

DOT Programme of T.B-A SUCCESS or FAILURE in Pakistan

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Abstract

To study DOT programme of T.B either a success or failure. As it is such a common disease, I decided to find either DOT programme of T.B prove a success or failure, this being the aim of my study. To study the impact of the Directly Observed Therapy (DOT) programme on the rate of infection and cure of TB. It was a retrospective study (relies on data on exposure or outcomes that have been collected through medical records). We visited Gulab Devi Hospital from June 18th 2010 to July 3rd 2010. Case histories of 40 patients were taken on a pre-designed form and significant and relevant points were noted such as age, sex, duration of hospitalization, causes, clinical diagnosis and treatment. DOT programme as a means of ensuring compliance and adherence to TB treatment among patients attending our clinic. Treatment was fully supervised in indoor and outdoor patient. The outcome was favourable (cure or treatment completion) in 90% and unfavourable in 10%. The study reveals that the treatment outcome is good among patients who receive DOT. DOT programme is a success. Conclusion was drawn on the basis of different issues of DOTS. It was observed that patient satisfaction level is high, rate of resistant cases of TB is decreased, and DOT has enhanced the adherence on therapy (85%). Patients want to complete their treatment. Remedies & strategies are implemented which can improve compliance. Record is maintained and follow up study is being done. Health care providers are fully engaged. All these make DOTS a success.

Key word: DOT, Failure, Success, Tuberculosis

INTRODUCTION

Tuberculosis has been present in humans since antiquity. The earliest unambiguous detection of *Mycobacterium tuberculosis* is in the remains of bison dated 18,000 years before the present [1].

Whether tuberculosis originated in cattle and then transferred to humans, or diverged from a common ancestor infecting a different species, is currently unclear. [2]

Skeletal remains from a Neolithic Settlement in the Eastern Mediterranean show prehistoric humans (7000 BC) had TB [3].

In the early 20th century, some believed TB to be caused by masturbation. [4]

Treatment of T.B is referred to as directly observed therapy (DOT) and represents the standard of care for TB treatment. DOT is considered to be the most effective strategy available for controlling the spread of TB. There are a number of variables inherent in DOT that have allowed it to become much more successful than traditional (non-DOT) treatments: case finding and diagnosis; patient categorization for treatment; treatment; progress toward cure; treatment follow-up;

results; logistical aspects (drug supply, lab, TB register); and political commitment. [5]

In addition to ensuring that the TB clients take their medication, it is the role of the DOT health care provider to monitor for side effects, watch for signs indicating potential relapse, ensure clients attend follow-up appointments, educate individuals about tuberculosis and provide continuous support, assistance and referrals for other issues. In order to help improve adherence, some DOT workers also provide incentives and enablers (food vouchers, subway tokens) [6].

World Health Organization (WHO) DOTS pilot project in the Leningrad region was moderately effective with patients with high epidemiological and medical risk. This study was followed by a 2003 study in Orel Oblast of a revised DOTS program that also had good results; an 81% cure rate for culture positive patients and a 91% cure rate for clinically diagnosed patients. [7]

Ecological study examining the effects of DOTS implementation on the Russian public health system. The measures used were hospital bed utilization and hospital admission of

patients in control and DOTS regions from 2002. The study concluded that DOTS implementation did not lead to fundamental structural changes in the Russian health care system. [8]

A clinical trial was conducted in Pakistan from 1996 to 1999 to determine which form of DOT was most effective. It concluded that the strengthened TB care (following the WHO/StopTB strategy known as DOTS) in the then operational conditions in Pakistan increased cure rates from 26% to 60% in the trial group as a whole. However, there was no statistically significant difference between the health worker DOT, family member DOT and self-administered (control) arms. There were similar results from the trial's three sites. Within the health worker arm, according to the international practice, if patients had reasonable access (less than 2 km/low travel cost), they were requested to attend their chosen health facility, while others were observed by a CHW of their choice, commonly a Lady Health Worker (LHW). The lack of a benefit from DOT, and poor results from health facility DOT in particular, raised some important questions for the implementation of the DOT strategy in this and other countries. [9]

Tuberculosis, one of the biggest health threats in India, kills two people every three minutes. The latest World Health Organization (WHO) report states that three million people develop tuberculosis in the Southeast Asian region every year, India reporting 22 per cent of these. DOTS was launched formally as the Revised National TB Control programme in India in 1997 after pilot testing from 1993-1996. India now has the second largest DOTS programme in the world and it is already expanding faster than any other country's program, adding more than 100,000 new patients to its treatment every month. The success stories shown on the programme web site emphasize the wide participation by ordinary people "to make DOTS services available and accessible even in the most remote corners of India." [10]

In Hong Kong, the study found an excess of TB disease risk and a less favorable treatment

outcome for elderly, male patients in Hong Kong. While consideration should be given to extending active screening programmes to such clearly identified risk groups, further studies and careful cost-effectiveness analyses are called for before implementation of such programmes is indicated on a service-wide scale. The treatment success rate seen at 12 months was reasonably good, although short of the WHO goal of 85%. [11]

A 2005 study in the southern region of Ethiopia indicated that the introduction of DOTS in 1996 and its subsequent expansion to reach a population coverage rate of 75% in 2001 led to an increase in treatment success and decrease in default and failure rates. Treatment success rates for smear-positive patients rose from 38% in 1994 to 78% in 2000, the default rate declined from 38% to 18%, and treatment failure declined from 5% to 1%. These results were echoed by a 2006 study in Rio de Janeiro. Soars et al. demonstrated that patients under DOT were more likely to convert to sputum negative than those under SAT, even when controlled for age, sex, and positive smear or culture upon enrollment. [12]

The use of traditional healers as DOTS supervisors were found to be a positive factor in patient satisfaction rates in a 2003 study from South Africa, although patients supervised by traditional healers did not have a statistically significant higher completion rate. [13]

The consequences of no adherence to treatment include increased rates of treatment failure. Noncompliance was associated with a 10-fold increase in the occurrence of poor outcomes from treatment and accounted for most treatment failures. Innovative programs are needed to deal with alcoholism and homelessness in patients with tuberculosis.

METHOD

It was a retrospective study relies on data on exposure or outcomes that have been collected through medical records). We visited Gulab Devi Hospital from June 18th 2010 to July 3rd 2010. Case histories of 40 patients were

taken on a predesigned Performa and significant and relevant points were noted such as age, sex, duration of hospitalization, causes, clinical diagnosis and treatment.

Diagnosis of tuberculosis was done by physical examination, lab tests and radiology reports. Data after collection was analyzed and the results were shown in graphical format.

The following procedure was adopted:

- developed a medication history/patient interview form
- Interviewed patients with tuberculosis.
- Comparison of national treatment guidelines with international treatment guidelines

Inclusion criteria

- 25patients of either sex i.e. both male and females randomly selected
- Patients of all ages were included
- Indoor and outdoor patients were included

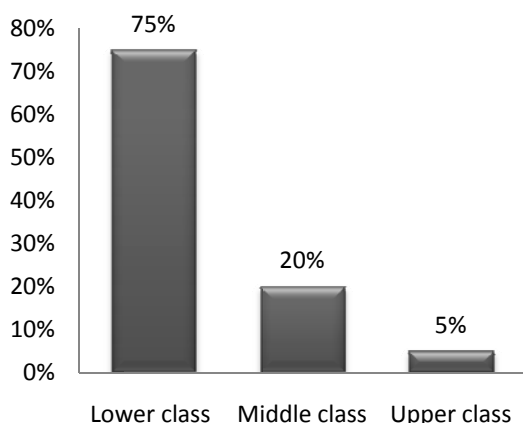
Exclusion criteria:

- Neonates were excluded from the study
- Very young children (5-15) were excluded

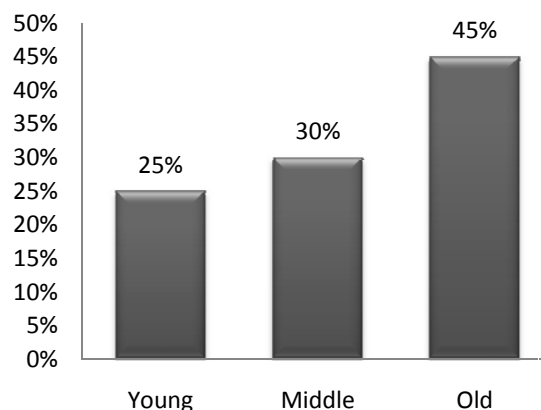
RESULTS

Data of 40 patients with tuberculosis was studied in a specialized hospital setting. The following parameters were analyzed during the study:

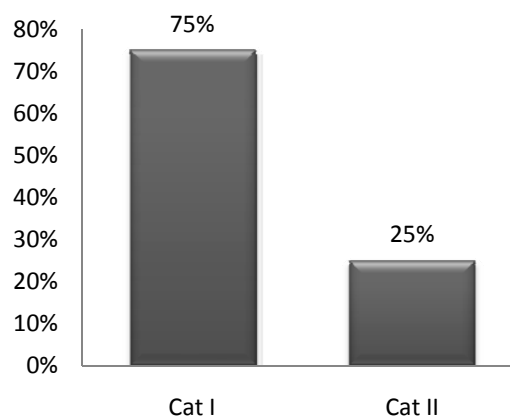
1. Prevalence of T.B on the basis of class status:



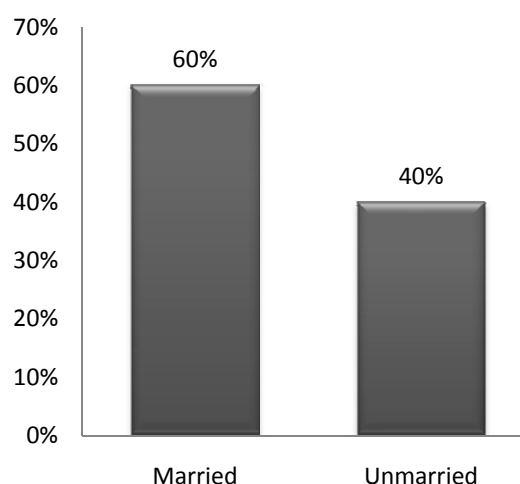
2. Prevalence of T.B on the basis different age groups:



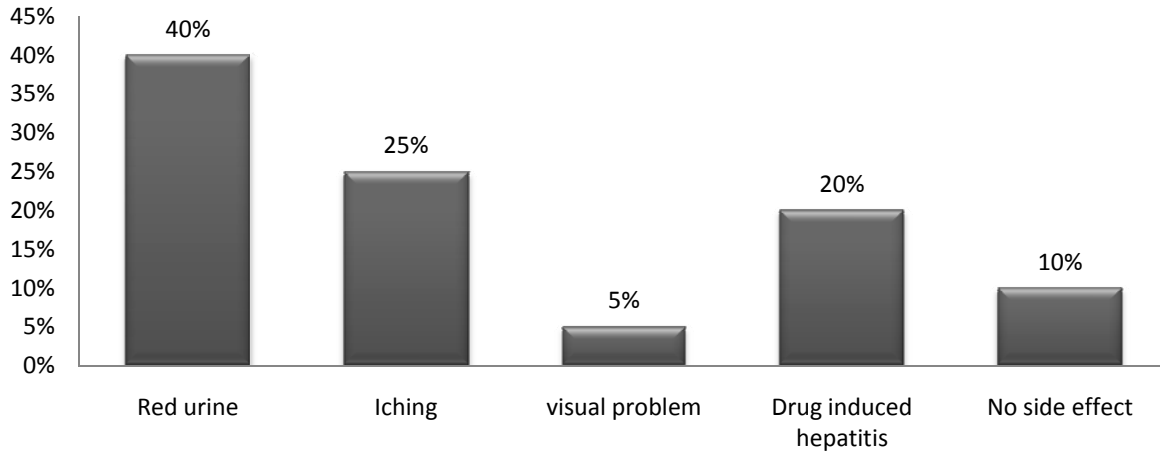
3. Type of patients:



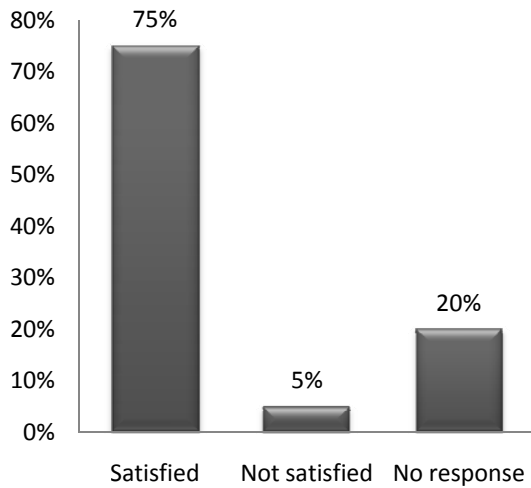
4. Prevalence of T.B on the basis of marital status:



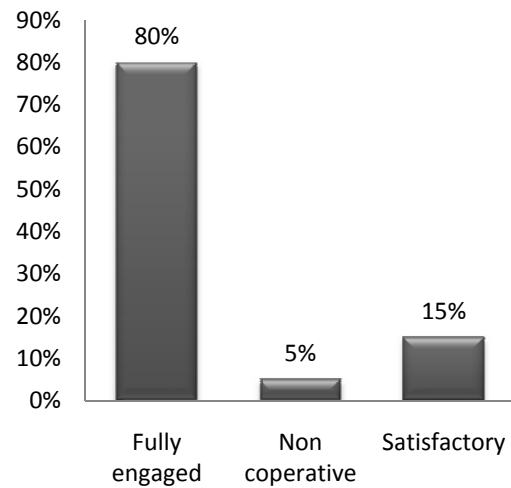
5. Side effects caused by using drugs:



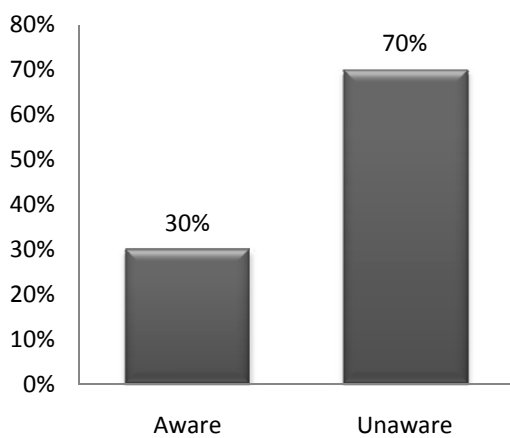
6. Satisfaction of patient on medication



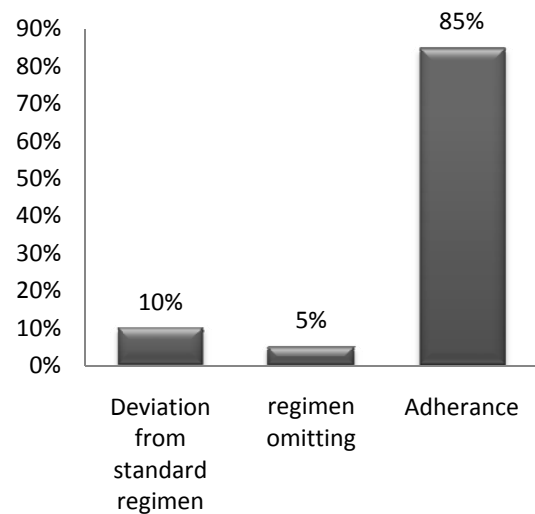
8. Role of health care providers:



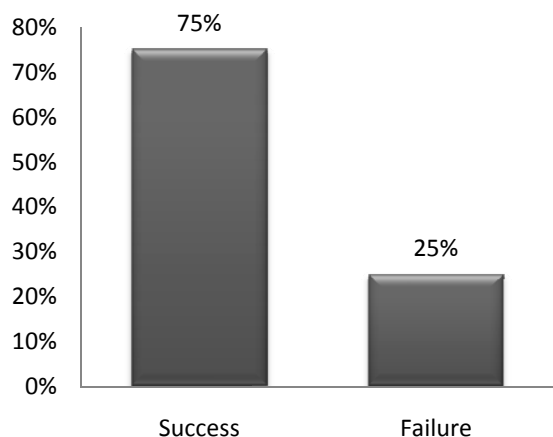
7. Awareness about DOT programme of T.B in patients



9. Adherence to DOT programme of T.B



10. Progress of DOT in Gulab Devi Hospital



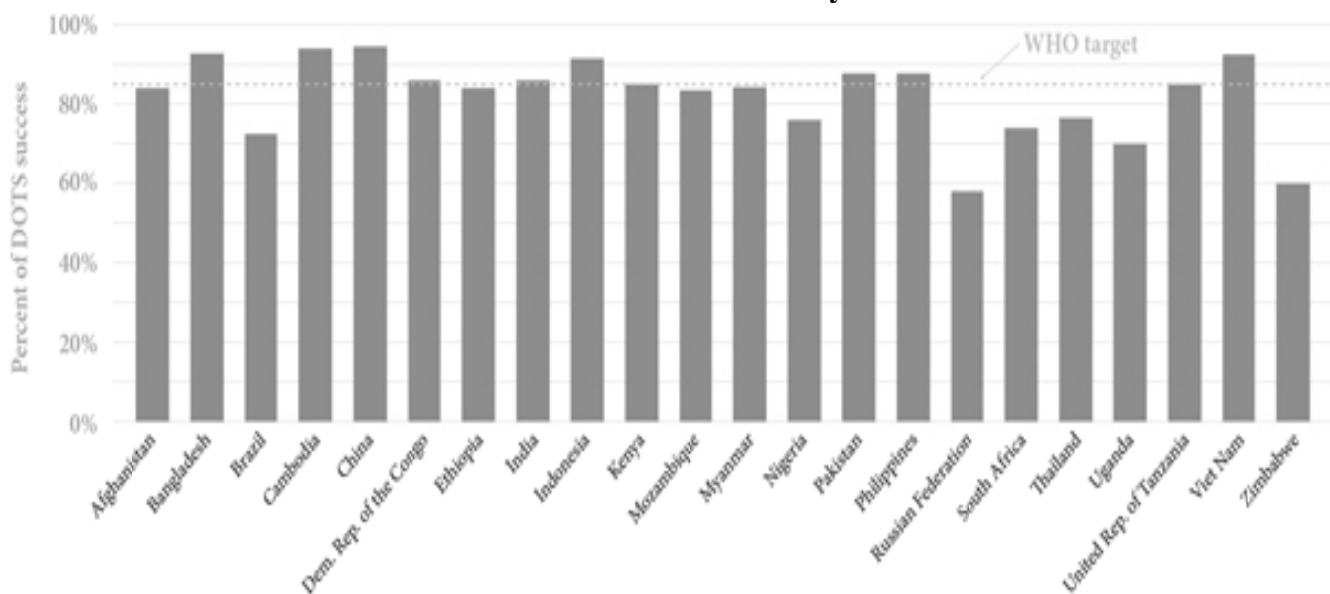
Directly observed therapy, short course, or DOTS, cures most TB in high-burden countries but only about two-thirds of active cases are ever detected.

DISCUSSION

TB constitutes a strong economic burden, which could cripple the work force of the nation. Low level of educational attainment of the patients recorded also means that majority could not understand their disease state and lack the ability to read the instructions of

dosage regimen on the labels. Prevalence of disease is: In lower class: 75%, in middle class: 20% & in upper class: 5% is observed. Prevalence of T.B in different age groups is in Young: 25%, in Middle age: 35% & in Old age: 40%. Treatment failure occurred when the TB patient still remain smear positive after 5 months of treatment. The treatment failure rate recorded could be as a result of multi-drug resistant TB in which *M. tuberculosis* exhibit resistance to at least Isoniazid and Rifampicin. Resistant cases were less so Cat I patients were 75% & Cat II patients 25% in hospital. Prevalence of disease regarding marital status in Married: 60% & Unmarried: 40%. The patients need education on TB and importance of DOTS. Therefore, enlightenment campaign and counseling are crucial for the objectives of the DOTS to be accomplished. Literacy level and social economic status should be improved to reduce barriers of DOTS programme. Awareness level in patients regarding DOTS is very low, Aware about DOT is 20% & Unaware about DOT: 80%. Satisfaction level of patients on DOTS: 75% Satisfied to DOT & 5% not satisfied, 20% show No response on treatment.

11. DOT success world widely



In this study, the patients experienced varying degrees of adverse effects including dark urine, yellowish eyes and impaired vision/blindness. Patients with yellowish eyes could be scared to continue medication in order to avoid liver damage, while the patients experiencing poor vision can stop their medication, many patients have adverse reactions that complicate treatments and invariably influenced treatment outcomes. Therefore, close monitoring and counseling on adverse effects of anti-TB drugs are imperative for ensuring sustainable solutions to Side effects observed are red urine in 40%, drug induced hepatitis in 25% & Itching:5%, Visual disturbances: in 20% & 10% show No side effect .However, side effects of anti-TB drugs are worrisome to the patients and could increase defaulting rates. Quality healthcare outcomes depend upon patients' adherence to recommended treatment regimen. Patients' non-adherence cannot only be a pervasive threat to health, but also carry an appreciable burden as well as human well being. In this research work, almost Deviation from standard regimen is 10% Regimen omitting cases are 5%, level of Adherence is 85%

Role of health care providers is fully engaged in patient's welfare which is 80%, where as Satisfactory behavior is 15%, only 5% are Non cooperative.

One of the major components of DOTS strategies is the provision of free, regular and uninterrupted supply of high quality TB drugs. The drugs were donated by International agencies such as USA's Agency for International Development (USAID), Canadian International Development Agency (CIDA), WHO, Global Drugs Facility. Cure rate of TB according to WHO in different countries through DOTS: in Brazil 70%_in Afghanistan: 79%, China: 90%, Pakistan: 85%, India: 81.

It was observed that Indoor patient were also irritated by their atmosphere while doctors and nurses paid them full attention. DOT is just concern to the fatigue of health care provider so he/she should be responsible. Community and home support is an important component of

successful long term drug compliance especially in rural settings of developing countries which have limited monitoring structured. Over all study reveals that DOT programme proves successful for the treatment of T.B.

CONCLUSION

Although the number of patients on which study is conducted was small, but our data suggest that implementation of DOT is effective in TB treatment. According to my observation DOT programme is an effective and inexpensive treatment of tuberculosis. According to Ministry of health of Pakistan, if cure rate in Pakistan is almost 85% and default rate is 5% than it consider a successful. While the cure rate in Gulab Devi is almost 75%.I think it's a great achievement. The concrete reality of DOT is an important determinant of the overall success or failure of the programme, and has implications in terms of equity and accessibility of care during treatment Direct, face-to-face contact between a TB patient and a health-care worker who observes each intake of medication, has been observed as the optimal means to achieve high cure rates. DOTS can cost as little as US\$20 per person. If the disease becomes resistant to first-line therapies, medication and other treatment costs can rise to US\$5,000, or much higher. In government hospitals treatment is free. There are some cases of deviation from standard regimen and regimen omitting but adherence to the treatment is in large percentage. This shows patient compliance. As DOTS has minimized these issues, which are hurdles in the management of T.B. patients those use DOTS medicines feel no problem in taste. Pills are pliable. In the light of these entire achievements one can say that DOTS of TB is working efficiently in Pakistan and also worldwide, it has improved the cure rate, lessen the resistant cases, involve the health care providers to educate the population, side effects are minimized, record of patients is kept and follow up study is being done. Cure rate up to 85% is achieved (WHO record) in Pakistan so this program is successful in treatment of TB.

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REFERENCES

- [1]. Rothschild B, Martin L, Lev G, Bercovier H, Bar-Gal G, Greenblatt C, Donoghue H, Spigelman M, Brittain D-"*Mycobacterium tuberculosis complex DNA from an extinct bison dated 17,000 years before the present*"(2001) **33**:305–311.
- [2]. Pearce-Duvel J-"*The origin of human pathogens: evaluating the role of agriculture and domestic animals in the evolution of human disease*"(2006) 369-82,
- [3]. Hershkovitz, I; Donoghue, HD; Minnikin, DE; Besra, GS; Lee, OY; Gernaey, AM; Galili, E; Eshed, V et al- "*Detection and Molecular Characterization of 9000-Year-Old Mycobacterium tuberculosis from a Neolithic Settlement in the Eastern Mediterranean.*"(15 October 2008) *PLoS ONE* **3** (10): e3426.
- [4]. Laumann, Edward O- *The Social Organization of Sexuality: University Sexual Practices in the United States*,of Chicago Press p 80(1994)
- [5]. Flynn JL, et al- *Tumor necrosis factor-alpha is required in the protective immune response against Mycobacterium tuberculosis in mice. Immunity.* (1995) Volume 2, Issue 6, 561-572
- [6]. World Health Organization. . *What is DOTS?: A Guide to Understanding the WHO-recommended TB Control Strategy Known as DOTS.* Geneva, World Health Organization(1999)
- [7]. Ontario Lung Association- *Tuberculosis: Information for Health Care Providers (Third Edition).* *The Lung Association:* Toronto,2003 28 p.: col.; graphs, refs., tables.
- [8]. Kherosheva T, Thorpe LE, Kiryanova E, Rybka L, Gerasichev V, Shulgina M, Nemtsova E, Aptekar T, Kluge H, Jakubowiak W, Grzemska M, Aquino G, Wells C, Kazionny B- "*Encouraging outcomes in the first year of a TB control demonstration program: Orel Oblast, Russia.*" *Int J Tuberc Lung Dis.* 2003 Nov; **7**. , Volume 7, Number 11 pp. 1045-1051(7)
- [9]. Marx FM, Atun RA, Jakubowiak W, McKee M, Coker RJ. "*Reform of tuberculosis control and DOTS within Russian public health systems: an ecological study.*" *Eur J Public Health.* 2007 February; **17** (1):98-103
- [10]. Walley J, Amir Khan M, Newell J, Hussain Khan M."*Effectiveness of the direct observation component of DOTS for tuberculosis: a randomised controlled trial in Pakistan*" 2001;357:664-9.
- [11]. <http://www.indiatogether.org/2008>
- [12]. Tam et al *Hong Kong Med J Vol 9 No 2 April 2003*
- [13]. Lonnroth K, Uplekar M, Blanc L. "*Hard gains through soft contracts: productive engagement of private providers in tuberculosis control.*" *Bull World Health Organ.* 2006 Nov;84
- [14]. Colvin M, Gumede L, Grimwade K, Maher D, Wilkinson D. -"*Contribution of traditional healers to a rural tuberculosis control programme in Hlabisa, South Africa.*" *Int J Tuberc Lung Dis.* 2003Sep;7(9 Suppl. 1): S86-S91