

CHAPTER II

LITERATURE REVIEW

2.1 Background Information about Thailand

The kingdom of Thailand is located between latitude 5°37'N. and 20 ° 27'N., Longitude 97° 22' E and 105° 37' E., on the Indochina and Myanmar peninsulas in the centre of South East Asia, with the Union of Myanmar and the Democratic People's Republic of Laos on the West and on the North, the Democratic Kampuchea and the Democratic People's Republic of Laos on the East and Malaysia on the South. The country occupies 513,115 square kilometers. The whole area is divided into four geographical regions: Northern, North Eastern, Central and southern region (MOPH, 1999).

There are at present 46 districts and 152 sub-districts in Bangkok, while the provincial administration comprises of 75 provinces, 876 districts, 7,255 sub-districts and 67,777 villages (1998). The Interior Ministry directly governs the province. Total population is 61,470,000 of which male population is 30,594,000 and female population 30,876,000. The total fertility rate is 1.98 and life expectancy at birth is male 69.9 and female 74.9 years. The crude birth rate, crude death rate, infant mortality rate and maternal mortality rate are 18.0, 6.7, 5.2 and 0.2 per 1,000 respectively. The literacy rate is 93 % in 1997 (Kani, 1999).

2.2 A Brief Introduction of Tuberculosis

Tuberculosis is infectious disease caused by *Mycobacterium tuberculosis*. The disease is transmitted through the air. It primarily affects lungs and causes pulmonary tuberculosis. It can also affect any parts of the body except nail and hair. The disease also affects animals like cattle, this is known as "bovine tuberculosis" which may

sometimes be transmitted to man (Toman K. 1979). *Mycobacterium tuberculosis* can infect any part of the body but pulmonary tuberculosis is common. The pulmonary tuberculosis is highly transmitted from patients to healthy person via airborne. Therefore, pulmonary tuberculosis is major public health problem. One sputum smear positive tuberculosis patient can transfer disease to 10 - 15 persons per year if untreated. Regular cough for more than three weeks, chest pain, fever/night sweats, loss of appetite, breathlessness, tiredness and haemoptysis are the symptoms of pulmonary tuberculosis. Cough for more than three weeks is the most common symptoms to suspect a symptomatic tuberculosis case for diagnosis (Crofton, 1992 ; NTP, 1998).

2.3 Brief History of Tuberculosis

If we look at history of tuberculosis, humanity has probably recognized tuberculosis as a killer disease since the Ice Age. It is noted before that traces of tuberculosis lesion have been found in lungs of 3000 years old Egyptian mummies. The Greek physician Hippocrates (459 - 377 BC) " the father of the medicine " wrote a description of the disease. Accumulation of clinical evidences showed that tuberculosis is a disease transmitted from man to man (Central Bureau of Statistics. 2001). In Classic Greek times, it was known as phthisis, from the verb phthinein, to waste away. Right up to the present century, it was commonly called "consumption" for the same reason. But it was in the 17th century that a Dutchman, Franciscus Silvius of Leydebn, first used the term "tubercle" to describe the knobby lesions found in the lungs of the people who had died of the wasting disease (Kani, 1990).

In 1882, German physician, Dr. Robert Koch announced the discovery of tuberculosis bacilli and published an article " Ecology of TB ". Within eight years, he was

able to make an extract of dead bacilli to form tuberculin purified protein (Central Bureau of Statistics, 2001), derivative (PPD), which could be used as a diagnostic test for tuberculosis infection. Another important development was provided by the French bacteriologist Calmette and Guerin who used specific culture media to lower the virulence of the *M. bovine tuberculosis* bacilli, creating the basis for the BCG vaccine. Initially BCG was given orally during 1921 - 1925. In 1927 the first human was vaccinated by intra-dermal Techniques in 1927. Recognition of the value of BCG came in 1948 when it was accepted by tuberculosis workers from all over the world as a safe preventive measure. After that BCG was used worldwide. Now developed countries stopped to use BCG thinking the tuberculosis is shifted to old age group but developing countries still have widespread use of BCG today (Park, 1994).

Before the availability of anti-microbial drugs, the cornerstone of treatment was run in the open air in specialized sanitarium, often in mountain areas. The modern era of tuberculosis treatment began in 1944 with high efficacy of streptomycin. In 1949, it was discovered that Para-aminosalicylic acid (PAS) prevented the emergence of drug resistance, if given in combination with streptomycin. Since then, the administration of two or more drugs in combination has been considered essential for adequate tuberculosis chemotherapy. In 1952 Isoniazid (INH) became available. After that it has remained an important component of all primary drug regimens because it is highly effective with relatively low toxic and inexpensive (Toman, 1979).

Ethambutol and Pyrazinamide, made tuberculosis curable in the great majority of patients. In 1967, Rifampicin went into the clinical trial and proved to have anti-tuberculosis bacterial effect. The discovery of Rifampicin was heralded as opening a new era in tuberculosis chemotherapy. By 1970 established the pair of drug

became as the best multi drug regimen for tuberculosis. The addition of Pyrazinamide to Isoniazid (INH) and Rifampicin made a short-term (4-6 month) regimen a successful option for tuberculosis treatment (Lee, 1988).

Millions of patients have been treated for tuberculosis and cured. Since then, the disease virtually disappeared from the many countries in America and Europe. But it never disappeared from Africa and Asia. A few years ago, tuberculosis re-emerged in many developed countries. There is a big question, if tuberculosis can be cured, why is it still such a huge problem? Why didn't it decline in developing countries and why has it reappeared in the west?

2.4 Global Tuberculosis Situation During 1990 - 2000

In 1993 the World Health Organization (WHO) declared tuberculosis a global emergency, and it was the first time that international community regarded the disease as a global health emergency. Every year, 7 to 8 million people develop tuberculosis. Estimation of the annual number of deaths from the disease ranges between 2 to 3 million. Tuberculosis kills more adults than any other single infectious disease. Forecasts of tuberculosis morbidity and mortality are presented for the decade 1990 - 2000. An estimated 88 million new case of tuberculosis of which 8 million will be attributable to HIV infection, will occur in the world during the decade, 30 million people are predicted to die in the same period including 2.9 million attributable to HIV infection. Tuberculosis poses a major threat to the health of people living in South East Asia. At least 1 in 3 people in this part of the world are infected with tuberculosis. It's the most important cause of death in the economically active population (WHO, 2003).

2. 5 The Tuberculosis Trend and Present Situation in Thailand

Thailand started tuberculosis control services since 1949 as a major public health problem. The mortality rate declined from 63.8 per 100,000 in 1950 to 8.2 per 100,000 in 1988. In 1997, tuberculosis was among the top ten leading causes of death, which accounts for 22 % of total deaths.

The first National Epidemiological Tuberculosis prevalence survey was conducted with WHO and UNICEF assistance to determine the magnitude of tuberculosis problem in 1960 - 1964. The tuberculosis morbidity rate was found to be 2.1 % as radiological prevalence and 0.5 % as bacteriological confirmed prevalence. In 1977, the second National Tuberculosis Prevalence survey noted a remarkable decline and reversal of tuberculosis morbidity rates and pattern in urban area and Bangkok. The third National Tuberculosis Prevalence survey released a similar picture with the second national survey that is the pattern of more prominent morbidity in urban areas and Bangkok, which was assumed to be due to the advent of rapid urbanization. There was a decline in the prevalence of tuberculosis infection in all age groups from 49.8 % in 1962 to 40.6 % in 1977 and 29.4% in 1991. In children age 0 - 14 years the decline from 12.7 % and 15.2% in 1962 and 1977 to 8.9 % and 4.7 % in 1983, and 1991 respectively was noted (MoPH, 1999).

According to the 2002 WHO external review report on Thailand national TB control program, Thailand reported 137 all forms of TB patients among 100,000 population in 2002. This means that 86,000 all forms of TB patients and 38,000 smear positive TB cases are estimated to occur per year. The number of 13,000 death of TB was reported 13,000 in 2002 as well. These statistics put Thailand as one of those 22 TB high burden countries in the world (WHO, 2003).

The situation in Bangkok is far worse than other areas of Thailand. For instance, in 2002, the estimated number of all forms of TB patients per 100,000 population in Bangkok is 189. It can, therefore, be estimated that Bangkok has 15,000 all forms of TB cases and 7,000 sputum smear positive cases (WHO, 2003).

Even though DOTS has already covered the entire country in Thailand, the quality of the program performance is very problematic. For instance, the mortality rates have increased because of the co-existing HIV/AIDS. Treatment success rate and default rate were reported 77 % and 8.9 %, respectively in 2002. With the comparison of global target, all these figures were very worse (WHO, 2003).

2.6 Functional Structure of National Tuberculosis Control Program

The Ministry of Public Health is responsible for the organization, management and administration of public health services and most of the medical services of the government especially in the rural areas. The ministry is organized in seven main components and two institutions.

- i. The Office of the Permanent Secretary for Public Health.
- ii. The Department of Medical Services
- iii. The Department of General Health
- iv. The Department of Preventive medicine
- v. The Food and Drug Administration
- vi. The Department of Communicable Disease Control
- vii. The Department of Mental Health
 - Government Pharmaceutical Organization and
 - Health System Research Institute.

All departments provide technical support to the provincial health office in their respective fields. **Tuberculosis Division** is under the Department of Communicable Disease Control, and there are **13 Zonal Tuberculosis Centres** are under the Regional Offices for Communicable Disease Control (MoPH, 1999).

District TB coordinator (DTCs) is posted at the district health offices. The DTCs will be in regular contact with the **health centers**, check the patients' treatment cards and help the health centre staff with any problems they face. Sputum smear examination is the main diagnostic tool for tuberculosis patients. **Diagnostic services** are provided in *Zonal TB centre, Provincial Hospital and District Hospital*. After diagnosis the tuberculosis patients are referred to health centre nearby patients' house for treatment (Sawert, 1999).

2.7 Factors Related to Treatment Compliance and Outcome Among TB Patients

Once infected with *M. tuberculosis*, a person stays infected for many years, and often for his/her whole life. The vast majority (90 percent) of people infected with *M. tuberculosis* do not develop the disease of tuberculosis. Active disease occurs in an average of 10 percent of those who are infected. Various physical or emotional stresses trigger progression from infection to disease. Any weakening of the immune system—for example, by malnutrition or HIV infection—increases the chances for disease to develop. Left untreated, a person with active TB will infect on average 10 to 15 persons a year. The most effective approach to TB control is the identification and cure of these infectious cases.

Proper treatment of infectious cases makes them very quickly non-infectious so that they can no longer spread TB to others. Because effective treatment breaks the cycle of transmission, cure is the best prevention. This is even more important because of the emergence of drug-resistant TB. Drug-resistant TB is a human-made phenomenon caused by inconsistent or partial treatment. This happens when doctors or health workers prescribe the wrong drugs or the wrong combination of drugs, the drug supply is unreliable, or patients do not take all their medicines regularly for the required period of time. Once the bacilli become resistant to one or more anti-TB drugs, the infected person can go on to infect others with the same drug-resistant strain. Multi-drug-resistant TB is more difficult and more expensive to treat, and more likely to be fatal.

There are various factors affecting patient compliance and outcome of treatment in Directly Observed Treatment Short Course (DOTS). They are health service related factors like types of DOT observer, treatment regimen, DOT duration, health education and convenience of travel, and demographic, socioeconomic, behavior, disease condition of patients and so on.

2. 7.1 Health service related factors

A study conducted by Uplekar in 1996 suggested that patients drop out of the programme at public facilities because of various health service related factors such as the widespread lack of confidence in the services provided, shortages of drugs and supplies, absence of staff and poor infrastructural facilities. Patients may also refuse treatment because of the inconvenience of frequently reporting to clinics with inconvenient opening hours situated far from their homes (Uplekar, 1996).

2. 7.1.1 DOT observer (DOT provider)

In ensuring the completion (compliance) of treatment, DOT observer plays a crucial role, and because of the complex of our environment and setting, in different countries and different settings, TB control programs are mobilizing different types of DOT observers such as community volunteers and family members as well as health workers.

However, there is a lot of argument on sustainability and effectiveness of different type of DOT observers between researchers. Some studies have been already conducted in different settings and region and there has been not yet a concrete and consistent agreement on those issues between different researchers.

The bellows are the summary of main findings of those studies done in Thailand and other countries.

Impact of different DOT observer on compliance and outcome of treatment

Pungrassami P. et al also in their study article titled "Are health personnel the best choice for directly observed treatment in southern Thailand? found that there were no significant differences in treatment success between different types of main observers. Result showed that the treatment success rates were 87.1%, 89.7% and 85.3% of health personnel, community member and family member, respectively and the overall treatment success rate in the study area was 85%.

From this result we could conclude that in the complex society, family member and community member can play the same role with the role of health personnel (Pungrassami, 2002).

Dr. Kamolratankul P. et al in the article titled as a “Randomized controlled trial of directly observed treatment (DOT) for patients with pulmonary tuberculosis in Thailand” found that no significant differences in outcomes could be observed between patient groups receiving DOT under the various options for treatment supervisors. The cure and success rates are 79% and 80% in health personnel group, 74% and 79% in community volunteer group and 77% and 84% in family member group, respectively.(Overall cure and success rates are 77% and 84%, respectively). Based on the above findings, they concluded that DOT appears especially suited for treatment at decentralized facilities, and while a general focus on program performance can improve outcomes, DOT provides significant additional benefits, and if basic conditions are met, a DOT strategy can be tailored to country-specific conditions by exploring multiple observation options, without decreasing its effectiveness (Kamolratanakul, 1999).

Mr. Mathema B, et al in their study “Tuberculosis treatment in Nepal: a rapid assessment of government centers using different types of patient supervision” found that at the government facilities in Nepal, the group under directly observed therapy (DOT) at the treatment center achieved WHO global target for cure (91%, 95% CI 80.3-97.2) and group under flexible DOT supervisors including community or family members showed better outcomes

(57%, 95%CI 48.8-64.0) than unsupervised therapy (34%, 95%CI 25.1-40.4) but did not achieve cure targets. (Mathema et al, 2001 Oct).

Initial assigned observer and. practical observer

Pungrassami P. et al in their cohort prospective study (411 patients with new smear-positive pulmonary TB followed up during 1999-2000 and the data analyzed by Cox and logistic regression models) found that of 379 patients assigned to an observers, 212(56%) changed their initially assigned observer during the treatment period, and 130 did so on the day of assignment. Of 177 patients assigned to health personnel, 84 changed on the day of assignment (Pungrassami et al, 2002).

Pungrassami P. et al also in their study article titled "Are health personnel the best choice for directly observed treatment in southern Thailand? A comparison of treatment outcomes among different types of observers" found that the health personnel (HP), community member (CM), and family member (FM) were initially assigned to be DOT observers in 177, 21, and 181 of the 411 analyzed patients, respectively. Of the 379 patients assigned an observer, 212 (56%) changed the observer during the treatment period, 130 of them on the day of the assignment. Among the 177 patients assigned to HP, 153 changed observer, 84 on the day of the assignment, and only 17% actually had HP as their main observer. The corresponding proportions for those assigned to CM, FM, and SA were 57%, 75%, and 34%, respectively and they concluded that health personnel may not be the best choice in the setting due to poor

sustainability and the availability of another promising choice (Pungrassami et al, 2002).

No practice of actual DOT

Pungrassami P. et al in their cohort prospective study found that during the first 5 months of treatment, the proportions of patients who practiced no actual DOT were between 7%-15% among HP, 20%-26% among CM, and 32%-38% among FM observers. The adjusted OR of no practice over practice of actual DOT was similar between CM and FM, but was only about 1/8 among HP over FM. The OR in non-FM (CM+HP) compared with FM was 0.3 (95%CI 0.2-0.5). The researchers also found that the odds of no practice of actual DOT were higher among patients who had no formal education, who had a higher income, who were treated at a general or regional hospital, or who had no other co-morbidity (Pungrassami et al, 2002).

Dr. Pethawan, P. said in her article titled "Has directly observed treatment improved outcomes for patients with tuberculosis in southern Thailand, that actual practice of DOT was quite different from what was intended at the assignment. The result showed that among 379 assigned to DOT, only 68 practised strict DOT for every dose during the 1st 2 months (Petchawn, 2002).

Change to no observer

Pungrassami P. et al in their cohort prospective study found that during the first 5 months of treatment, between 10%-16% of patients with HP observers changed to self administration, compared to 0%-3% with CM and 0.5%-4% with

FM observers. The risk of change to self administration was four-fold higher among HP over FM, but was only about a half among CM compared with FM. The relative risk for change in the non-FM compared with the FM group was 2.6 (95%CI 1.5-4.5) (Pungrassami, 2002).

They also found that change to self administration was about two-fold more likely among patients who had no living partner than those with a living partner, and about 2.6-fold more likely among patients who lived in more than one place than those who lived in only one place during treatment (Pungrassami, 2002).

2. 7.1. 2 DOTS and Non-DOTS

Directly Observed Treatment is necessary to ensure that people take TB medicines correctly. Unsupervised treatment commonly results in mistakes in taking medicines. Various studies have demonstrated that about 30% of people do not take medicines as prescribed. Common mistakes include missing doses of medicines, selective avoidance of some medicines and dividing doses inappropriately (Narain, 2002).

The basic principle of DOT is therefore to assist patients to help them adhere to their treatment. Without DOT, the cure rate in TB patients is usually less than 60% and often much lower. With DOT, it is possible to achieve cure rates in excess of 90% (Narain, 2002).

The research of Dr. Pethawan, P. et al showed that practice of strict DOT during the first 2 months was not associated with sputum conversion or treatment success in the study area, because the result of study showed that adjusted odds

ratios (Odds Ratios) for no sputum conversion' and 'unsuccessful treatment' were 1.1(95%CI 0.6-2.1) and 1.3(95% CI 0.6-2.8), respectively, for those who practiced strict DOT vs. the rest (Petchawn, 2002).

Dr. Akkslip S. et al concluded in his research article titled " Direct observation of tuberculosis treatment by supervised family members in Yasothon Province, Thailand, that supervised family members may contribute to more widespread effective implementation of the revised tuberculosis strategy in Thailand. The result of the study showed that the cure rates of new smear – positive patients were 85.2% (95% CI, 80.5-89.9) with DOT versus 70.9% (95% CI 62.4-79.4) with self-administration (Akkslip, 1999).

Dr. Merrick Z. et al showed that in his research, at high rates of treatment interruption, self supervision achieved equivalent outcomes to clinic DO at lower cost. Self-supervision achieved better outcomes for re-treatment patients. Because the findings of the study was that treatment for tuberculosis was more successful among self-supervised patients (60% of patients) than among those on DO (54% of patients). Re-treatment patients had significantly more successful treatment outcomes if self-supervised (74% of patients) than on DO (42% of patients) (Merrick, 1998).

Dr. Kamolratankul P. et al conducted a controlled trial of DOT at 15 health care facilities at various levels of the government health care system in Thailand, with a sample of total of 836 patients diagnosed between August 1996 and October 1997, who were randomly assigned to be treated either under DOT or self-supervised using monthly drug supplies (SS), in order to assess the feasibility and efficiency of DOT, found that cure and

treatment-completion rates were significantly higher in the DOT cohort (76% and 84%) than in the SS group (67% and 76%) and the benefits of DOT were more pronounced at district and provincial hospitals (DOT cure rate 81 % vs. 69% in the SS group), while differences for patients treated at referral centers were non-significant (DOT cure rate 72% vs. 66% in the SS group) (Kamolratanakul, 1999).

A study conducted in Nepal was also found that the compliance rate had been found much higher among those who had been observed during the having medicines at DOTS centre compared to who were not and there was significant relationship between availability of DOT and compliance with DOTS (Tara, 2003).

The result was quite similar with the WHO Report-2002 (WHO, 2003). The report showed that treatment success rate is high with DOTS strategy of those countries who have implemented DOTS. Directly Observed Treatment (DOT) is one component of DOTS, and refers to the specific action of observing treatment. DOT is necessary to ensure that people take medicines correctly. Unsupervised treatment commonly results in mistakes in taking medicines. Common mistakes include missing doses of medicines, selective avoidance of some medicines, and dividing doses inappropriately. DOT, by a person who is accountable to the health services, and accessible and acceptable to the patient, is a means for supporting patients, and enabling them to achieve the highest possible chance of compliance. In this study patients who did not get DOT might be collected the medicines by their family and relatives from the DOTS centre or they just received the drugs from the DOTS centre and took at their convenience.

2.7.1.3 Relationship between DOT observer and TB patients (Communication skill and kindness)

Many health personnel believe that health education of the sick and of the public is all that is needed to ensure that patients comply with medical instruction. However, experience has shown that such efforts, or even detailed instruction by a doctor, are generally not sufficient to motivate patients to take the prescribed regimen.

There is a far more to motivation than informing and instructing people : It is a matter of mutual human relation, requiring an understanding of the patient's non-medical problems, his way of life, work, religion, wants, fears and attitudes towards traditional and modern medicine. Motivations require a person who speaks the patient's language and is capable of bridging intellectual and social distance, removing cultural barriers and if necessary changing attitudes and habits. Positive motivating factors are efficient professional performance and success, good working morale, the compassion of the staff and their identification with the community they serve highlighted by Toman K in 1979 (Toman, 1979).

Motivation is a problem of human communication, differing from one patient to another and one community to another. That is why no uniform and generally applicable recipe can be given. Failure to communicate with the patients will embarrass him; a patronizing approach or bad behavior will alienate him and instead of confidence will create distrust, resulting in the rejection of treatment.

The problem of treatment default due to the lack of communication is by no means restricted to developing countries. In technically advanced countries also, as has been reported, treatment default is not uncommon. It is a problem frequently encountered in communities with minority groups of various ethnic, religious and

social background, where in addition to tuberculosis, patients are suffering from economic insecurity and other social stresses pointed out by Toman K in 1979 (Toman, 1979).

After decades of war, the tuberculosis situation in Angola is alarming. The author describes his experiences with the implementation of a DOTS TB programme adapted to the difficult circumstances in a town partly inhabited by displaced people. The high motivation of both patients and health care workers is an important factor for its successful implementation. The need for international support of tuberculosis control programmes also in war-ridden countries is stressed and suggested by Doveren RFC in 2001 (Doveren, 2001).

Patient compliance depends upon mutual understanding and trust between the health service and provider and patients. Other aspects of service provider and patients communication are also important. The service provider should explore and attempt to fulfill the patients' expectations for treatment. The accurate gauging of patients' compliance required attempt at reduction of social distance between service provider and patients and a bridging of barrier that are due to difference in education, social class, occupation status and ethnic identification highlighted by Francis V in 1969, According to researchers, service provider should clarify what is expected of each patient in order that the task of collecting information can be properly performed (Francis, 1969).

A study in Colombia reported by WHO in TB notes 2002 found that providers had created an unfriendly clinic environment by stigmatizing patients and then blamed the patients for failing to complete treatment. In Israel, Ethiopian immigrants experienced condescension and paternalism from physicians, which exacerbated

patients' hesitance to seek or remain in care. Studies have demonstrated a cultural gap between patients and providers and strikingly different perceptions of barriers to adherence and of the information exchanged (WHO, 2002)

The quality of communication between provider and client and degree of rapport established during provider-client interaction have been found to influence both client satisfaction and compliance. Robbin DM in 1982 mentioned that prescribing and complying are complex and outcomes of the patient provider interactions are influenced by the nature and quality of the interaction (Robbin, 1982).

A study result pointed out by Tekle B in 2002, the majority ignored the advice even when it was presented as crucial to their health. One of the most frequent complaints about physicians is that they do a poor job of communicating with their patients. As the trend in medicine moves away from primary care and toward specialization, the trusting relationship between patient and professional deteriorates. The number of visits to physician has increased but the visits tend to be shorter and more symptoms oriented. Compliance may frequently be the result of the relationship between service provider and patients (Prapasi, 1985).

A study conducted in Taiwan by Lee RP, Chiou YF indicated that client-provider relationship were better than those of the non-compliance behavior ones (Lee, 1997).

2. 7. 2 Demographic factor

2.7.2.1 Age

Most productive age group (15 to 49) has been infected with this disease in the world. For instance, in Thailand , nearly 65.6% of TB cases occur in 15-55 age

group in 2002. It is also stated that the national cure rate is 71% and default rate is 9%, respectively (WHO, 2004).

Age and treatment compliance is closely associated. But a study was conducted in Thailand by Kandel SL. regarding the compliance of tuberculosis patients with treatment in 2000 showed that the treatment success was not significant different among the various age groups (p-value = 0.442) (Kandel SL. Compliance of tuberculosis patients with treatment in Bangkok chest clinic, Thailand [M.P.H.M Thesis in Primary Health Management]. Nakhon Fathom: Faculty of Graduate Studies, Mahidol University; 2000.). It also indicates that age of respondents has no impact on compliance with treatment. A study conducted by Suhadev M. indicated that the default rates are higher in the older (45+) age group (Suhadev, 1995).

A study conducted in Nepal showed that There was a 2 fold increase in patient non-compliance with DOTS in older age groups (p=0.044) and the younger age group had more compliance rate than the older age group and there was a significant relationship between age and patient compliance with DOTS.

The study showed that more than one quarter (27.1%) had the high level of knowledge among the younger age (15-34 yrs). The proportion was more than double compare to the older age (>54 yrs.) and this is one of the explanations for the higher compliance rate among the younger age group compared to the older age group. The another explanation for high compliance among younger age group is that the younger age (15-34 yrs.) had high level of social support from their family and friends. For example, majority (89.2%) of respondents of the group had

the high level of family support and more than two thirds (71.6%) had the high level support from their friends (Tara, 2003).

A study conducted in India by Morankar S. showed that TB patients who are older than 40 years, and who have completed their family responsibilities and roles (marriage and departure of children), feel lonely and have often no will to live and to be cured (Morankar, 2000).

2.7.2.2 Gender

TB is a leading killer disease among women (WHO, 2002.).

Especially in developing countries, health seeking behavior is poor in women due to the various religious, community, and health related elements. More male patients are diagnosed and treated. For example, in Nepal, the ration is 2:1 male and female (Ministry of Health, 2001). But among registered TB cases in 2000, the cure rate among female was above 85% where as cure rate was among male less than 80% (Ministry of Health, 2001). A study conducted by OBoyles S.J. showed that there was no statistically significant difference between the groups for sex differences (Boyles, 2002).

Similar type of study was done in Vietnam in 2000 by Nguyen DH also showed that there were no significant differences between the sexes (Nguyen, 2000). A study conducted by Suhadev M. indicated that men default more than women (Suhadev, 1995).

A study in Nepal showed that 65% of respondents accounted male and the incidence of TB among women is less than man. This is due to that males have more chance of exposing to TB during their working period and seeking the work

in different places. But the Proportion of compliance was higher in female compared to male and it was explained that more than half of the female respondents had high level of susceptibility (55%) and severity (60%) toward the disease and its impact. However there was no significant difference between sex and compliance with DOTS (Tara, 2003).

Physical recovery from TB is affected by female patients' psychological problems such as feeling of insecurity, fear of isolation, fear of spreading disease to children etc. and the lack of support at family and community level. A study conducted by Morankar S. in 2000 showed 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 (Morankar, 2000).

2.7.3 Socioeconomic factors

2.7.3.1 Marital status

Patients either married or unmarried or even in divorced, no body wants to be labeled as TB patient due to the social stigma in developing countries. Most of people try to hide their disease. If single young male or female gets TB disease, it is difficult to get married due to the ignorance of societies and highly stigma. If married female get the disease, she tries to hide her disease because she is afraid to get divorce from her husband. In Thailand also, the highly stigmatized societies still exist both in rural and urban. Marital status affects the patient compliance using DOTS. But the study conducted in Southern Viet Nam by Nguyen DH, showed there was no significant in compliance among different types of marital status (Nguyen, 2000).

A study conducted in India, 2000 by Morankar S, showed that married women are worried about their husband's sexual behavior during the period of their treatment and the risk of his marrying another woman due to the highly social stigma. This worry and tension compel them to complete the treatment as soon as possible. The researcher also describes that about 18% of married women stopped their treatment after disappeared the symptoms of TB using two to 5 months treatment (Morankar, 2000).

A study report carried out by Liefoghe R in 1997 indicated that single patients had half the defaulter rate (6.1%) than married patients (12.6%), while those widowed, separated or divorced had the highest rate(14.3%) (Liefoghe, 2001).

A study carried out in Taiwan in 1997 by Lee RP and Chiou YF, showed that the percentage of non-compliance behavior among widowed patients was significantly higher than single or married ones (Lee, 1997).

A study report carried out in Nepal showed that there was a statistically significant ($p=0.043$) variation in non-compliance between singles (17.5%), married (27.8%) and others (widowed and divorced) (50%), which was the similar results in some previous study and it was excused that most of the single patients had high and moderate level of knowledge compared to married and others group (Tara, 2003).

2.7.3.2 Occupation

TB is a disease of poor. Most of the TB patients belong to poor especially in developing countries. They have to work for their every day life. Therefore patients are engaged in different kinds of occupations. In developing countries

most of the TB patients are closely associated with farming and laboring. So it is claimed that occupation affects the TB patients to take daily dose medicines using DOTS. But a study conducted in Thailand in 2000 by Kandel SL, showed that there was no significant difference in compliance among different types of occupations (Kandel, 2000). Whereas a study OBoyles showed that there was statistically significant in compliance among different levels of occupations (Boyles, 2002).

Non compliance patients were more likely to be white collar workers (p-value <0.01) and students (p-value <0.01) whereas compliance patients were more likely to be not working (p-value <0.01) (Boyles, 2002).

In a study report conducted by WHO, the reasons for inability to adhere to treatment have been reported to be different for men and women - while men dropped out due to pressures to return to wage work or due to alcohol and drug addiction, women dropped out because of the pressures of housework and the strain of keeping their condition secret (WHO, 2000).

In a study conducted in Nepal, the result found that the treatment success rate was significantly high among the housewife and those who were in government services than those who were in private services. The compliance rate was almost similar among the farmer, labor and others (students and businessman). It could be explained that the housewife might have adequate time, can receive the DOTS services without losing any job. The government servants can manage their time to receive the DOTS services within the working time without loss payment. While labor might have difficulty in this regards. Either they might be loss their daily earnings or loose the job as well. But the study showed that there was no statistically significance between occupation and treatment success (Tara, 2003), which is

consistent with the results of the study conducted by Kandel Shyam Lal and opposite with the result of study by Oboyles S.J.

2.7.3.3 Social support

A study conducted by Jagota P in 1996 revealed that having contracted TB, 15 per cent of female patients - rural and urban — faced rejection by their families, 11 per cent of school going children of women TB patients discontinued studies and an additional 8 per cent took up employment to support the family. This type of social pressure makes the patients discontinuity to treatment (Jagota et al, 1996). Green D. in 2001 pointed out that due to low family and community support in terms of emotional and informational, the efficacy of DOTS regimen is only tenable. Approximately 20% of smear positive TB patients fail to take recommended course of treatment and the cure rate was only 57% which was very disappointing. He also indicated that patients receive little support from health professionals in coming to terms with their diagnosis of TB, and in completing full course of therapy. It has been suggested that improving treatment outcomes will involve improving support for patients (Green, 2001).

A study was conducted by Port Elizabeth Municipality in 2001 in order to find out the effectiveness of the intervention which is community based support for TB patients and patients focused services of health workers in large urban primary health clinic of Zwide, Port Elizabeth Municipality of South Africa and the study report showed that after implementation of that intervention, the sputum conversion rate increased from 67% to 84%. This means that the patients' treatment outcome,

after getting the support from the community and health personnel, had been improved significantly (Port, 2001).

In Cape Town, South Africa, The Compliance Service is a new, unique service taking proactive steps to help people self-manage their chronic conditions and enhancing adherence to treatment by providing them with timely email and reminders to take their medication as prescribed. The report showed that after the intervention, patient adherence to treatment was improved from 57% to 77%. So the health workers support to TB patients play the vital role to take the daily dose medicines as prescribed which was reported by Green D in 2002 (Green, 2002).

In Zambia, two community-based programmes, coordinated by the Family Health Trust and the Ndola Catholic Diocese, in 2000 are providing needed home based care for people with HFV/AIDS and people with TB. In both programmes, the community is harnessed as a health care partner. Teams of mobile community nurses provide direct patient care and support community health workers. Nurses and community volunteers perform a wide range of tasks, including direct patient care, self-management support, and support to family caregivers. The integration of HIV/AIDS and TB home based care appears to be a success factor for the programmes. High TB cure rates are possible through community-based DOTS, and the detection of HIV is facilitated in TB patients, and vice versa (Nsutebu, 2000).

Ethiopia is exploring ways to improve TB treatment adherence and outcomes, in a context where access to health facilities is limited and TB is often highly stigmatized. One innovative approach, in the remote rural district of Estie, is the establishment of TB clubs among the TB patients. Each club members meet to each other weekly where members can support each other and share problems.

Anyone who is failing to make good progress or who is experiencing drug side effects is referred to the local health facility by the club leader. The TB clubs have also identified people in the community with suspected TB, encouraged them to seek diagnosis and treatment, and helped to promote adherence to treatment and to trace defaulters. What have the TB clubs achieved? During the first six months of 1997, the clubs referred 181 people with suspected tuberculosis for investigation, of whom two-thirds were diagnosed as TB cases. TB clubs have helped to increase community awareness of the symptoms of TB and the need for treatment, Attendance at TB clinics has also improved significantly and treatment success rates are higher than in other parts of the country that was indicated in the study report of Getahun H in 2000 (Getahun, 2000).

Physical recovery from TB is affected by female patients' psychological problems such as feeling of insecurity, fear of isolation, fear of spreading disease to children etc. and the lack of support at family and community level. A study conducted by Morankar S. in 2000 showed 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 (Morankar, 2000). The study also pointed out that the female TB patients face problems in having access to TB services, particularly if services are not available close by. TB creates often problems related to the economic and family situation. On the other hand even if services are available at their doorstep the risk of social stigma plays a hindering role in access. Therefore it is also the community's responsibility to reduce inequalities in TB care within the social, cultural and economic context in which they occur (Morankar, 2000).

A study carried out by Lee RP and Chiou YF. in 1997 indicated that the financial support of the family became important in the continuation phase and patients who had no financial support had thrice the risk for 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 (Liefoghe, 2001).

A study was carried out in Ethiopia by Tekle B in 2002 regarding the defaulting from DOTS and its determinants. The study report showed that Major factors contributing to high default rates were found to be lack of family support, inadequate knowledge about treatment duration and medication side effects. Control programmes that take these factors into consideration should be successful in reducing defaulting (Tekle, 2002).

A study done in Nepal found that the family support (Score 10.97 v 10.53 $p=0.02$) and support from friends (Score 10.17 v 9.37 $p=0.016$) was significantly higher in compliant than in non-compliant groups (Tara, 2003).

2. 7. 3. 4 Residence-migrant (local or non-local)

Migrants are particularly vulnerable to a wide range of communicable infections such as tuberculosis and HIV. They often encounter considerable difficulties in accessing health care and adhering to prescribed treatment regimens. TB control programmes thus face the problems of providing accessible care for migrants with TB and ensuring that patients with TB, who migrant, can complete the treatment. Many migrant group exist: permanent, temporary and seasonal; voluntary, forced and trafficked; legal and illegal; and internal and international. Migration is

predominantly due to economic reasons, or to seek refuge. TB is likely to spread, especially among migrants (Narain, 2002.).

There are some studies conducted in different setting and they showed that there were no significant difference between the local and non local patients in their treatment outcome (Tara, 2003 ; Boyles, 2002).

2.7.4 Behavior factors of patients

2.7.4.1 Alcohol and drug abuse

In the study report conducted by WHO, the reasons for inability to adhere to treatment have been reported to be different for men and women - while men dropped out due to pressures to return to wage work or due to alcohol and drug addiction, women dropped out because of the pressures of housework and the strain of keeping their condition secret (WHO, 2000).

2.7.4.2 Compliance with treatment

Among the different factors that lead to completion of full course of treatment and cures of the disease, compliance of patient with treatment is an important factor which can be defined as " cooperation with the recommendation of the health care personnel" or the consistency of patients' behavior with a program of treatment as prescribed by a medical authority pointed out by Counte MA (Counte, 1981).

Getting a patient to cooperate with a prescribed ongoing treatment programme is a significant problem for the clinician. The patient may refuse to adhere to therapeutic instruction by not taking the prescribed medication or by not

participating in recommended activity. The long-term effect of such non-compliance is, of course, the inability to maintain whatever good result. Counte and Christman considered theoretical approaches that explain patient's non compliance, patient's attitude towards medical treatment, facilities, the quality of instruction between health care professional and patients which directly affects patient's satisfaction and compliance reported by Salloway JC in 1978 (Salloway, 1978).

2.8 Conclusion

According to the literature review, TB is one of the serious public health issues in Thailand. Under such a situation, DOTS strategy has been fully implemented in entire country. In order to ensure the quality of DOTS program, different types of DOT observers have been mobilized in TB control program. However overall figure of program performance are still not meet the global targets and situation in Big urban areas, particularly Bangkok is far worse than any other area of the country in terms of treatment success and default rates.

To improve the program performance of the urban area is essential to improve the overall program performance of the country and many factors such as a DOT observer- related factors, socioeconomic, demographic, behavioral characters, and disease conditions of TB patients, and health service related factors are closely linked with the program performance and a lot of previous studies had proved those associations.

However the studies about the effect of different types of DOT observers on treatment outcome had shown the different results, and there was no consolidated agreement about effectiveness of different types of DOT observers.

Most importantly, no study has been done in Bangkok for the effect of DOT observers on treatment outcome, and even some factors such as DOT duration, regimen and utilization of combination form of drugs, and physical or disease condition of patients such as initial AFB status, sputum conversion status at the end of intensive phase treatment, side effect of drugs, co-morbidity and severity of disease had never been investigated in the previous studies. Therefore, this study would like to investigate the association between DOT observer and, treatment success and default along with other factors including DOT duration, regimen (intermittent or daily regimen), kind of drug formulation and so on in Bangkok, Thailand.