further analyzed for their TB status. Twenty-eight (10.8%) cases were further diagnosed as TB/HIV Co-infected. Among the twenty-eight TB/HIV Co-infected cases, 75% were males and 25% were females. Among the TB/HIV co-infected cases 24 (85.7%) were suffering from pulmonary tuberculosis and 4 (14.3%) were extra pulmonary tuberculosis. TB/HIV Co-infected patients age ranged from 25 years to 50 years. The highest rate of prevalence of TB/HIV Co-infection was observed in the 31-40 year age group followed by 21-30 age groups. A greater number of TB/HIV Co-infected cases were found among migrant workers. Moreover, a larger number of those Co-infected revealed that having multiple sex partners.*

*There were 53 HIV positive cases, in which tuberculosis could not be detected and 115 (44.23%) were tuberculosis patients with HIV negative status. The association between tuberculosis and HIV infection was found statistically significant*

*Prevalence of TB/HIV co-infection rate is on rise hence it is necessary to enhance all the measures to prevent HIV transmission in the communities in Western Nepal.*

### Introduction

Tuberculosis (TB) an infectious bacterial disease caused by the bacilli, *Mycobacterium tuberculosis*. It has become a major public health concern worldwide as one third of the world's

population is infected with tuberculosis. Every year, more than 8 million people develop active TB and over 2 million die from TB. The annual incidence of TB rose from 8 million in 1997 to 8.4 million in 2000, and is expected to rise to 10.2 million new cases annually by 2005<sup>1</sup>. Approximately 75% of TB cases in developing countries are in the economically productive age group<sup>2</sup>.

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The SAARC region bears 29% of the world's TB patients yet, with an incidence of approximately 2.5-3.0 million new cases per year<sup>3</sup>. Nepal has an elevated annual risk of TB infection, estimated to be 2.0% in rural and 4.5% in urban areas<sup>2</sup>. It is estimated that six out of 10 adults in Nepal are infected with TB and 80,000 Nepalese populations have active TB disease. There are 40,000 new TB cases each year, among them, 20,000 are infectious TB cases and 6,000-7,000 deaths per year, making TB the primary cause of death attributed to a single infectious pathogen among adults in Nepal<sup>4-5</sup>.

HIV/AIDS have become frighteningly familiar words across the globe, conjuring up feelings of suffering and death. It is estimated that almost 58 millions people worldwide have been infected with HIV and almost 25 million people have died from it. HIV continues to spread, causing more than 15,000 new infections daily. Low- and middle-income countries comprise approximately 95%<sup>1</sup>.

HIV/AIDS has emerged as one of the major problem within South Asian countries, revealing low general population prevalence rates, but with concentrated epidemic. Nepal as one SAARC country is ripe with vulnerability due to evidence of high-risk sub-groups<sup>5</sup>. The first AIDS case in Nepal was detected in foreign tourist in 1988. Since then the number has jumped to at least 2550 HIV- positive (including AIDS) identified cases and 623 full blown AIDS (out of total HIV), with some estimates reaching as high as 60,000 HIV positive cases in Nepal<sup>6</sup>. Nepal ranks sixth amongst Asian nations in absolute numbers of HIV positive persons. Considering existing open borders with India, the threat of HIV/AIDS in Nepal is tangible because of migrant working population in Metros of India, lack of job opportunities in Nepal

and drug transfer silk route<sup>7</sup>. The main identified mode of HIV transmission in Nepal is heterosexual contact; primarily commercial sex workers and their clients, intravenous drug users (IVDUs), migrant workers<sup>4,8</sup>.

It is known that TB and HIV/AIDS are two of the world's major pandemics. The pandemic of HIV/AIDS opened a new chapter on the role of mycobacteria in causing human disease in both the developed and less-developed world. An ominous development in resurgence of TB has been the emergence of multi-drug resistant *M. tuberculosis* particularly in HIV infected persons<sup>9</sup>. The number of people Co-infected with TB and HIV- already stands at over 10 million and is expected to increase dramatically over the next 10 years. Evidences suggest that one third of HIV infected persons are co-infected with TB bacilli. Moreover, people with HIV are 30 to 50 times more likely to develop active TB, making TB the biggest AIDS-related killer in the world today. To make matters worse, global rates of MDR-TB are also on the rise<sup>10</sup>. MDR-TB is very complicated and difficult to treat, very expensive to treat and often fatal.

HIV infection is the strongest risk factor for TB infection becoming active TB disease, speeding the progression from latent or recently acquired infection to active clinical disease<sup>11</sup>. TB and HIV/AIDS epidemics are fueling each other in a deadly spin. TB is responsible for death of one out of every three people with HIV/AIDS worldwide..

The HIV epidemic has thus increased the burden of TB, especially in populations where the prevalence of TB infection is high among young adults. A person dually infected with HIV and *M. tuberculosis* has a 50% lifetime risk of developing TB<sup>2</sup>. TB is a major opportunistic infection of HIV-infected persons. For individuals infected first with

M. tuberculosis and then with HIV, the risk of developing TB is 5-10 percent per year.

This study has been planned with an objective to study the prevalence of TB/HIV Co-infection cases visiting UMHT Hospital;

### Materials & Methods:

This study was done in UMH Tansen, a hospital with HIV care facility, the location is an exit and entry point to and from India for migrant workers of western Nepal. Furthermore there was increased prevalence of TB and HIV infection based on hospital records during the last 2-3 years. This study was, therefore, carried out at UMHT, suspecting higher prevalence of TB and HIV co-infection in this region.

### RESULTS

The study was carried out on 260 suspects of TB/HIV, among the 8510 OPD patients visiting UMHT during July 2001-June 2002.

**Table 1. Age distribution of patients tested for TB & HIV**

Age group	HIV positive TB positive		HIV positive TB negative		HIV negative TB positive		HIV negative TB negative		Total
	Male	Female	Male	Female	Male	Female	Male	Female	
11 – 20	0	0	0	0	13	4	6	2	25
21 – 30	7	3	17	5	18	12	17	4	83
31 – 40	13	4	17	3	18	4	17	3	79
41 – 50	1	0	6	1	14	1	7	0	30
51 – 60	0	0	1	0	11	5	3	2	22
61 – 70	0	0	1	2	13	0	3	0	19
71 – 80	0	0	0	0	1	1	0	0	2
Total	21	7	42	11	88	27	53	11	260
Total %	10.76% (28)		20.38 % (53)		44.23% (115)		24.61% (64)		100% (260)

Of the total 260 patients analyzed for presence of both tuberculosis and HIV infection, 28 (10.76%) cases were found to be positive for both tuberculosis and HIV. Among TB/HIV Co-infected cases, highest

This study was carried out during July 2001 to June 2002. During the study period, 260 suspects of TB and HIV were tested for tuberculosis by microscopic examination of acid-fast bacilli utilizing Ziehl-Neelsen staining method, Chest X-ray, culture, Tuberculin test, response to anti-TB drugs, following standard protocols<sup>12-14</sup>, and HIV test was done by anti HIV-1 & 2 antibodies using rapid HIV TRI-DOT test as per the instruction of kit manufacturer<sup>15</sup>.

Data obtained after the study were analyzed using Standard Statistical tools.

The prevalence of TB/HIV Co-infection was calculated from the obtained data.

prevalence was detected in age group 21-40 followed by 41-50. Of the 81 HIV sero positive 28(34.6%) were having tuberculosis, No HIV could be documented in patients of age group 11-20,

where as TB could be detected in 17 of 25 cases studied in the same age group.

Among all 260 patients tested for HIV infection, 31.2 % (81) were found HIV-seropositive. Of the 81 HIV sero-positive cases, 64(79%) were males, and 17 (21%) were females. There was no significant difference between male and female having HIV infection ( $P>0.05$ ,  $\chi^2$  test).

Age and sex distribution of HIV positive patients is shown in table 2.

**Table 2. Age and sex distribution of HIV sero positive patients:**

Age group	Male	Female	Total
11-20 year	0	0	0 (0%)
21-30 year	24	8	32 (39.5%)
31-40 year	30	7	37 (45.7%)
41-50 year	7	1	8 (9.8%)
51 and above	2	2	4 (4.9%)
<b>Total</b>	<b>63</b>	<b>18</b>	<b>81(99.9)</b>

Distribution of TB and HIV among tested patients is shown in table 3.

**Table 3. Distribution of Tuberculosis & HIV among tested Patients**

Particulars	HIV positive Patients (%)	HIV negative Patients (%)	Total
<b>TB Positive Patients</b>	28(10.76%)	115(44.24%)	143 (55 %)
<b>TB Negative Patients</b>	53(20.38%)	64(24.62%)	117 (45%)
<b>Total</b>	81 (31.15%)	179 (68.85%)	260 (100%)

The association of TB disease and HIV infection was found significantly different ( $P>0.05$ ).

**Table 4. Age & sex distribution of TB / HIV Co-infected patients**

Age/ sex	21 – 30 year	31 – 40 year	41 – 50 year	Total
<b>Male</b>	7	13	1	21(75%)
<b>Female</b>	3	4	0	7(25%)
<b>Total</b>	10	17	1	28(100%)

Among 28 TB/HIV Co-infected patients, 21(75%) were males and 7(25%) were females. Of the 28 Co-infected cases, 24 (85.7%) were pulmonary tuberculosis and 14.3% (4/28) were extra-pulmonary tuberculosis. Out of 28 TB/HIV Co-infected patients, 57.1 % (16/28) were sputum smear AFB positive pulmonary tuberculosis (PTB), 28.6 % (8/28) were sputum smear negative (AFB negative) PTB and 14.3 % (4/28) were Extra-pulmonary TB (3 patients with TB Meningitis and a patient with Miliary TB).

TB/HIV Co-infected patients of this study were ranged in age from 25 years to 50 years. The higher prevalence of 60.7%(17/28) of TB/HIV Co-infected patients during the study belonged to the age group (31-40) year, 35.7% (10/28) patients were belonged to age group (21-30) year and only a patient (3.4%) was belonged to age group (41-50) year.

### Discussion & Conclusion:

The high prevalence rate (10.76%) of TB/HIV Co-infection among suspected TB/HIV Co-infection at UMHT hospital observed in this study is found in agreement with a similar study done at Kathmandu (6.7%) during 2001 by Sherchand et al<sup>7</sup>. This may be because of the HIV care facility available at UMHT and Palpa is an entry point for migrant workers. This increased prevalence rate of TB/HIV Co-infection observed during this study is corroborating with different studies conducted in different places of the developing World for example Ethiopia-54.8%<sup>16</sup>, Malawi-61%<sup>17</sup>, Santo Domingo-14.6%<sup>18</sup>.

Similarly, Thakker et al.<sup>2</sup> reported the prevalence of TB/HIV Co-infection was increased by each year i.e. 5.9%, 6.3%, 7.2%, 7.9% and 8% from 1997 to 2001 respectively<sup>19</sup>. The study in

Myanmar<sup>20</sup>, 1998 was also found the increased TB/HIV Co-infection rate each year and obtained the results in 1995, 1996, and 1997 as 2.20%(31/1407), 3.56%(47/1332) and 4.13%(58/1404) respectively<sup>21</sup>. Another study at Amargadh Hospital, India<sup>6</sup> is also suggested that TB/HIV Co-infected patients were increased from 5.9% in 1997 to 7.02% in 1999 <sup>22</sup>.

The prevalence is lowering in developed countries [Bolivia-0.5 %, West Canada-4.5 %]. From our study data it is observed that the prevalence of TB/HIV Co-infection rate is increasing in Nepal.

Among 28 TB/HIV Co-infected patients, pulmonary TB (85.71%) was common than Extra-pulmonary TB (14.28%). There is domination of males (75%) over females (25%). This finding is similar to the findings of similar studies at different places<sup>19, 23, 17</sup>.

TB and HIV Co-infected patients of this study were in the age group of 25-50 years. The ratio of male and female was found 3:1. This result is in agreement with similar other study results<sup>9, 20, 24</sup>.

In conclusion, the results of the study have demonstrated an alarming situation of the TB/HIV co-infection infection in the Western Nepal. Similar operational research covering the nation should be carried out to visualize the exact national scenario; which is a necessary for framing and operationalize the national policy for HIV/AIDS and TB control.

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# RESISTANCE TO ANTI-TUBERCULOSIS DRUGS IN KATHMANDU

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## ABSTRACT

**Back Ground:** *Tuberculosis is one of the major health problems of Nepal. Drug resistance tuberculosis is most difficult for the treatment and cure of the patient.*

**Objective:** *Find out the current drug resistance pattern in an urban referral setting in Kathmandu, Nepal.*

**Method:** *Eighty-five isolates of Mycobacterium tuberculosis, isolated from the sputum in German Nepal TB Project Clinic were studied to find out the drug resistance pattern by utilizing proportional method.*

**Results:** *Among the total studied cases 12.9% isolates were resistant to one or more anti-tuberculosis drug (Rifampicin, Ethambutol, and Isoniazid & Streptomycin). Initial and acquired MDR was found in 4.6% and 5% of the isolates respectively.*

**Conclusion:** *It is concluded that regular monitoring of MDR-TB and making policy according to research finding is necessary as it is changing every year, which helps to control MDR TB.*

## Introduction:

The anti-microbial resistance is one of the biggest challenges to global public health. Drug resistance tuberculosis is a case of tuberculosis (usually pulmonary) excreting bacilli resistant to one or more anti-tuberculosis drugs. Exposure to single drug due to irregular drug supply, inappropriate prescription or poor adherence to treatment suppresses the growth of the susceptible bacilli to that drug but permitting the multiplication of drug resistant organism, is known as acquired resistance. Subsequent transmission of such bacilli to other person may lead to disease, which

is drug resistant from the outset, a phenomenon known as primary or initial resistance. Multiple Drug Resistant Tuberculosis (MDR-TB) is termed when the tubercle bacilli are resistant to at least Isoniazid and Rifampicin, the main anti-tuberculosis drugs<sup>1</sup>.

Directly Observed treatment short-course (DOTS) strategy was adopted as policy in 1995 in Nepal, introduced in 1996 and presently DOTS coverage is more than 95 percent<sup>2</sup>. The WHO target of 70% case detection was achieved in 2001 and present treatment success rate is 90 percent<sup>3</sup>. This study was conducted with the objective of updating the anti TB drug resistance pattern especially in urban referral clinic setting in a situation where DOTS has been successfully implemented.

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## Methodology

The study was carried out during Sept 2002 to June 2003 in GENETUP laboratory, Kalimati, a referral laboratory for tuberculosis drug sensitivity testing located at Kathmandu, capital of Nepal. Eighty five isolates of Mycobacterium tuberculosis obtained from Lowenstein and Jensen media were studied. Among them 65 were from untreated TB patients and 20 from previously treated TB patients. The isolated culture were confirmed by biochemical tests (Niacin, Nitrate, Catalase & Urease)<sup>4</sup>. Susceptibility testing was done using proportional method<sup>8</sup> with critical concentration of 0.25 µg/ml Isoniazid, 2 µg/ml Ethambutol, 4 µg/ml Streptomycin & 40 µg/ml of Rifampicin.

Approximately 4 mg moist weight of the growth visualized as 2/3 loopful of 3 mm internal diameter 24 SWG nichrome wire loop was added to 0.2 ml of sterile distilled water in a 7 ml bijou bottle containing 2-3 mm glass beads. These bottles were shaken mechanically for 1 minute at a speed which just lifts the beads from the bottom of the bottle, to produce a uniform suspension. Then, 3.8 ml sterile distilled water was added and the bottles were shaken by hand. These suspensions

approximately contain 1 mg/ml of the organism. From these suspensions, 4 serial 10 fold dilutions viz. 1/10, 1/100, 1/1000, 1/10000 was made by adding 0.2 ml to 1.8 ml sterile water. One loopful of the suspension was inoculated on two slopes each of the drug free control medium and one slope each of different drug containing sensitivity test media. Standard drug sensitive strain was included in each new batch of test medium. All the slopes were incubated at 37°C and read after 28 and 40 days of incubation.

## RESULTS

Among the 85 cases of Tuberculosis, 12.94% were found to be resistant to at least one drug (Table -1).

### Initial Drug Resistance Cases

Initial Drug Resistance to only one drug among the four, showed by 4.62 % (n=3) of the isolates. Resistance to two drugs showed by 1.54% (n=1), three drugs to 4.62% (n=3) and four drugs to 3.08% (n=2) of the isolates. Initial Multi-Drug Resistance found in 4.61% (n=3).

Table 1: Anti-tuberculosis drug Resistance pattern among PTB isolates

S. No	Drug Susceptibility	Untreated TB patients		Treated TB Patient		Total
		No.	%	No.	%	
1	<b>Total tested</b>	<b>65</b>	<b>76.47%</b>	<b>20</b>	<b>23.53%</b>	<b>85</b>
2	<b>Resistance to single drug</b>					
	INH	1	1.54	-	-	1
	RIF	-	-	-	-	-
	SM	2	3.08	1	5.0	3
	EMB	-	-	-	-	-
3	<b>Resistance to INH + SM</b>	1	1.54	-	-	1
4	<b>Resistance to 3 drugs</b>					
	INH+EMB+SM	2	3.08	-	-	2
	INH+EMB+RIF	-	-	1	5.0	1
	INH+SM+RIF	1	1.54	-	-	1
5	<b>Resistance to all 4 drugs (INH+EMB+SM+RIF)</b>	2	3.08	-	-	2
8	<b>Sensitive to all 4 drugs (INH, RIF, SM, EMB)</b>	56	86.15	18	90	74

## Acquired Drug Resistance Cases

Among the resistant cases, only 2 isolates were found acquired Resistance to one or more drugs. Resistance to one drugs was found in 5% (n=1) and three drugs to 5% (n=1). (Acquired Multi-Drug Resistance was found in 5% (n=1).)

## DISCUSSION

This study was performed with an objective to assess the prevalence of drug resistance for four anti-tuberculosis drugs incorporated in DOTS Programme as per national protocol. This study showed 12.9% cases were drug resistant to one or more anti-tuberculosis drugs. The level of primary or initial MDR was found to be 4.6% and acquired MDR 5% of the isolates. The anti-tuberculosis drug sensitivity test conducted in Nepal during 1987-1990 revealed that 2.8% of the isolates were resistant to Rifampicin, 17.6% to INH and 4% Ethambutol. In this study initial or primary MDR was 5.7% and acquired MDR was 30% cases respectively. In a similar study conducted in 1991-1994, 0.5% isolates were rifampicin resistance, 3.2% resistance to INH, 2.5% resistance to Ethambutol. Initial MDR was 1.6% and acquired MDR 9.6%, respectively<sup>5</sup>. In study (1994-1997) WHO and IUATLD demonstrated 5.7% of the isolates were mono-resistance and 1.1% MDR<sup>6</sup>. The global surveillance data of WHO and IUATLD, 2000 revealed that 4.8% of the initial isolates were mono-resistance, initial MDR was 1% and acquired MDR was 7.4%<sup>7</sup>. Another study conducted in tertiary care centre, Tribhuvan University Teaching Hospital in 2000 demonstrated that mono-resistance to untreated cases was 9.8% and initial MDR was 8.6%<sup>8</sup>. Our study findings does not correlate with studies conducted by WHO because of limitation of study.

This study like other study done in tertiary care referral hospital have shown relatively high-level drug resistance. Those referral centers<sup>8</sup> where patients were coming from all parts of country and concentrated with relapse, treatment interrupted as well as serious patient for admission. Therefore those study conducted in referral centers should not be generalized.

It is concluded that regular monitoring of MDR-TB and making policy according to research finding is necessary as it is changing every year, which helps to control MDR TB.

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# SUCCESS STORY OF TUBERCULOSIS CONTROL IN NEPAL

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## I. INTRODUCTION:

In Nepal during the year 2003 over 32,000 patients were diagnosed with Tuberculosis and treated free of cost with drugs supplied by the Ministry of Health. The documented chances of a cure rate are over 85% of those starting treatment and around 90% complete the treatment. Death rates are less than 5%.

It is estimated that the National Tuberculosis Programme is now treating over 70% of all estimated cases. The two global targets in tuberculosis control are a treatment success rate of 85% and a case detection rate of 70% to be reached by 2005. Historically Nepal has had a very severe problem with Tuberculosis. About 45% of the total population is infected with TB, out of which 60% are in the productive age group. Every year, 40,000 people develop active TB, of whom 20,000 have infectious pulmonary disease. In 1994 it was estimated that annually some 12,000 people were dying of the disease. At that time only 15572 cases of TB were notified to the National Tuberculosis Programme (NTP). From a situation in 1994 when the NTP piloted DOTS in four districts with total population coverage of 1.7%, it now has 356 DOTS Treatment centres and 1520 DOTS Treatment sub-centres in 75

districts in Nepal with 94% total population coverage<sup>1</sup>. Introduction of treatment by Directly Observed Treatment Short course (DOTS) has already reduced the numbers of deaths. However 5,000-7,000 people continue to die every year from this disease<sup>1</sup>.

Statistics from the 2003 Global Tuberculosis Control Report showed that of the 99 countries that make up the Euro-asian Landmass and the Western Pacific, Nepal is one of the six countries with a smear positive Tuberculosis rate higher than 90 per 100,000 population. Among these six countries only Nepal was approaching Global Targets for case detection and treatment success rates in 2001<sup>2</sup>.

In recognition of the success of its DOTS programme Nepal has been given green signal by the Green Light Committee based at WHO in Geneva, for receiving second line drugs to treat a national cohort of MDR TB, the only National Programme in South East Asia to have achieved this<sup>3</sup>.

This article describes how Nepal got this far and what challenges remain for the Tuberculosis Programme.

## II. SUCCESS STORY:

The Nepalese Tuberculosis Success story can be classified under the headings of the five pillars of DOTS:

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## 1. COMMITMENT

**Central Government Commitment:** The NTP has had consistent leadership from within for many years now. The continuity and commitment of key people in the National Tuberculosis Centre (NTC) has been vital in promoting the program. This commitment has also been seen in the Ministry of Health, with the increasing prioritization of Tuberculosis in Health planning. The NTP is one of the top priority programs of His Majesty's Government of Nepal. Tuberculosis funding has increased and tends to have been ring-fenced from more recent cut-backs.

**International Donor Commitment:** The health-funding situation in Nepal reflects the country's economic position and thus about 60% of the NTP funds are secured from foreign donors. One very important landmark came in 1987 when an agreement was signed between the HMG and the Government of Japan to establish the National TB Centre in Kathmandu and Regional TB Centre in Pokhara. The HMG Nepal constructed National TB Centre under the grant aid of the government of Japan in 1989. After the establishment of NTC, both the Chest clinic and TB Project merged into one organization under the name of NTC to strengthen the National TB Control Program. This initial commitment from international donors particularly Japan International Cooperation Agency (JICA), NORAD and Norwegian Lung and Heart Association (LHL) strengthened the National Tuberculosis Centre and enabled the program to succeed.

This success has resulted in a gratifyingly positive cycle with donors keen to fund this program.

Partnerships: the Tuberculosis program has worked with many partners. The INGOs, particularly the International Nepal Fellowship

(INF) and the British Nepal Medical Trust (BNMT), Netherlands Leprosy Relief (NLR) and German Nepal TB Project (GENETUP) who were supporting Tuberculosis at Regional and District Level were drawn towards the NTP, and were invited to help shape and implement policy. The local authorities and the National Anti Tuberculosis Association together with the Media helped the NTC in setting up, publicizing, and rallying support for the establishment of local Tuberculosis Treatment Centers within and as part of the Government Health Clinics. An early principle was to establish Treatment Centers only after the creation of a community DOTS Committee to support the centers activities. The result was Grassroots support for the running of the services. A national protocol was developed for successful DOTS implementation, which describes in detail the structure and function of these committees<sup>4</sup>.

Community participation is one of the key elements for local planning, decision making, monitoring and late patient tracing. Local leaders, private practitioners, medical colleges, volunteers, teachers, students, media people, social workers, as well as TB patients and local NGOs and other organizations are all involved in the DOTS Committee. A DOTS Committee, whose membership consists of these sectors of society, is created for each Treatment Centre. A key role of the DOTS committee is to solve local problems and in this they have been very successful. DOTS committee is the key elements to success of DOTS in Nepal. It is the unique feature of TB control program in the Nepal, which have been an example of South East Asia Region as well as rest of the world. The function of the committee is to increase the public awareness about TB in the community through advocacy and education. To support people with TB in the

community by providing treatment observers and late patient tracers, to identify local problems and their solutions, to encourage cooperation between health institutions, health workers, volunteers and NGOs are also major functions of the DOTS committee

## **2. DIAGNOSIS USING MICROSCOPY**

To ensure proper diagnosis prior to treatment, the NTP focused on the establishment of a national network of Microscopy laboratories. Training for laboratory assistants and supply of microscopes and adequate materials were put in place. A quality assurance system was set up. All the positive and 10% of the negative slides are being rechecked for quality assurance. This has been vital for demonstrating the effectiveness and credibility of the program. Now NTP Nepal is at a stage where there are 326 peripheral laboratories in the 5 regions carrying out sputum diagnosis and 5 Regional Reference Laboratories carrying out the Quality Assurance under the umbrella of National TB Reference Laboratory located in NTP.

## **3. DAILY DOTS – SUPPORTED BY GUIDELINES AND TRAINING**

The National Tuberculosis Program adopted DOTS in 1994 and set up 4 pilot districts for implementation in 1995. The guidelines for the health workers and training modules were put in place at the beginning of this process. The Daily DOTS delivery concept required extensive training of all cadres of health workers. Thus the NTP embarked on an extensive cascade-training program in all regions, districts and at community level to familiarize everyone with the guidelines of the NTP. The guidelines had also been worked

through with the INGOs so that they were acceptable and used by them in their training programs. This meant that in the whole country, the TB program was speaking with one voice. The initial training has been institutionalized so that a regular training program for all levels exists. The NTP has produced 5-year plans, which have ensured donor commitment for this training program. This means that new recruits to the Health Services get trained on DOTS and the Tuberculosis program activities.

It is through the insistence on DOTS that the NTP has achieved very high cure and treatment success rates. At the beginning DOTS cure rates in the 4 pilot areas covering 1.5% of the population were around 90% and it is of note that the treatment success rates for the whole country is now near 90%.

## **4. REGULAR DRUG SUPPLY**

From the beginning of DOTS the Tuberculosis Program insisted that Tuberculosis treatment should be free and freely accessible. The policy was zero stock out. This was achieved by creating 4 months supply of buffer stock at regional district and health center level. The order forms were designed that each center calculates its requirements for the next four months based on the existing patient workload and adds an extra 4 months requirement for buffer stock. The NTP has been fortunate in finding International Donors to fund yearly drug supplies without interruption. This has led to a system of drugs supply that the patient can trust. The knowledge that the treatment is free is also made public at every opportunity through the DOTS committees through the World TB day and as recent research proved it most effective.

## 5. ACCOUNTABILITY (Recording and Monitoring)

The Nepal Tuberculosis Program adapted the WHO/IUATLD reporting guidelines on the basis on four monthly cohort of patients, and put in place regular review meetings at all levels. Thus three times a year every DOTS health unit reports to the district Tuberculosis and Leprosy Assistant who in turn presents the district figures at a regional meeting. These meetings act as an opportunity for exchange of ideas problem solving and further training. These meetings are arranged in a cascade fashion so that national meeting occurs at the end of the process. Here the Regional TB and Leprosy Assistants present the data to the NTC and problems first raised at local level and there these problems are discussed in a national forum. During this occasion all the NGO's and INGO's and other partners in Tuberculosis Control are also invited to discuss Program strategy. Reporting is thus closely monitored in systematic way. In addition NTP national reviews involving WHO, IUATLD, SAARC TB Centre, LHL, DFID, JICA, RIT, and others national and international organizations have been conducted annually to measure the effectiveness of the program since 1994. These reviews advise the NTC on strategy for the coming years.

Supervision and Training is carried out according to national guidelines at all levels with predetermined frequency. Government funding for this very important activity has also been augmented by donor contributions.

The most recent development for the National Tuberculosis Programme is the regular production of a feedback document 3 times a year from the national level. This provides quarterly data indicators and comments to be sent back to the district level and even health centre level. Bar

charts and Maps complement the Tables and enable more use of data for planning at local level.

The success of the program has been due to paying attention to the five pillars of DOTS: Commitment, Microscopy, Directly Observed Treatment, Drug Supply and Monitoring.

### III. NEW CHALLENGES FOR THE NTP

The NTP has now reached the end of its expansion phase. More than 90% of the population has access to DOTS services. Work is being carried out to ensure that treatment is available more locally through further DOTS sub-clinic expansion.

#### 4 MAIN ISSUES THAT GO BEYOND DOTS

1. Improving Case finding from beyond the NTP: Private Public Partnerships
2. Improving Case finding from within the NTP: PAL NEPAL
3. Improving Case finding in emerging risk groups: TB & HIV.
4. Treatment of Resistant Tuberculosis: MDR- TB

The main work in the consolidation phase is to re-emphasize the 5 pillars of DOTS. In addition the NTP is tackling 4 main issues that go beyond DOTS (See Box):

#### 1. *Improving Case finding from beyond the NTP: Private Public Partnerships.*

It is acknowledged internationally that the National Tuberculosis Programs need to collaborate with the private sector to offer DOTS to patients from this sector<sup>5</sup>. In Nepal it is estimated that the Private sector treats anywhere between 15% to 25% of all Tuberculosis patients. The approach taken by the NTP has been able to establish a credible

Tuberculosis Program in the Public Sector. With this in place the NTP has been in a position to approach the private sector to discuss the possibility of referring Tuberculosis Patients to the Government sector, or even to set up NTP linked and supervised DOTS clinics within the Nursing Homes, Private Hospitals and Colleges. The NTP provides free drugs, training, and the reporting and recording system, with the private sector in return making these drugs available free to patients and participating in the monitoring and reporting system of the NTP. This system has provided Nepal with DOTS clinics in all major private medical colleges in the country. Many hospitals and nursing homes have also started to treat TB patients in line with guidelines and reporting requirements of the NTP. It has been demonstrated in Lalitpur that during the same time the sale of TB drugs in Private Pharmacies plummeted. The partnership is bearing fruit.

## **2. Improving Case finding from within the NTP: PAL NEPAL**

A further internationally recognized concern is that patients who come for treatment for chest complaints are not always correctly diagnosed and treated for TB. It has been estimated that a 10% improvement in diagnostic yield for Tuberculosis could be achieved through better training in the treatment of Adult Lung Health. To research this further the WHO in collaboration with the NTP, the National Research Council of Nepal, the Institute of Medicine and Rotterdam and John Hopkins University have initiated the PAL NEPAL pilot research project in Nawalparasi. The impact of intensive Adult Lung Health Training on improved referrals and diagnosis of Tuberculosis is being assessed. This is part of the Global PAL initiative by WHO and potentially represents the

cutting edge of further initiatives in Tuberculosis Control<sup>6</sup>.

## **3. Improving Case finding in Emerging Risk Groups: TB & HIV.**

Although the HIV infection rate remains low (among adult 0.5%) the country is facing a concentrated epidemic in Sex Workers, and Drug Addicts (IDU). The NTP has been working with NGOs dealing with high-risk groups to make the treatment of Tuberculosis in people with HIV easier and less stigmatizing. The program is working with national AIDS partners to develop joint training materials and programs. The NTP carries out a regular sentinel surveillance of Tuberculosis patients to monitor the HIV prevalence amongst them. The latest survey in 2002 showed an HIV prevalence of 2.4% mainly in men over 24 years old. The NTP is aware that it needs to keep reviewing its responses to match the progress of the epidemic.

## **4. Treatment of Drug Resistant Tuberculosis: MDR-TB**

MDR Tuberculosis is a constant danger confronting any successful NTP program. A successful DOTS program is the best guardian against drug resistance. The Nepal NTP has carried out repeated National Surveillance Surveys of new and re-treatment Tuberculosis Cases. The latest report shows that there has been no significant rise in MDR TB spread in the community. There is no increase in the MDR TB prevalence in new cases of Tuberculosis (1.3%). However like elsewhere, Nepal has a pool of chronic cases of and around 100 patients each year who fail Category 2 re-treatment regimens. In order to offer these patients a chance of a cure



for their illness and to work on diminishing the pool of chronic patients, the NTP has received approval from the Green Light Committee to receive 2<sup>nd</sup> line quality drugs at a subsidized price for a DOTS PLUS PILOT Project. This will give Nepal a second line regimen in the National Program with prices of drugs reduced by 95%. This means that these 100 patients will be offered a further chance of treatment free of charge. We are very clear that this program must in no way deflect from the effectiveness and efforts given to the DOTS program.

#### **IV. CONCLUSION:**

Nepal is one of the countries in Asia where Tuberculosis has traditionally been a very serious problem. The problem has been approached by the National Tuberculosis Program in a systematic fashion, applying the five pillars of DOTS. As a result Nepal has reached the Global Targets and a stage where the successful expansion of the program is being followed by the very important consolidation phase. In this phase the program is also tackling the issues beyond DOTS, involving the private sector, research for better diagnosis, engaging with HIV high-risk groups and tackling MDR TB. This article recounts what has

been achieved and shows what remains to be done with regard to the Nepal Tuberculosis Programme.

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## BEGINING OF A PUBLIC PRIVATE PARTNERSHIP IN BANGLADESH

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TB is still continued to be a major public health problem in Bangladesh. It is number one killer amongst infectious diseases in the country. It is estimated that 305000 new cases including 137000 sputum positive patients occur every year. The disease annually takes a toll of 70,000 lives. The annual risk of infection is 2.16%. To combat this alarming situation, the government of Bangladesh launched a TB control program based on DOTS strategy in 1993 to gradually raise case detection rate to 70% and cure rate to 85%. To achieve this goal, the project was gradually extended to all the 460 Upazillas (Sub Districts) of the country in collaboration with the leading NGOs working in this field. By 2002, the national TB control program established a network of 558 diagnostic and treatment centers all over the country as against 56 in Pre DOT era, which was undoubtedly a major achievement in the field of control of Tuberculosis in the country. But case detection rate was raised to only 34% as against the national target of 70%.

Treatment success rate, however, was 83.68% during the period. To achieve the national target of 70% case detection, the national Tuberculosis program needs further expansion of its activities.

It is believed that private practitioner play a major role in TB care. As per WHO estimate 60-70% of all patients with Tuberculosis first report to the

private health providers for diagnosis and treatment. Their collaboration with the public sector and participation in the national Tuberculosis program is, therefore, crucial for raising case detection rate. With a view to involve the private practitioners in national TB program, a pilot project under the title "Public Private Partnership Pilot Project" was undertaken in November 2002 with technical and financial assistance from WHO. The main objectives of the project were:

1. To develop a framework of collaboration to implement DOTS by the selected private practitioners of Dhaka city.
2. To introduce recording and reporting system in the private sector and
3. To gradually expand this program to other areas of the country to achieve the national target of 70% case detection by the year 2005.

To start with, a study on 119 selected private practitioners of Dhaka city was conducted to assess their knowledge, attitude, practice and behavior through a WHO questionnaire. It is revealed from the study that out of the total 119 practitioners only 61 was willing to collaborate with the project and agreed to prescribe drugs as per national program if drugs are supplied. It also appeared from the study that they treat a total of 1070 TB patients per month and differ one another in diagnosis and treatment. Recording, reporting and follow up system is almost absent in their practice. The table I, II & III shows their difference in diagnosis and treatment.

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**Table I: First investigation by the practitioners by list of priority:**

List by Priority	Type of investigation:										
	X-ray chest P.A view	Sputum for AFB	ESR	Blood Cp	Blood CBC	Uric Acid	HB	Lft	Sgpt	S. bilirubin	Rbs
1 <sup>st</sup> Priority	29	27	2	-	-	-	-	-	1	-	-
2 <sup>nd</sup> Priority	28	14	13	-	-	-	9	1	-	-	
3 <sup>rd</sup> Priority	1	10	16	4	8	-	-	3	-	5	
4 <sup>th</sup> Priority	-	-	-	-	-	1	-	-	1		1

**Table II: Follow-up investigation by the practitioners by list of priority:**

List by Priority	Type of investigation:										
	X-ray chest P.A view	Sputum for AFB	CBC ESR	Blood Cp	Blood CBC	Uric Acid	HB	MT	ESR	Rbs	
1 <sup>st</sup> Priority	32	29	2	-	-	-	-	-	-	-	
2 <sup>nd</sup> Priority	31	26	-	-	-	-	1	2	3	1	
3 <sup>rd</sup> Priority	-	5	-	10	20	-	5	24	24	11	
4 <sup>th</sup> Priority	-	1	-	-	-	1	-	4	-	-	

**Table III: TB drugs usually prescribed by the practitioners:**

Period	Drug used				
First 2 month	HRZE=55	HRZ=1	REHT=1	HRZES=1	HRZEHT=1
Subsequent 4 month	HR=33	PD not stated	HE	-	-
Subsequent 4 month	HRZ=1	-	-	-	-
Subsequent 5 month	HR=2	-	-	HR	-
Subsequent 6 month	HR=1	-	-	-	HT
Subsequent 4-7 month	HR=2	-	-	-	-
Subsequent 6-9 month	HR=1	-	-	-	-
Subsequent 7 month	HR=2	-	-	-	-
Subsequent 6-12 month	HR=1	-	-	-	-
Subsequent Period not stated	HR=8	-	-	-	-
Subsequent Period & name of drugs not stated	=2	-	-	-	-
Subsequent Period not stated	ZE=1	-	-	-	-
Subsequent Period not stated	HRZE=1	-	-	-	-

It appears that most of the physicians follow the treatment regimen (HRZE) as done by the national program for the initial intensive phase for two months but treatment regimen and duration of treatment are variable in the continuation phase.

After compilation of the report on the study, a team of 15 resource persons including members from the NTP, Private practitioners, Chest and Heart Association of Bangladesh, Bangladesh Private Practitioner's Association and College of General Practitioners of Bangladesh were selected to identify the area and the frame of collaboration, develop monitoring and case management system in the private sector and to identify and develop tools of collaboration. The team after elaborate discussion in a meeting resolved that case definition as recorded in the national guideline would be followed and diagnosis made primarily on sputum microscopy. Treatment should be uniform and the private practitioner will be free to refer or to diagnose a suspect. DOTS will be the treatment strategy and proper recording and reporting should be maintained. Tools of collaboration, the responsibility of NTP, partnership project and the private practitioners were identified. The meeting formed a partnership committee including members from NTP, partnership project and private practitioners for finalization of all these tasks.

The members of the partnership committee in several meetings developed a guide line for the private practitioners, simplified and updated three existing forms viz. TB treatment card, TB register and patient identity card which are in use in the national program and developed a new form titled "Referral/Transfer Form". Two draft MOU, one between NTP and the Partnership project and the other between partnership project and the Private practitioners were also developed and finalized.

After completion of the above task MOU between the respective parties were signed and the listed 63 Private practitioners were oriented through workshop. Forms, Cards & drugs were supplied to the private practitioner as per need and they started case registration in their chamber by September, the last month of the third quarter of 2003.

The report from the private practitioners were collected and consolidated by third week of October 2003. Out of the 63 private practitioners, reports were received from 49 and the remaining 14 practitioners could not keep any record of the TB patients they treated during the month under report. While 5 out of the 49 reporting physicians did not get any patient for recording. The private practitioners treated a total 222 patients during the month of Sept. 2003 of which 71 were sputum positive, 6 relapse, 111 sputum negative & 34 extra pulmonary cases (details shown in table IV).

**Table IV: Monthly report: September 2003**

Pulmonary Tuberculosis						Extra pulmonary tuberculosis (4)		Total (5)			
Smear positive			Smear Negative (3)								
New Cases (1)		Relapses (2)									
M	F	Total	M	F	M	F	M	F	M	F	Total
46	25	71	4	2	74	37	17	17	141	81	222

- Total physicians under the project: 63 - No. of reporting physicians 49(78%)
- Average patients per physician: 4.53
- Total No. of patients treated : 222 (M-41, F-81) M: F:64:36
- Number of smear positive patient: 71 (32%) M-46, F-25, M:F:64:36
- Number of sputum negative patients: 111(50%) M-74, F-37, M:F:67:33
- Number of extra pulmonary patients: 34 (15%) M-17, F-17, M:F:50:50
- Number of relapse cases: 6 (3%) M-4, F-2, M:F:67:33

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# MANAGEMENT OF COPD : BANGLADESH PERSPECTIVE

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Bangladesh

Bangladesh is a tropical country situated between latitude of 20.34 degree and 26.38 degree north, longitude of 88.12 & 92.41 degree east with an area 56977 sq.miles. Population is 12,31,246 00 according to the 2001 census with very limited resources.

Asthma and Chronic Obstructive Pulmonary Disease (COPD) are very much common respiratory diseases in Bangladesh. About 7 million people have asthma at present but data on COPD is lacking<sup>1</sup>. The prevalence of risk factors for COPD are highly prevalent (Table-1). Prevention of the risk factors in the development of COPD is a difficult task.

The national and multinational tobacco companies promote smoking, a well-recognized risk factor. Being a developing country with huge financial constraints, our government can not effectively control this promotion due to significant amount of revenue being generated from tobacco sales.

Multinational tobacco companies promote their products through the sponsorship of games, cultural programs and even through the poverty alleviation activities. They only abide by a formal rule to include a health warning in their advertisement. "Warning: smoking is injurious to health".

**Table-1. Risk factors in the development of COPD<sup>2</sup>**

Risk factors	Comments
Cigarette smoking	Important risk factor in Bangladesh
Increasing age	Not an important factor in BD
Gender	More common in male
Airway hyper-responsiveness	?Poorly treated asthma/ ? Dutch hypothesis
Lower socio-economic status	Low birth weight; malnutrition of the fetus and serious ARI in infancy are important in BD
Poor diet	May have an effect in BD
Occupation	Jute, Cotton processing, Farming and other dusty occupation and poor Industrial hygiene are important in BD
Air Pollution	Urban dwelling in densely populated BD is a risk factor.
Deficiency of alpha-1 antitrypsin	Rare in BD
Fume from wooden fire <sup>3</sup>	Women in BD are exposed. <b>May be a topic of research</b>

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In the absence of uniform treatment guidelines most of the patients with COPD are being deprived of optimal treatment.

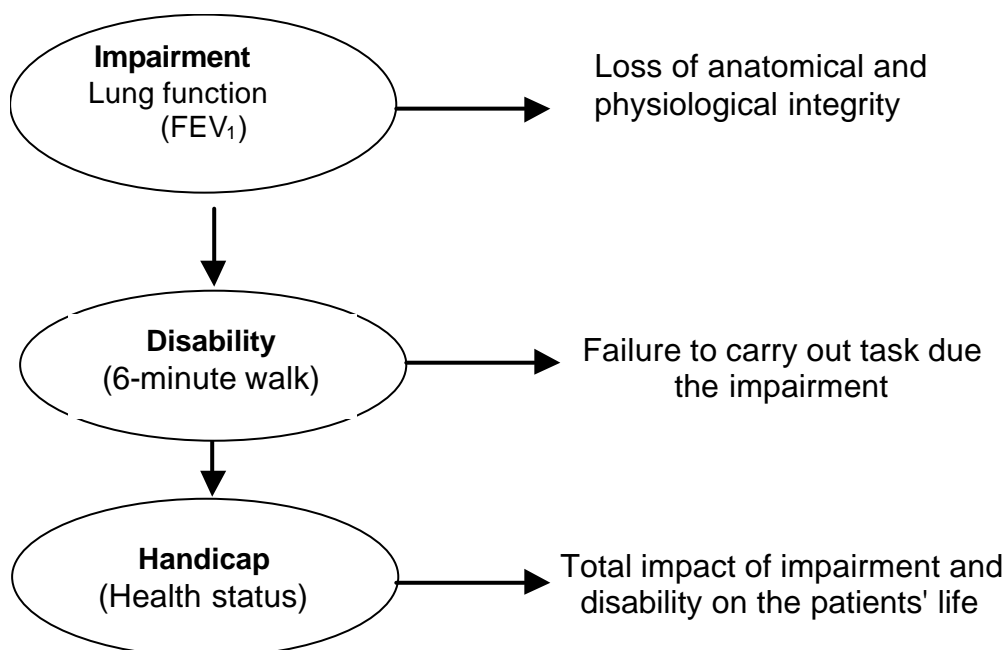
## Diagnosis of COPD:

As per the guidelines of Global Initiative for Obstructive Lung Disease (GOLD), we consider the diagnosis of COPD if the patient has cough sputum production, or dyspnoea, and/or a history of the exposure to risk factors for the disease<sup>4</sup>. We confirm the diagnosis by spirometry<sup>5</sup>. Bangladesh is a country of high prevalent pulmonary Tuberculosis and as such we leave no stones unturned to exclude the diagnosis of Pulmonary Tuberculosis<sup>6</sup>. We exclude other possible diagnosis e.g. Asthma, Congestive Heart Failure, Bronchiectasis

The conventional method of COPD treatment in Bangladesh was to relieve the symptoms. Now, more organized methods/approaches are being introduced. After the diagnosis we assess (Fig.1) the 'impairment', 'disability'<sup>7</sup>, and 'handicap' of COPD to set up a rationalized approach for the management<sup>8</sup>.

Thereafter we try to find out any of the reversible part of the airway obstruction by therapeutic trial (Bronchodilator or Steroid)<sup>9</sup>. If the reversibility is significant we try to keep our patients lung function at the maximum level<sup>10</sup>.

**Figure 1: Impairment, Disability and Handicap in COPD**



**The degree the each component of the impact of airway obstruction should be determined first for the formulation of appropriate support.**

We record and analyze the profile of few exacerbation of COPD of a patient and individualize the nature of attack for that patient so that we can anticipate and take preventive measure for a further attack in future<sup>11</sup>.

Monitoring the treatment and the disease process is very important part of the disease. Patient buys 'satisfaction' rather than the 'goods'. Our patients are not different. They

want to be more active in their life. They are less aware of the progressive nature of the disease. Keeping these ideas in mind we have made a plan to manage the patient with three fundamentals as<sup>12</sup>:

- Education
- Caution
- Medication

Therefore we arrange a follow up visit schedule as per the need of the individual patient. The important information is that our patient has to pay for the service in the major part of the health care service (Private practice). In every follow up visit we discuss the symptom score as:

The following questions are concerned with the effect of your chest trouble on your everyday life. Please respond Yes, No or Not Applicable (N/A) to each item<sup>13</sup>.

1. Do you suffer from coughing attacks during the day?
2. Because of your chest trouble do you often feel restless?
3. Because of your chest trouble do you feel breathlessness maintaining the garden?
4. Do you worry when going to friends house that there might be something there that will set off an attack or chest trouble ?
5. Do you suffer from chest symptoms as a result of exposure to strong smell of cigarette smoke or perfume?

In the follow up visit we also monitor pharmacotherapy and other medical treatment, co-morbidities etc.

The reduction of the risk factor is very important in the management of COPD<sup>14</sup>. We have no well trained professionals for the smoking cessation but still then we organize smoking cessation clinic for the smokers. In the management of stable COPD we follow the Guidelines of GOLD<sup>15</sup> with few exceptions such as:

We do not give Influenza vaccine as it is not available in our country. We prescribe more oral

bronchodilator than the inhaled one as the former is cheaper (probably more bronchodilator are ingested worldwide than inhaled).

As we can not improve the lung function significantly<sup>16</sup> we prefer the non-pharmacological treatment of COPD ie. pulmonary rehabilitation. We teach the patient reconditioning exercise, breathing exercise and how to make best use of their daily activities as a part of the exercise<sup>17</sup>.

#### **Our future plan is to develop:**

- A good team for the management of COPD and a national guidelines for the management of COPD.
- Visual analogue scale<sup>18</sup> for the measurement and monitor the treatment and progress of COPD effectively.
- A low cost or cost effective schedule for the poor patients in the management of COPD
- A project of Long Term Oxygen Therapy for the poor patients<sup>19</sup>

#### **Conclusion:**

The initial response of our initiative is very encouraging. We have already started a model centre for the management of COPD patients and working hard to develop it successfully<sup>20</sup>.

#### **Acknowledgement**

We would like to thank IPCRG (International Primary Care Respiratory Group) and Miss Sam Knowles, Secretary, IPCRG for the support and encouragement.



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## GENDER ISSUE IN TB CONTROL - SAARC REGION

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Diseases exert differential impacts on men and women, based on their gender. Gender is not merely the biological difference but the differences between men and women in their roles, behaviours, expectations and opportunities, within a socio-cultural and economic context<sup>1</sup>. People in SAARC member countries encounter gender disparities profoundly in many aspects in their lives such as education, job opportunities, food and nutrition, morbidity and mortality pattern of diseases and health care etc.

TB can be regarded as a symptom of poverty caused by the unequal distribution of resources globally. However, poverty within a society is not distributed equally among its social classes, and among the two sexes. Estimates show that 70% of the world's poor are women<sup>1</sup>. Poverty and gender are implicated in a woman's vulnerability to TB. The low status accorded to women in most male dominated SAARC countries, their limited

decision-making power, restricted mobility and poor access to health care resources make them particularly vulnerable to ill health and reduce opportunities in accessing basic and available health care. On the other hand men being the breadwinners of the families, run a high risk of exposure to infectious diseases such as TB and predisposing factors like smoking, alcohol, drug abuse etc as they are constantly on the move within their societies.

SAARC Region comprising seven member countries, namely Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka shares a 22% of the 6,233,821,945, global population, and accounts for approximately 29% of global TB burden.<sup>2,3,4</sup> The male to female ratio of the population within each member country as well as the entire SAARC Region is approximately one (Range 1:0.93 -1:1).

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**Table 1:** Population of SAARC Countries by Gender 2001

	Male	Female	Total	M: F Ratio
Bangladesh	67,808,334	64,938,350	132,746,684	1:0.96
Bhutan	1,080,260	1,013,916	2,094,176	1:0.94
India	531,277,078	495,738,169	1,027,015,247	1:0.93
Maldives	159,232	151,532	310,764	1:0.95
Nepal	11,359,378	11,377,556	22,736,934	1:1.00
Pakistan	73,957,500	68,542,500	142,500,000	1:0.93
Sri Lanka	9,633,964	9,942,879	19,576,843	1:1.00
SAARC Region	695,275,746	651,704,902	1,346,980,648	1:0.94

Source: CIA, THE WORLD FACT BOOK 2002: Bangladesh, Bhutan, Sri Lanka, Maldives, Pakistan Population 2002, Statistical Profile, Census of India 2001. Provisional Population Totals: India Part 1, Annual Report of TB Control Programme, Nepal

**Table 2:** Smear Positive Pulmonary TB Case Detection by Gender, SAARC Countries, 2001

	Number of cases			Case Detection Rate		
	Male	Female	M:F Ratio	Male	Female	M:F Ratio
Bangladesh	28243	12244	1:0.4	42	19	1:0.5
Bhutan	173	148	1:0.8	16	15	1:0.9
India	129821	55456	1:0.4	24	11	1:0.5
Maldives	34	25	1:0.7	21	16	1:0.8
Nepal	9130	4534	1:0.5	80	40	1:0.5
Pakistan	4360	3628	1:0.8	6	5	1:0.8
Sri Lanka	3092	1216	1:0.4	32	12	1:0.4
SAARC Region	174853	77251	1:0.4	25	12	1:0.5

Source : Global Tuberculosis Control, WHO Report 2003.

**Table 3:** New Smear Positive Case Detection Rate (%) in SAARC Countries, 2001.

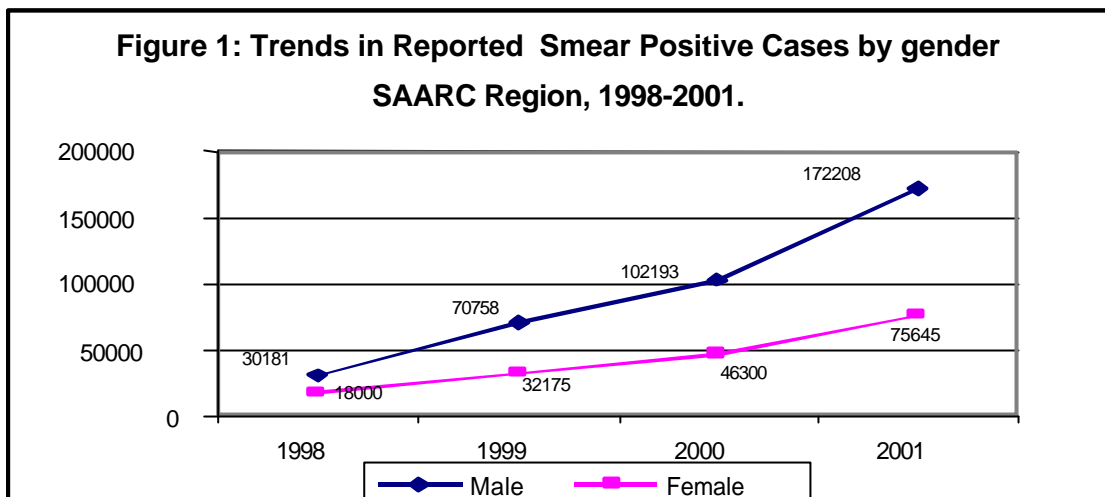
Bangladesh	28
Bhutan	26
India	21
Maldives	88
Nepal	64
Pakistan	10
Sri Lanka	86

Source : Global Tuberculosis Control, WHO Report 2003.

Although population distribution among males and females in each member country is almost equal, distribution of smear positive Pulmonary TB cases between both sexes do not represent the same population ratio and it is consistently lower for females in each member country ( Table2).

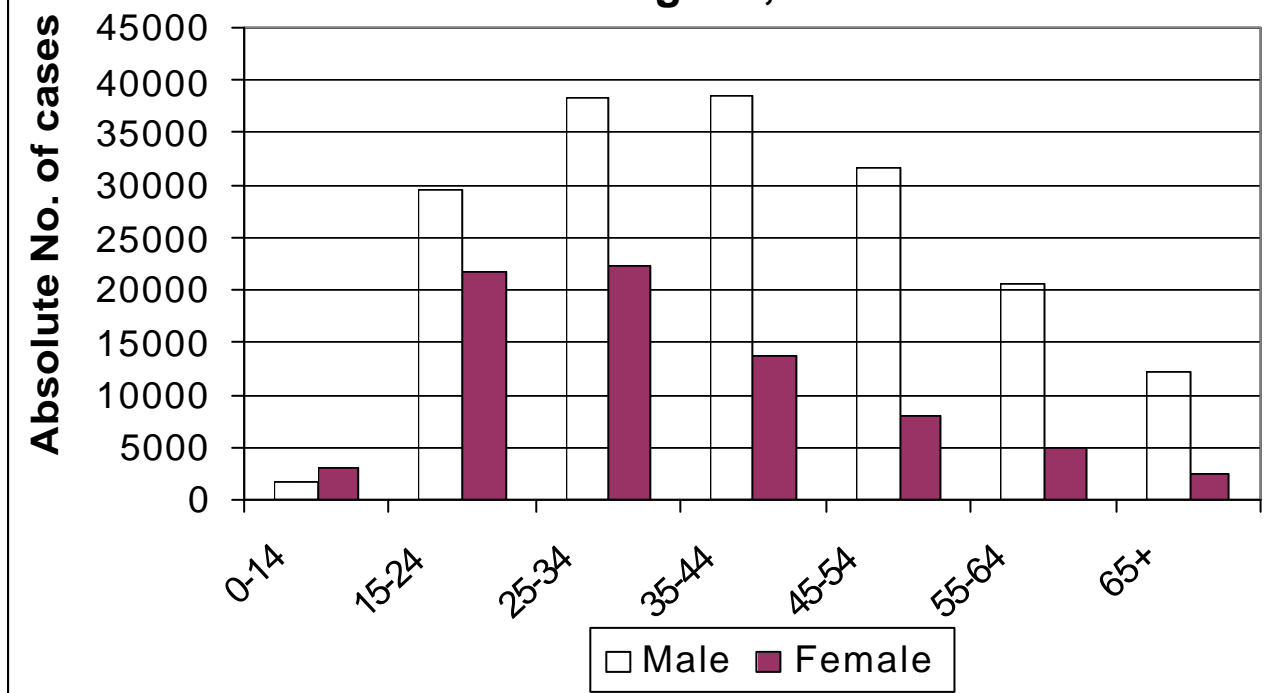
The trends of smear positive case detection for both sexes in the entire SAARC Region between 1998 to 2001 reveal that males outnumber females consistently. Moreover and most importantly, the disparity trend appears to be an increasing one between male and female cases into the near future (Figure 1).

Absolute No. of cases



Source : Global Tuberculosis Control, WHO Report 2003.

**Figure 2: Age & Sex Distribution of Smear Positive Pulmonary TB Cases in SAARC Region, 2001.**



From figure 2, it is apparent that there is a little difference in number of cases between males and females in 0-14 age group (up to adolescence) and following this, a significant difference between males and females at each age group where males outnumber the females. This similar pattern of age and sex distribution occurred during the period 1997 to 2000.<sup>5,6,7,8</sup> With almost equal population distribution between sexes (table 1), this low detection of female cases remains a troubling public health issue demanding urgent focused study. Do this gender differential really exist? Or is this a reflection of unequal access to health care? Is this due to unequal treatment by the medical profession in terms of referring for sputum microscopy for suspected cases? These are some of the questions requiring urgent attention as if females actually comprise a larger portion of TB cases and are not presenting for testing etc., then this has major implications in terms of treatment and care for women, and also leaves many 'potential' infectious TB cases within the population capable of infecting non-infected persons. Since passive case finding is practiced for TB case detection under National TB Control Programmes, the number of cases ultimately diagnosed as TB, basically depends upon the overall number of cases seeking health care in the first instance, and as importantly, the number of cases being referred for testing etc. Hence another reason for the gender differential may be

poor female health seeking behaviour and this very fact demands further operational research.

Currently the smear positive case detection rates (total for both sexes) are well below the WHO target of 70% within many of the SAARC countries (Table 3) in spite of WHO's TB Control strategy: the directly observed treatment short course (DOTS) protocol. One possible reason for the low case detection rates may be under-reporting of female TB cases. Capturing more females within health care systems may increase passive case detection and thus bring more closer, the WHO's global target in case detection. Hence it is important to make the TB control programmes gender sensitive in such a manner to meet the health care needs of both women and men. If there is a true gender differential, then this must be assessed and not based on anecdotal evidence.

There is no gender difference in age-wise distribution of proportions of people affected by smear positive pulmonary TB. Moreover, for both sexes, high proportions of cases are detected within the age groups 15-24, 25-34, 35-44 and 45-54 or overall 15-54 year age group. Most importantly, this is the most economically productive age group within any society. It is apparent that as a disease, Tuberculosis has a direct impact on the economic development of the SAARC member countries.

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Use double spacing throughout, including title, abstract, text, acknowledge, reference, table and legends for illustrations. Begin each of the following sections on a separate paper. Number pages consecutively.

Title page should contain (a) concise title, (b) a short summary, (c) first name middle initial and last name of each author, (d) name of department(s) and institution(s) to which the work should be attributed, (e) name, e-mail and postal address of author responsible for correspondence about the article.

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Should not be of more than 200 words and should state the purpose of the study or investigations, basic procedure, main findings (give specific data and statistical significance if possible) and the conclusion, (emphasize new or important aspects of the study).

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It should be divided into sections with headings as Introduction, Methods, Results Discussion, Conclusion and References.

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Describe the criteria for selection of cases; identify the methods, apparatus (manufacturers name) and procedures in detail.

**Results:**

Present the results in sequence in the text, tables and figures. Do not repeat all the data in the tables and/or figures in the text. Summarize the important points only. Mention the methods used for statistical analysis.

**Discussion:**

Comment on the observations of the study and the conclusions derived from it. Do not repeat the data in detail already given in the results. Give implications of the findings, their limitations and observations to other relevant studies. Avoid unqualified statements and conclusions, which are not completely supported by the data. Avoid claiming priority. New hypothesis may be labeled as recommendations.

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Type, each table on a separate sheet, use double space. Give a brief title for each table. Cite each table in the text in consecutive order.

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Should be professionally drawn. Free hand lettering is unacceptable. Illustrations can be photographed (Black and White glossy prints) and numbered. If photographs of persons are to be used, either take permission from the person or make the picture unidentifiable. Each figure should have a label pasted on its back indicating name of the author at the top of the figure.

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# EDITORIAL

Since its inception in year 1992, SAARC TB Centre has identified dissemination of information regarding prevention and control of Tuberculosis and HIV related tuberculosis diseases, as one of its major activities.

STC felt the need to publish a journal on tuberculosis Lung diseases and HIV/AIDS mainly focusing on the latest developments. The journal will be published every six months and articles/papers in the field of TB, Lung diseases, HIV/AIDS and TB/HIV co-infection will be entertained in the journal.

This journal is an effort by STC with a hope to create a forum for discussion and provide an opportunity to share experiences with medical community.

From the readers point of view we expect that there may be some discrepancies in the format or the contents of this very first issue of the journal. We highly appreciate if you could point out such discrepancies and keep us informed with your ideas and suggestions in order to bring forward a best kind of journal in future.

# **1st SAARC Conference on TB, HIV/AIDS and Respiratory Diseases**

SAARC Tuberculosis Centre is organizing a SAARC Conference on TB, HIV/AIDS and Respiratory Diseases from 14 to 17 Dec. 2004, TB & HIV/AIDS and Respiratory Disease specialists of SAARC Region and other countries of the World can participate. Outstanding researchers and experts of the field would present the Scientific Session and Special Oration on priority areas of TB and HIV/AIDS TB/HIV co-infection and Respiratory Diseases.

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