

CHAPTER III

RESEARCH METHODOLOGY

The objectives of this study were to determine tuberculosis treatment default rates in various health care settings and to evaluate comparatively the contributing factors between various health care settings. In order to meet these objectives, the following research methodology was used in this study.

1. Study Design

Two research designs were used : retrospective descriptive study using health records to determine the tuberculosis treatment default rate and to evaluate the contributing factors comparatively between various health care settings, and cross-sectional study to find out the institutional factors contributing to default through interviews with health care providers and observation of health care delivery in those settings.

1.1 Retrospective descriptive

Tuberculosis patients who were put on the treatment regimen from October 2001 to September 2004 were reviewed on their treatment cards which were available in various health care settings. Defaulters were those who interrupted treatment continuously for more than 2 month in all health service settings where the study was carried out. Health care settings for study were those involved in DOTS program. In

Bangkok, DOTS program is being implemented mainly through a Chest clinic under TB cluster, health centers under BMA, General hospitals and University hospitals, and private hospitals. In addition, there are hospitals belonging to the military, the police, the port authority, the tobacco monopoly and the prison services where TB patient receive treatment under a general health service package. Hospitals belonging to the military, police and prison service were excluded because those settings were not involved in DOTS program.

1.2 Cross-sectional study

Health personnel who deliver health service for Tuberculosis patients in those settings mentioned above were interviewed with the questionnaire. Observation of health service delivery was also carried out to find out the institutional factors which may contribute treatment default.

2. Study Site

This study was carried out at the Bangkok chest clinic under TB cluster, 3 TB clinics under the coordinating health center No 4 under BMA system and Hua Chiew private hospital.

- A TB chest clinic under TB cluster, Bureau of AIDS, TB and STIs department of Disease Control, Ministry of Public Health is specialized TB clinic where health service are delivered only for TB patient. In Bangkok, there is only one TB chest clinic under TB cluster
- In Bangkok, there are 6 coordinating health centers, sub served by a central network of 61 health centers and 85 sub-centers distributed in six

zones across the city under Department of Health, Bangkok Metropolis System, where public health service for TB patients surrounded by general service are delivered. Among 6 coordinating health centers, one was selected purposively. Central zone (No.4 coordinating health center) coordinating center was chosen due to the fact that other study settings like Chulalongkorn university hospital and private hospital are delivering health service for patients in the same geographical area.

- A TB clinic of Chulalongkorn University hospital was to be included for the study. However, due to the limitation of the time allowed for data collection, this hospital was not visited for data collection. It was requested to pass an ethical committee for the data collection at the Chulalongkorn university hospital which would have taken at least 3 weeks.
- Hua Chiew Hospital which is the only one private hospital currently involved in DOTS in Bangkok.

3. Population and Sample

The population and sample for two study components were as follow;

3.1 Retrospective study

The study population were all types of tuberculosis patients who received treatment in health care settings where health service for tuberculosis patients were delivered under DOTS program; coordinating health center No 4 under BMA, and Hua Chiew private hospital.

For the determination of default rates, tuberculosis patients who were put on treatment regimen in those settings from Oct 2001 to Sep 2004 were reviewed by their treatment cards.

3.1.1 Sample estimation

For the determination of default rates in certain health care settings, minimum number of patients need to be enrolled in the study based on sampling calculation method.

The following formula were used for estimation of sample

$$n = Z^2 \alpha pq / d^2$$

$$n = (1.96)^2 \times 0.18 \times (1-0.18) / (0.05)^2 = 226$$

The estimated total number of sample size in the study = 226

Where :

n=calculated sample size

$$Z\alpha = 1.96 (\alpha = 0.05)$$

P=assuming that the default rate among tuberculosis patients in

Bangkok 18 % = 0.18 (data source; TB cluster under MoPH)

$$q=1- p=1 - 0.18 = 0.82$$

d =error allowance = 0.05

The number of patients to be enrolled in one health care setting should be at least 226.

3.1.2 Sampling method

Step 1 Preliminary information

Average number of patients per year in each health care setting was checked prior to sampling calculation. According to the information from TB cluster, MoPH (based on the report from health settings through BMA), number of all types of patients treated in one fiscal year (Oct 2002- Sep 2003) were 150cases (No 4. Coordinating Health center), 89 cases (Hua Chew private hospital), 67 cases (TB clinic in Chulalongkorn University hospital) and 698cases (TB chest clinic).

Step 2 sampling in each health setting

Based on the above information, sampling method was used as follows ;

- Hea Chew private hospital All patients who were put on treatment from Oct 2001 to Sep 2004 were planned to be reviewed by their treatment card. However, it was found that this hospital joined in the TB program in October 2002 and withdrew from the program at the end of 2004. Therefore, all patients (174 cases) who were treated in this hospital under TB program were taken as study subjects.
- Coordinating health center No. 4 First, the number of health centers sub served by the coordinating health center were identified. There were 3 TB clinics coordinated by No 4 health center. In each health center every other patients were taken as study population .95 cases in TB clinic of health center No 3 (located at the coordinating health center), 78 cases in TB clinic of health center No.19 and 73 cases in TB clinic of Health center No 24 were reviewed by their TB register and treatment card.

- Bangkok Chest Clinic According to the review of TB register, total number of patients treated for three years in this clinic were about 1610. Systematic sampling technique was used to select more than 226 cases. Every 7th patient was taken on the TB register, which reached to 229 cases totally.

3.2 Cross-sectional study

Health care providers who delivered health service for tuberculosis patients in those health care settings above mentioned composed the study population.

3.2.2 Health center

Each TB clinic has a TB coordinator (registered nurse) who has responsible for recording and reporting of all data related to the program implementation default tracing activity, health education for the patients and so on. There was one doctor in each clinic who was responsible for clinical service for patients. Therefore, doctors had little information of the program implementation such as defaulter tracing, treatment observation, recording and reporting system supervision activity, and so on. There were another two or three nurses in each clinic, but they have their own responsibility not in relation with the TB program. Therefore, only TB coordinators in each clinic were interviewed using semi structured questionnaire.

3.2.2 Bangkok Chest clinic

First of all, deputy director of the chest clinic was interviewed to gather general information about health service organization and TB program implementation. He

raised concern about interview with health personnel in the clinic because health service organization and TB program implementation are the main responsibility of director or deputy director and therefore other health personnel do not know much about those things. Therefore interviews were conducted with director and deputy director of the Chest Clinic.

3.2.3 Hua Chiew hospital

In this private hospital, there are three departments such as internal medicine department, universal coverage department and social security welfare department where TB service is delivered along with other health services. It was said that in the internal medicine department and social welfare department patients should pay money or use health insurance for the service, while 30bahtscheme patients were accepted in the universal coverage department.

It was assumed that there would be little problem in terms of access to health service in department where health services were paid. Therefore, the interview with health personnel and the observation of waiting hour of the patient were observed only in the universal coverage department.

4. Inclusion Criteria

Inclusion criteria for two study components were as follows:

4.1 Retrospective study

- Health care settings involved in DOTS program under Bangkok TB control program were included in the study.

- Tuberculosis patients aged 15 years or more who were put on the standardized short course chemotherapy ; Category I, II and III. Type of patient were new smear positive, new smear negative and new extra – pulmonary cases and re treatment cases (failure, relapse and re treatment after default). All types of TB patients and treatment category were reviewed to identify association between treatment defaulting and type of TB and treatment category.

4.2 Cross-sectional study

Health personnel who were responsible for the management and coordination of the TB program and for the organization of health service .

5. Exclusion Criteria

Exclusion criteria for two study components were as follow;

5.1 Retrospective study

- Health care settings where DOTS program were not covered were excluded from the study, such as military, police, port authority and prison services.
- Patients who were put on treatment regimen during study duration but “transfer in” during the treatment were excluded because their treatment results were supposed to be recorded for reporting in their originally registered health center.

5.2 Cross-sectional study

Health care providers who did not know about the TB program such as reporting and recording system, defaulter tracing activity, health education and training for staff and so on were not interviewed.

6. Data Collection Methods

Since this study consists of two components, methods for data collection also incorporated two techniques.

6.1 Retrospective study

This study reviewed health record such as patient treatment card and TB register. Data collection was carried out using an already developed data collection form by researcher with the assistance of data collector.

Random double –checking on 10 % of collected data was performed for the quality control.

6.2 Cross-sectional study

The data collection instrument for this study component included ;

6.2.1 Questionnaire

Semi structured questionnaire was used for face to face interview with health care providers to gather health service characteristics in particular health care settings

6.2.2 Observation on the process of health care delivery

Flexibility of the opening hours of the clinic was learned during the interview with health personnel in each setting. Waiting time of the patients were measured at the place where patients were waiting to see doctor or treatment supervisor, or to collect TB drug. This observation was carried out differently according to the situation of the health setting.

- Health center

In every TB clinic, patients who came to the clinic for taking TB medication were observed at the waiting room.

- Bangkok chest clinic

It was difficult to figure out which patients came to collect TB drugs or were new patients at the waiting room. Therefore, the time from the arrival at the waiting room to the leaving point for doctor were measured in general.

- Hua Chiew hospital

It was also difficult to figure out which patients were TB patients at the waiting room because there was no separate TB section in this hospital. Therefore, the time from the arrival at the waiting room to departure was measured in general.

6.3 Variables

Dependent and independent variables for the study and their definitions were as follows ;

Dependent variables

Treatment default

Independent variables

Two groups of independent variables were applied for the study

6.3.1 Service type

Public service

Private service

Specialized TB service

University hospital

Definition of variables

Defaulter ;Patient who did not collect drugs continuously for 2 months or more at any time after registration.

Public health service; delivery of health service for tuberculosis under Government organizing health service institution

Private health service ; delivery of health service for tuberculosis patients by private health service practitioners in private hospital or clinic

Specialized TB service ; health institution serving only for TB patients under Government organizing institution

University hospital service ; health care delivery for tuberculosis patients in Hospital attached to medical college where TB service are integrated with general health service

6.3. 2 Characteristics of service

- Health personnel (trained status, workload)
- Equipment (microscope, chest X-ray machine)
- Management (defaulter tracing activity, supervision activity, type of treatment supervision, health education, incentive system, recording and reporting system)
- Patient's convenience to health service (Waiting hour, opening hour)

Definition of variables

Trained status ;whether medical staff who deliver health service to TB patients received training on the management of TB patients in DOTS program as well as whether it is regional, national or overseas training.

Workload ; whether health setting serves only for TB patients or serves for TB patients along with other diseases within integrated health service package.

Equipment ; status of availability of microscope and chest X-ray machine in particular health care setting which will ensure the one-stop service for patients.

Defaulter tracing activity ; according to the program requirement, patient who defaulted during the intensive phase should be traced within 1 day and during the continuation phase should be within 1 week.

Type of treatment supervision ;whether or not patient is supervised for medication intake by somebody else such as health worker, family member or community volunteer.

Supervision activity ; according to the program requirement, supervisory visit should be done from upper level to ensure the proper running of the program in terms of defaulter tracing activity, recording and reporting system and laboratory quality assurance system and so on.

Health education; according to the program requirement, health education should be provided to the TB patients when they are put on the treatment regimen and during receiving treatment to ensure that patients actively participate their treatment with knowing potential risk of treatment defaulting and importance of treatment completion and so on.

Incentive system ; motivation of health provider in the way that certain amount of money, meal coupon or increase of salary are given to them when they traced defaulted patient back to the hospital or clinic.

Recording and reporting system ; according to the requirement of the TB program, TB register, treatment card, laboratory register and quarterly report should be recorded .and reported to the National TB Program.

Flexibility in the Operation hour of treatment centers ; flexible opening time of the clinic or hospital convenient to the patients.

Waiting hour of the patient; average waiting hour of the patient when they visit health service setting to collect drugs in general, but in case of difficult situation that doesn't allow to figure out which patients come to collect drug, average waiting hour o f patients at the patient's waiting room were measured in general.

6.4 Approach for data collection

Regarding data collection, some steps were followed as below;

6.4.1 Retrospective study

- Registered nurses in each health care settings were hired to help researcher with reviewing the health record. Fortunately, registered nurses who spoke English were available in every health setting visited. They were well aware of TB program so training on medical terminology was not required for them. Some explanation was done to let them know the purpose of research and methodology of data collection.

All treatment cards and TB registers for the patients who started treatment during study duration kept in health center were reviewed to count total number of cases for the calculation of sample size with the assistance of data collector. The data were collected from the TB register and patients' treatment card.

- Data collection form developed by the researcher before data collection was filled by researcher with assistance from the data collectors
- 10 % of data collected was selected randomly for rechecking to ensure the quality assurance of the data collection

6.4.2 Cross-sectional study

6.4.2.1 Interview with health service providers using semi-structured questionnaire

- Director and deputy director of Bangkok Chest Clinic were interviewed using the questionnaire
- TB coordinators (registered nurses) in TB clinic of health center No 3, 19 and 24 coordinated by coordinating health center No 4 were interviewed.
- Deputy director of the hospital, one doctor and two registered nurses who were involved in DOTS program implementation were interviewed.

6.4.2.2 Observation on the health service delivery

- Opening hours of the health setting were learned during the interview with health personnel

- Researcher sat at the patient waiting room to calculate average of waiting hour of the patients

7. Validity of Instrument

Content validity for the developed questionnaire was carried out by 3 TB experts via e-mail.

8. Analysis Method

Data analysis was done by descriptive statistics such as percentage and maximum minimum. Bi variate analysis was used to look at the association between independent variable and dependent variable. Conditional multiple logistic regressions were used to find out the strength of association between default rate and other independent variables.

9. Limitation of the study

As mentioned in the conceptual framework of treatment defaulting problem, defaulting behavior of the patients are associated with many factors such as socio economic, behavioral, disease, regimen, and health system and health provider.

However, due to the limitation of time for the research considering linguistic and cultural barriers which interfere contacting people for the identification of various factors related to defaulting behavior, study was designed to determine the default rate and the contributing factors through health record review available in health facilities, which might not have sufficient data to find out all factors.

Also, a cross-sectional study was designed to comparatively evaluate the factors contributing to treatment defaulting through interviews and observation of health service delivery. In this study, only provider perspective were considered while satisfaction of the patients with the particular health service were not investigated.

10. Benefits of the Study

This study found default rates in 3health care settings in Bangkok and some Factors associated with treatment default. It is expected that these findings can be useful for the TB program managers and TB practitioners for further improvement of program implementation and stepping for war din the area of identifying the main determinants of this problem.

11. Ethical Consideration

Any research which involves human beings as a subject should be considered ethically. In this research, the health workers were interviewed, who deliver Health service to the tuberculosis patients in various health care settings in Bangkok such as health centers under BMA system, general hospital, and private hospital, to investigate health service related factors affecting treatment defaulting among urban TB patients. Health record such as treatment card and TB register in the health care settings were reviewed, in order to find out default rate in those settings.

In this research, ethical issues were addressed as below

- Approval from the relevant health authorities in every health care settings to carry out data collection activity in those settings such as health record review and interview with staff
- Informed consent from health workers before interview
- Confidentiality to be assured for all data including data from health record and interview.
- Patient names not to be recorded in data collection form

In the field of study, approval by an ethical committee which would have taken more than 3 weeks was raised by health officials of Chulalongkorn University Hospital besides the issues mentioned above. From this experience, it is recommended that ethical issues should be strictly addressed before one starts a study that involves human beings.