CHAPTER III

RESEARCH METHODOLOGY

3.1 Research Design

This study design was a quantitative and retrospective analytical study, data was collected from TB registers and TB treatment cards through a checklist, covering socio-demographic characteristic, disease condition and behavior of tuberculosis patients, and health service related factors.

3.2 Study Population

The study population was all tuberculosis patients who were registered and were treated at the Bangkok Chest clinic of TB cluster under Ministry of Public Health, and health Center 7, 16, and 23 under Bangkok Metropolitan Administration (BMA), in Bangkok, Thailand, during the period of October, 2002 to September, 2004.

3.3 Sample Size

Required sample size was calculated by using Epi-infor 2000 software for cohort/cross sectional study.

The cure rate of health personnel supervising DOT group and family member supervising DOT group were taken as 85 % and 70 %, respectively (Mathema, 2001). Ratio of patients supervised by health worker and by family member is 1:1. The confidence level is 95%. This means that probability of making type 1 error is 5%. The power of the study was set at 80%. This means that probability of making type II error is 20%, and there was 20% chance that a difference would not be detected if there really is a difference. So sample size

was 133 : 133 = 266. (In case of the self administration group was 133 subjects, then the total sample size was 400).

The purposive and simple random sampling method (Multistage sampling method) was applied to get the required number of subject.

3.4 Study Site

Bangkok, Capital of Thailand was selected for this study area. There are one Chest clinic under TB cluster of ministry of public health and 65 public health centers under Bangkok Metropolitan Administration (BMA). All of them are involving in national TB control Program.

Chest clinic of TB cluster under Ministry of Public Health (MoPH) is treating TB patients who are being supervised by the family member, and self-administration TB patients. The chest clinic is the only place for family member supervised DOT group and self-administration group in Bangkok. Chest clinic, therefore, is purposively selected as a study site.

The 65 health centers under Bangkok Metropolitan Administration (BMA), which are all treating TB patients who are only being supervised by the health personnel, are divided into 6 regional TB networks. Among those 6 regions, region one was purposively selected with the consideration of geographic proximity to MoPH chest clinic and convenience. The reason for this selection was that in order to investigate the effectiveness of different types of DOT observers on treatment outcome, there should be a similarity between health centers under BMA and chest clinic of MoPH. In the region one, there are 13 health centers. Among those 13 public health centers, health center, 7,16, and 23 are responsible for TB control program in the catchment area of Region one.

All the Health centers 7, 16 and 23 constitute all of the higher-level centers, administratively.

All the TB patients registered and treated at these selected health facilities during October 2002 to September 2004, were selected as a study population. However among those TB patients, the sputum smear negative, extra pulmonary, and re-treatment (Relapse, failure and return after default) positive TB patients were excluded from the study subjects.

In a word, the sampling technique applied was the multistage sampling design. Please refer to the figure 2 on sampling process in below.

Inclusion criteria: All new smear positive pulmonary TB patients registered in the 4 selected health centers during the period of Oct. 2002 to Sept. 2004 were included in the study.

***Exclusion criteria*:** All the sputum smear negative, extra pulmonary, and re-treatment (Relapse, failure and return after default) positive TB patients registered in the 6 selected places, during the period of Oct. 2002 to Sept. 2004, were excluded in the study.

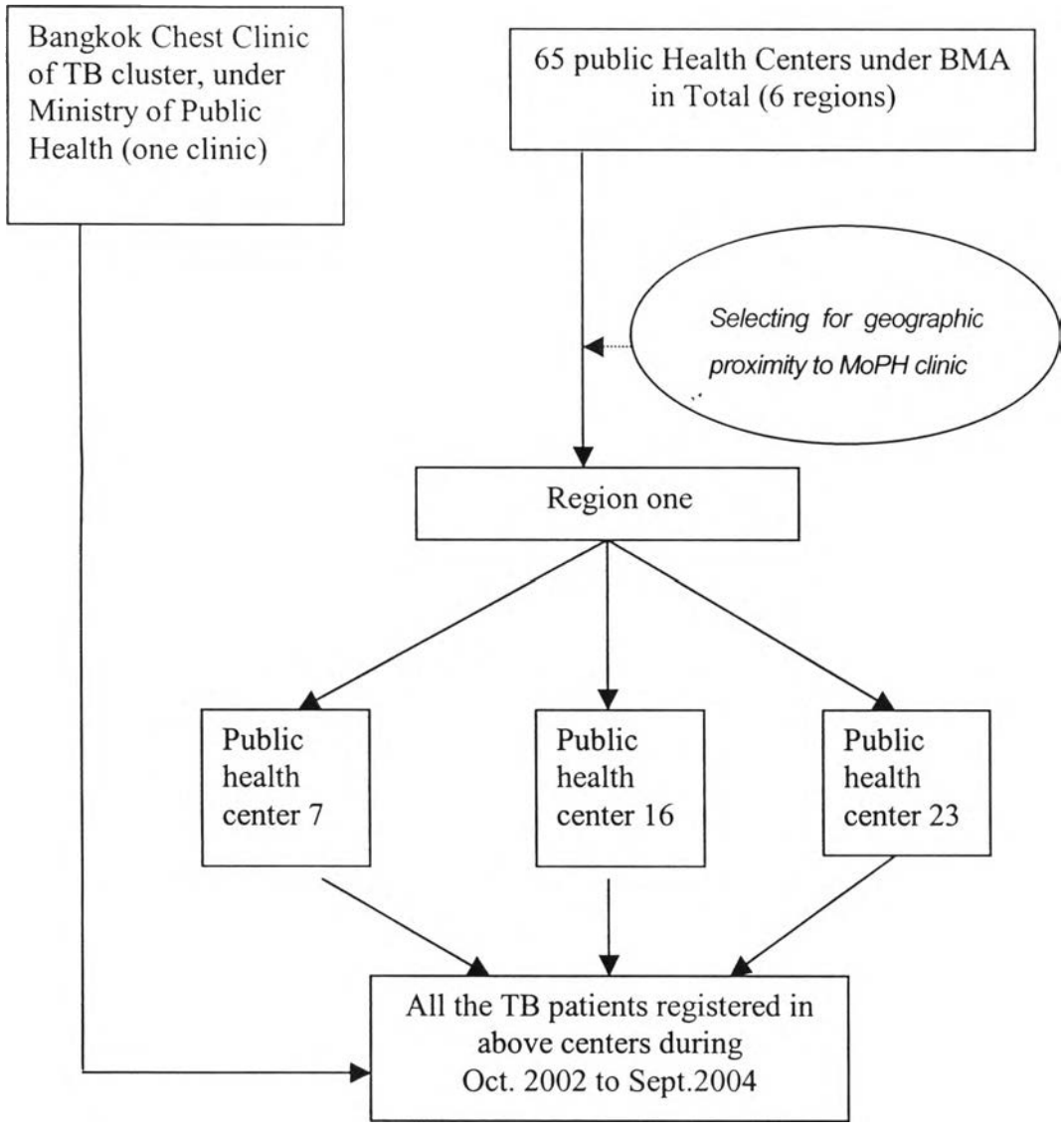

Figure 2: Sampling process

The detailed information of the places for data collection are as follows

For family member supervising DOT group and self administration group

- Chest clinic under TB cluster of Ministry of Public Health

For health personnel supervising DOT group

- Center 7, Boonmee Pururacharangsun, 663 Satupradit Road, Bangpongpang Subdistrict, Yannawa District, Bangkok 10120.

- Center 16, Mongkol-Wornwangtal, 862/2 Yeuangwatpaingern, Jantr Road, Bangklo Subdistrict, Bangkolaem District, Bangkok 10120
- Center 23, Sripraya, 383/3 Sripraya Road, across from Wat Gaewjaemfa, Sripraya Subdistrict, Bangrak District

3. 5 Research Instrument

The standard checklist (WHO standard) was prepared in English and translated into Thai language and it was used as a tool for the data collection.

The content of the checklist consists of 5 parts as follows:

DOT observer related information: this part contains the information related to DOT or non- DOT (self-administration), and types of DOT observer such as a family member and health worker

Socio-demographic characteristics of TB patients: the questions in this part are related to the age, gender, marital status, and occupation. All this information will be obtained from the TB treatment card, TB register book and laboratory register books.

Behavior factor of TB patients: the questions in this part are related to alcohol and smoking, and the treatment compliance behavior. All this information will be obtained from the TB treatment cards, TB register and laboratory register books.

***Health service related information*:** This part includes the questions related to Directly Observed Treatment (DOT) and non-DOT, type of DOT

observer, place registered TB patients, treatment regimen, fixed dose regimen and duration of DOTS.

Clinical information: This part contains the questions pertaining to the initial AFB status, sputum conversion status after 2 month treatment, drug resistance status, side effect of drugs, other co-morbidity and treatment outcome

If the data collected from the medical records is not sufficient to present the association between dependent and independent variables, the prep-prepared questionnaire will be utilized to collect the supplementary information from the individual patients. (Please refer to the annex II of questionnaire for the data collection).

Validity and reliability

The content of the standard checklist was reviewed and approved by the experts of the thesis committee regarding its validity in the light of the given operational definitions.

Pre-testing for face validity has been conducted.

For the reliability of the checklist, pre-test was conducted in one health center (10 cases) for Cronbach's Alpha level, before starting the formal data collection.

3.6 Data Collection Procedure

Permission for data collection was obtained from Ministry of Public Health and Bangkok Metropolitan Administration (BMA) prior to the data collection.

Training for data collectors was conducted before the data collection.

Using the checklist, Data was collected from the medical records such as a treatment cards, tuberculosis patients register books.

The data included diagnosis and treatment related information such as symptoms of tuberculosis, results of investigations, treatment regimen given and treatment outcome as well as socioeconomic and demographic factor related information.

The data was collected from the end of January, 2005 and was ended by the end of February 2005. In order to assure the quality of the data collection, a number of procedures was established, and the training for the data collectors was conducted, and after training, post-test was taken of the data collectors.

3. 7 Data processing

Data processing is an important part of the study. After data collection each completed set of checklists were checked in order to correct any error in the data. If any error is found, the investigator went to the relevant place again to correct that error. After the data collection, the data wias first coded and edited.

3.8 Coding and grouping of data

Socio-demographic characteristics of TB patients

Age (ratio, continuous data): ages of the respondents will be divided into 7 groups based on the WHO guidelines. They are 0-14(1), 15-24(2), 25-34(3), 35-44(4), 45-54(5), 55-64(6) and 65 or more (7).

Gender (nominal): Male (1) and Female (2)

Marital status (nominal, categorical data): Unmarried (1), Married (2), and widow/widower/separate (3).

Occupation (nominal, categorical data): Government officer(1), Employee(2), Unemployed(3), Housewife (4), Farmer/labor(5) and other(6).

Behavior factor of TB patients

Treatment compliance (ordinal, categorical data): It was first measured whether patients had never or ever missed treatment. And then further measured by counting the missing dose of TB drugs and it was re-categorized as high, moderate and poor compliances based on the number of days missed treatment.

Health service related information

DOT status (nominal, categorical data): treatment under DOT (1) and treatment under non-DOT (2).

Type of DOT observer (nominal, categorical data): family member (1), Health personnel (2), and self-administration (3).

Places registered TB patients (Nominal, categorical data): chest clinic (1) and health center 7 (2), health center 16 (3), and health center 23 (4).

Drug supply interval (nominal, categorical data): daily supply(1), weekly supply (2), monthly supply(3), others (4)

Treatment regimen (Nominal, categorical data): daily regimen (1) and intermittent regimen (2).

Fixed dose regimen (Nominal, categorical data): loose (separate) drug form (1) and three or four drugs combination form (2).

DOT duration (Nominal, categorical data): Initial 2 or 3 month (1), whole 6-8 month (2), and never DOT (3).

Clinical information:

Initial AFB status (Ordinal, categorical data): + (1), ++(2), +++(3).

Sputum status after 2 or 3 months treatment (Nominal, Categorical data): AFB positive (1) and AFB negative (2) and no tested (3).

Drug resistance status (Ordinal, categorical data): no tested (1), no drug resistance (2), one drug resistance (3), both Isoniazid and Rifampicin or more resistance (MDR TB) (4).

Side effect of drugs(Nominal, categorical data): Yes (1) and No (2).

Then each side effect was measured in frequency and percentage

Symptoms (nominal, categorical data): Yes-1 and No-2

Then if yes, give it one score, and if no, give that symptom zero. After that, make sum all the score for each patient, based on that total score, the study subjects were categorized into three groups i.e. high, moderate, low severity groups. High severe group was defined by the total score more than 80% of 9 in total, Moderate group was defined by the total score between 60-80% of 9 in total, the low severe group was defined by the total score less than 60% of 9 in total.

Other co-morbidity (Nominal, categorical data): Yes (1) and No (2)

Then also each co-morbidity was measured in frequency and percentage.

Treatment outcome (Nominal, categorical data): cured (1), completed (2), failed (3), default (4), transferred out (5), died (6) and success (7).

3.9 Data Analysis and Presentation

The collected quantitative data was processed and analyzed on computer by using SPSS software program.

- First of all, Assessed degree of association of different types of DOT observer and treatment outcome.
- Then, Ascertained degree of association of DOT group and other independent variables,
- Compared treatment outcome at different levels of other independent variables.
- Performed T-test or Chi-square test depending on the nature of variables.
- Performed multi-variable analysis, by using logistic regression method.

3.10 Ethical Consideration

This study is aimed to assess the effect of different DOT observers on outcome of treatment along with other confounding factors and thereby contribute to improvement of TB control program in Bangkok Thailand. In this course, the endeavor of research team collected data from the medical records and individual TB patients for the supplementary data, if necessary, but not to hurt or harass them or their feelings. In almost of the developing countries, TB still holds stigma. People still think that TB is caused due to the wrong doings, so those who have TB are usually seen as untouchable persons. The patient's children might not get married. Therefore all the unethical procedures, violation of people's rights and dignity will be avoided.

The written informed consent was obtained from the director of each health center prior to data collection,

All the information was collected without personnel information such as a name, address, and telephone number, and the information collected from the medical record and from the patients will not be exposed, will be kept in the safe box for the confidentiality and will not be used against them at any cost. All the data was only used for this study purpose.

The whole process of the data collection from the medical records was carried out as per the guideline for the secondary use of research records or biological specimens written on page 36 of "International Ethical Guidelines for Biomedical Research Involving Human Subjects" Geneva, 2002.