

CHAPTER 3

RESEARCH DESIGN AND RESEARCH METHODOLOGY

The present research was designed based on the feasibility and the required information. Suitable methodology was developed to collect and analyze the data.

The design of the study was a cross sectional descriptive study. The research methodology was divided into following sections.

- Population and sampling
- Measurement of variables
- Operational definition
- Ethical consideration

3.1 Population and sample

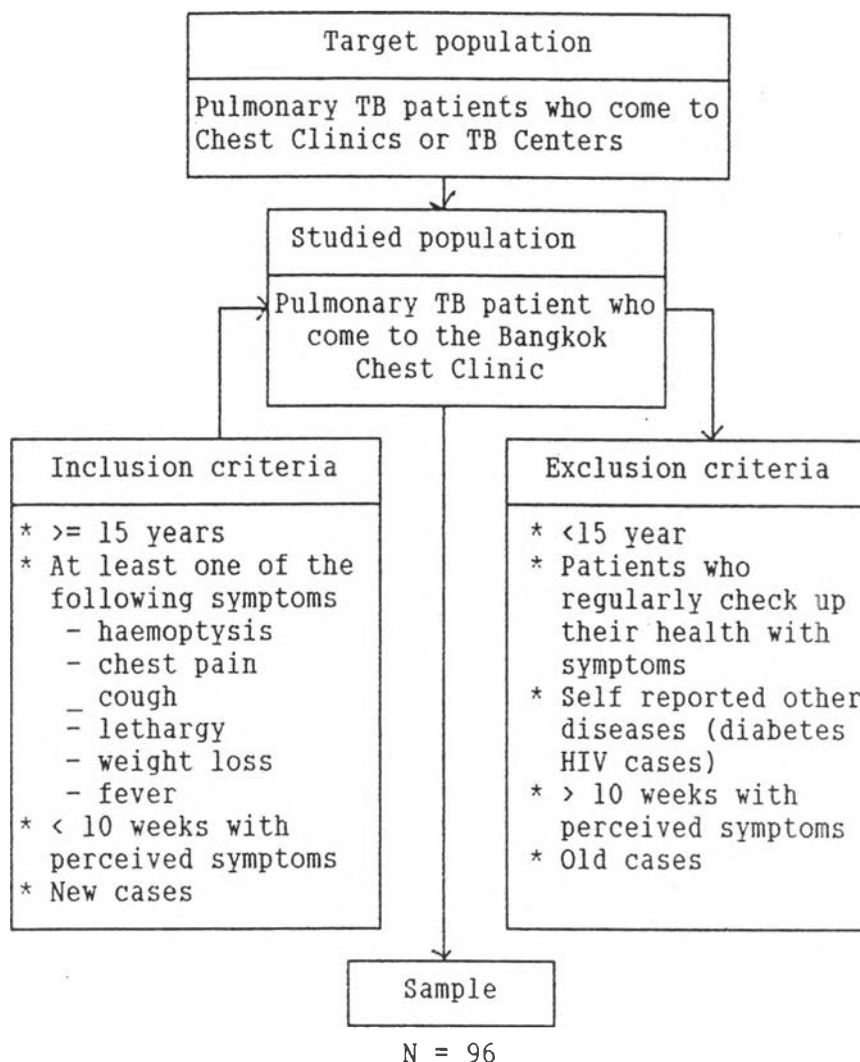
Study population: the study population included pulmonary TB patients who attended to the Bangkok Chest Clinic for diagnosis and treatment.

Study site: Bangkok Chest Clinic chosen as a study site due to the limited resources and time. Which was situated in Bangkok Metropolitan area at Yosse (near the China town). It covered the urban slum population. On an average 20 new cases per day attended at this clinic. Patients were transferred to their nearest hospital if they were far from this clinic. The population sampling has shown in Figure 3.1.

Study sample units: sample units of this study were the eligible patients who detected smear positive of *Microbacterium tuberculosis* at the Bangkok Chest Clinic.

Method of selection: simple random sampling technique was used to select the patients. Random table was used to select the patients for interview. The approach in selecting more study sites could be covered due to time and resources constraints. However adequate samples were collected within this single service point.

Figure 3.1 Population and sampling procedure



Eligibility criteria of the patients for the study was determined based on the following inclusion and exclusion criteria.

Inclusion criteria

- Those patients whose age was ≥ 15 years. This was because to get valid information without any bias due to age and maturity. (Kamolratanakul 1989)
- Only those patients who experienced of pulmonary TB. Other cases were not the target of the study.
- Only 10 weeks period to avoid memory bias. This was based on an earlier report of only 3 percent omission rate among those who reported within 10 weeks (Canaille, 1970).

- Only new cases in order to avoid under reporting.

Exclusion criteria

- Those patients whose age was <15 years because they were too young.
- Asymptomatic patients because their health care seeking behavior would be different.
- Patients who came after 10 weeks because of memory bias.
- Patients who had diabetes or HIV positive to avoid confounding effect due to morbidity.
- old cases prone for under reporting.

3.2 Sampling and sample size

The concept of sampling followed in the present study was that it should be representative of the study population. Each study unit (patients) should have had equal chance (likelihood) of selection from study population. Random sampling techniques were considered more appropriate than non random.

Simple random sampling was used in this study. Everyday patients were chosen for interview using random table. Some patients were excluded during interviewing period due to exclusion criteria. Sample size was calculated using appropriate statistical methods.

Desired sample size:

$$n = \frac{(z)^2 * (p) * (q)}{d^2}$$

n = desired minimum sample size required:

z = the degree of confidence (95%) assumed that sample size is in approximately normal distribution.

p = proportion of pulmonary TB patients who have the symptom and seek the care of Chest Clinic or TB clinic (0.5)

q = 1 - p,

d = acceptable error 0.1

Using the above formula yields the following sample size,

$$n = \frac{(1.96)^2(0.5)*(0.5)}{(0.1)^2} = 96$$

$$n = 96$$

3.3 Measurement of variables

The variables were measured in following way (Figure 3.2).

Figure 3.2 Measurement of variables

Variable	Unit of measurement	Instrument	How to measure
- Distance to the service point	Km.	questionnaire	direct interview
- Days with perceived symptoms (performance of patients)	days	''	''
- Travelling fare	per person Baht.	''	''
- Consultation & drug cost	''	''	''
- Travel time	hour	''	''
- Days of work lost before seeking care	days	''	''
- Time cost of care taker at home	days	''	''

3.4 Operational definition

- A. Patient performance: time between perceived symptom(s) and seeking formal care.
- B. Formal care: the care which is provided by TB Center or TB clinic.
- C. Informal care: that care which is provided by traditional healer, drugs store or other cares prior to the formal care.

E. Pulmonary TB cases definition,
(according to the TB Division)

- (a) - TB patients with AFB +ve by microscopic examination, in at least 2 successive examination
- or - TB patients with AFB +ve by microscopic examination in one examination together with abnormal X-ray suggestive of TB
- or - TB patients with AFB +ve by microscopic examination together with M.tuberculosis complex +ve
- (b) - TB patients with AFB -ve by microscopic examination in at least 2 successive examinations with abnormal X-ray suggestive of TB and decision to give full treatment has been made by physician
- or - TB patients with AFB-ve by microscopic examinations in at least 2 successive examinations with M. tuberculosis complex +ve by culture

F. New Case:

- TB patients with no more than one month previous history of treatment.

G. TB Suspect: person with chronic cough more than two weeks and or with hemoptysis, other suggestive symptoms i.e. weight loss, low grade fever, loss of appetite etc

3.5 Data collection

Patients were interviewed using structured questionnaire to gather the information on costs and patient's behavior in seeking care and in consumption cares prior to the formal care.

Following information were collected on external costs, patients performance and patients behavior in seeking care and consumption cares prior to the formal care. The information profile for the present study is shown in the Figure 3.3.

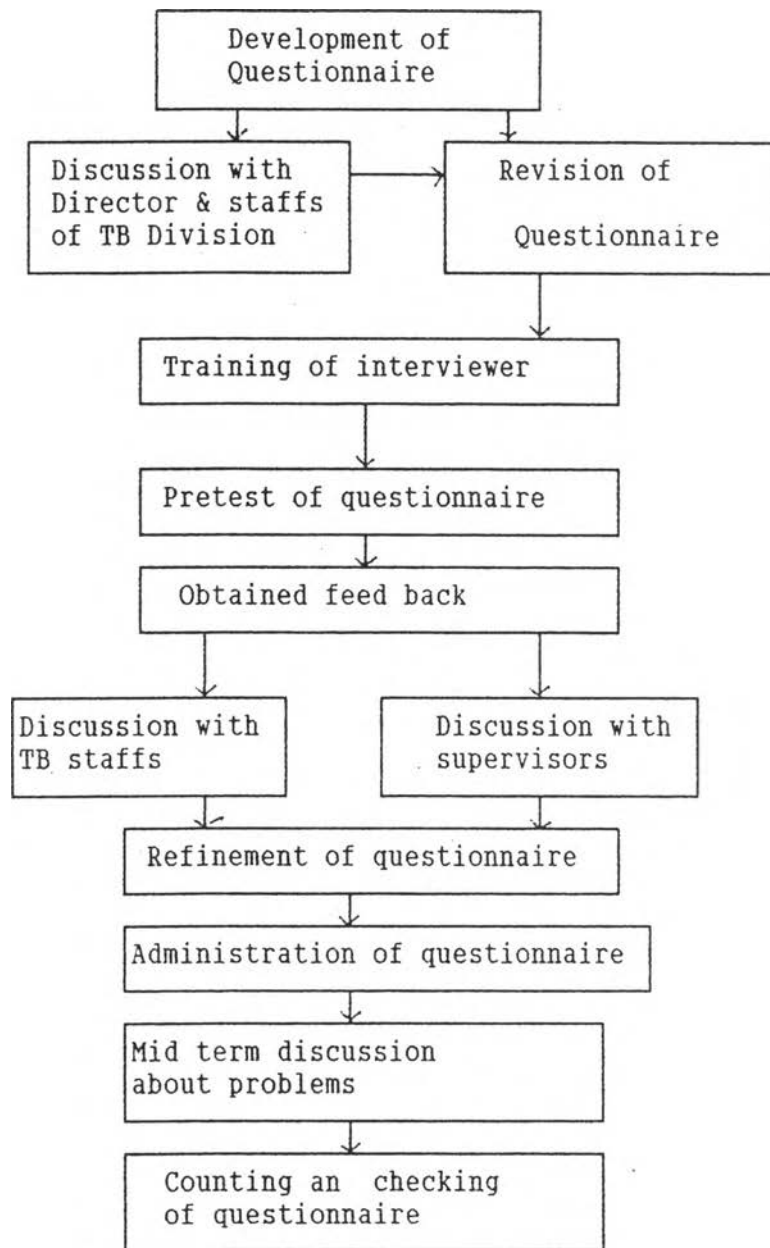
Figure 3.3 List of information

Information	Variables
1. Personal demographic	<ul style="list-style-type: none"> - Age - Sex - Marital status - Occupation - Education - Personal income
2. Patients behavior in seeking care point	<ul style="list-style-type: none"> - Reason for seeking care - Distance to the service - Mode of travel - Choice of service points
3. Patient's performance	<ul style="list-style-type: none"> -Days with perceived symptoms
4. Cost incurred by patient	<ul style="list-style-type: none"> - Travelling fare - Consultation & drug cost - Travel time costs - Time cost (days of work lost)
5. Cost incurred by accompanying persons	<ul style="list-style-type: none"> - Travelling fare - Travel time cost
6. Cost incurred by person who take care at home	<ul style="list-style-type: none"> - Time cost

Note: Some secondary data were collected by TB Control Division and relative offices.

The different steps followed in the process of collecting data are shown in Figure 3.4.

Figure 3.4 Steps in data collection



3.5.1 Development of questionnaire

The questionnaire was developed in relation the objective of the study. Questions that were not related to the objective of the study were also included considering their importance in serving indirectly objectives. Behavior of the patients were not directly related to the objectives but indirectly served the objectives. Some

researchers argued that non relevant questions on behavior should be asked to reduced the bias in respondents' information. However non - relevant questions were omitted from the questionnaire because it would prolonged the interviewing time and would diverted the attention of both interviewer and respondents

When the questionnaire survey was planed, questionnaire administration time, material and availability of respondents were considered.

Defining information - some information could be collected by one question; however some information needed more questions. In this study, many question were asked to determine the time costs.

In the process of formulating draft questionnaire, full attention was paid to the wording of questions because slight variations might result in different responses. e.g.the question like how many days you could not work due to sickness? If illness is omitted, patients responses may be different.

Jargon of words were avoided and language was made simple. e.g. illness instead of symptoms.

This study tried to avoid long questions, negative questions, leading questions and hypothetical questions.

Closed-ended structured questions was constructed. The interviewer asked questions with closed list of responses in open way,e.g. where did you visit for care before coming to this clinic? Interviewer held a list of alternatives and circled those mentioned.

Translation of questionnaire was done in to Thai and local common words were used to make it understandable to the TB patients.

Questionnaire was longer enough to collect the defined information but not lengthier to cause bias. Patients only responded the selected service points and its costs. Thus an average of 10-15 minutes was taken for administering a questionnaire.

Order of questions was followed to maintain cogency. In the initial part questions consisted of basic demographic information but sensitive questions (days off due to illness) were asked at the end of interview. Other questions were asked in their order of importance.

Layout of questionnaire was prepared carefully. Instructions were printed on the top of the questionnaire. First part of questionnaire covered basis demographic information, 2nd part the performance of the patients and behavior of the patients, 3rd part was cost-related and it was to be completed as per the choice of service points. The four part was critical (days of work lost due to illness) time cost.

Coding of questionnaire is a process of converting the recorded answers in to numerical or alphabetical code. Numerical code was used to make it easier during data imputing time. Boxes were put in a column down the right hand side of the form. It simplified the data entry process. Interviewer put the circle on appropriate alternatives then after completion of administration of questionnaires each day circle were converted into code.

A social worker of fair sex was selected to administer the questionnaire based on the following criteria:

- knowledge and skill of interview,
- previous experience in interviewing,
- English speaking skill,
- time available,
- cooperative and polite

The place of interviewing the patients was a clinic. Social section was chosen for interview, where social workers impart health education to the patients. It was an appropriate place for interview because patients were diagnosed before coming to this section and social worker has enough time for interview.

The interview was conducted from feb. 15 to march 22,1995. Patients were interviewed after from 10 a.m. to 2 p.m. and they paid full attention during interview.

The staff of TB Division were consulted for more information related to the following aspects.

- Objective of the study
- Information adequacy
- Point of interview
- Interviewer
- Time frame

The questionnaire was revised after the discussion with supervisors and TB staff.

Detailed instructions were given to the interviewer e.g. eligibility criteria, interviewing technique etc.

Pretest of questionnaire and feedback was also carried out. A draft questionnaire was administered to 10 TB patients. Appropriate change in the process and questions were carried out.

Midterm discussions were also conducted during the survey period with TB staff to accelerate the data collection process.

- Complete information
- Time frame

Finally all responded questionnaires were checked for its correct entry and consistency.

After completion of interview each day, the records were collected, coded and entered in the record forms.

3.5.2 Minimization of error and variation

Source of error were considered before data collection. Sampling and non-sampling error were tried to minimize.

Sampling error was minimized by using probability sampling (simple random sampling technique).

Recall error (non sampling error) was tried to minimize by cross checking the time of various components of care and costs. The days with symptom was based on reasonable recall memory.

Reporting error (non sampling error) was tried to minimize by checking service points and costs, e.g s/he did not mention drug store but mentioned drug cost or healers' services but did not mention costs therefore by using cross checking could minimize the bias.

Non response error (non sampling error) was minimized by encouraging respondents.

The variation was minimized by following ways.

- Only one interviewer was used to avoid inter observer variation.
- Orientation was given to reduce the intra observer variation.
- Same questionnaire was used in interview therefore there was no instrument variation.

3.6 Ethical consideration

The primary data gathered from the patients were kept confidential. All the patients interviewed, volunteered their response to the questions.

3.7 Data processing and analysis

Data were entered in EPI Info. Entry of data from survey was checked by matching a print out of original data form. The time between data collection and entry in the computer was kept as short as possible. Data were entered into computer on the following the day of collection.

Analysis was done using EPI Info, lotus 123r23 and TSP. Data was edited by using the same programme.

Summarization of data

Continuous variables (age, weight, days with symptom, travel time, distance to the service point, income of patients, travel fare, days of work lost, drug and consultation costs) were summarized in terms of percent, ratio, mean, median as appropriate.

Discrete variables (education, occupation, gender, mode of service point) were summarized in terms of percentage, ratio.

Statistical tests

Simple and multiple regression analysis were done for the relationship between the performance of the patients and the cost incurred by the patients prior to formal care.