

CHAPTER IV

RESEARCH METHODOLOGY

4.1 STUDY LOCATION

This study was conducted in a sub district hospital in Bangladesh named Keshabpur sub district hospital. This is a rural based primary health care center situated in the district of Jessore. This sub district is situated about 350 kilometers south from the capital city Dhaka and 45 kilometers from the district headquarter. This hospital provides health care delivery services among 300,000 population within this sub district by the clinical staffs in the hospital and preventive care by different trained field level health workers.

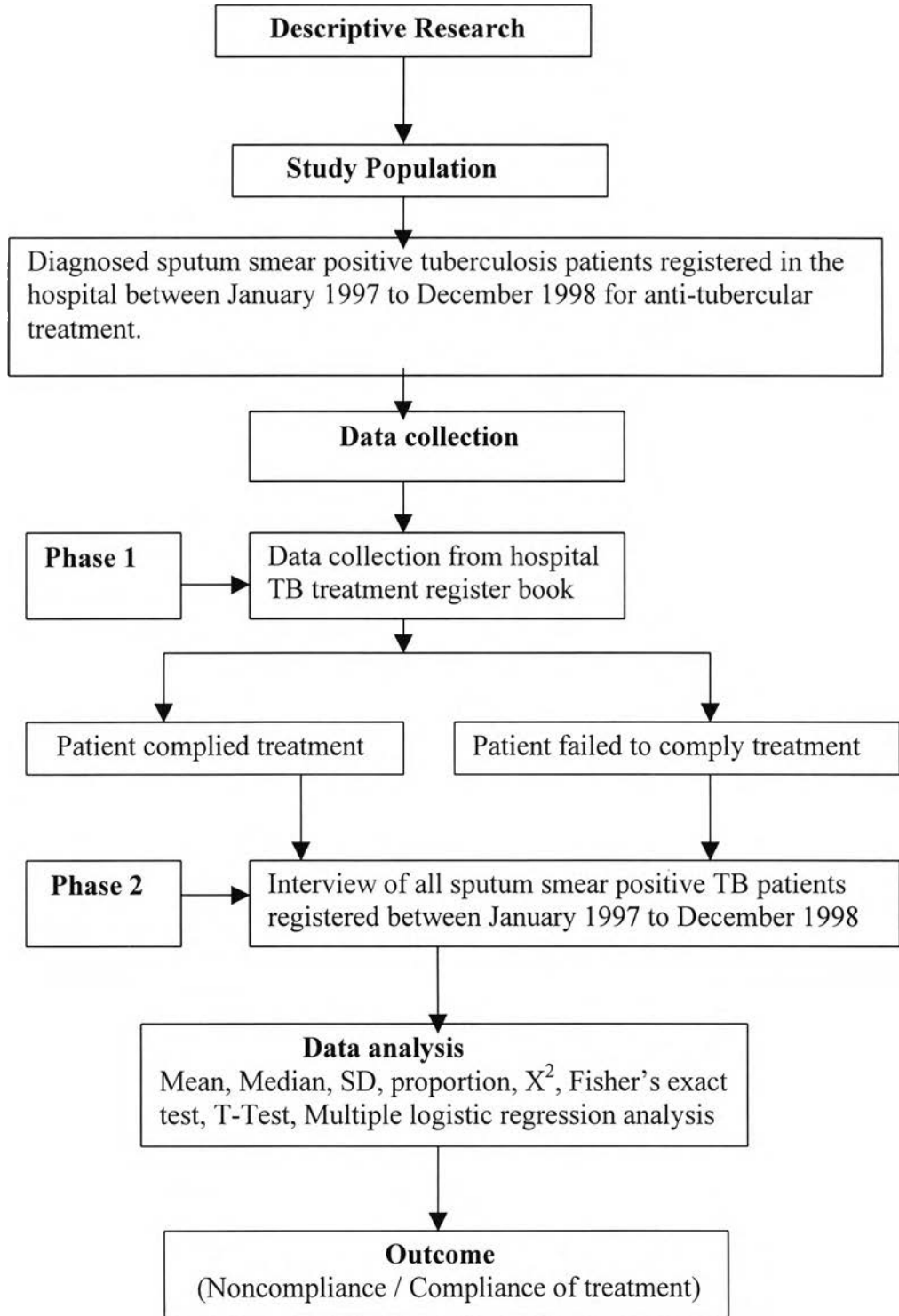
In Bangladesh under the National Tuberculosis Control Program all tuberculosis related medical care is provided free of charge to the patients. Directly observed therapy is followed for the patients. In the DOTS strategy patients relatives or the health worker of that particular area looked after the daily intake of drugs. Patients with sputum smear positive tuberculosis are treated with category one treatment, which includes 2 months intensive phase having four drug regimens (Rifampicin, Isoniazid, Pyrazinamide and Ethambutol) followed by 6 months continuation phase of two drugs (Isoniazid and Thiacetazone). In the intensive phase patient has to attend hospital weekly and in the continuation phase every fourteen days after to collect the anti tubercular drugs. Completion of therapy is determined by the ingestion of the prescribed number of doses; missed doses are “made up” effectively lengthening the course of therapy. Patients are

considered cured if their signs and symptoms disappeared, sputum had converted to negative and if the full duration of treatment course (8 months) had been followed.

4.2 RESEARCH DESIGN OVERVIEW

The study design was a descriptive study. Study sample consisted of Sputum smear positive tuberculosis patients who were registered for treatment at Keshabpur sub district hospital between January 1997 to December 1998. In this study the dependent variables were the Noncompliance / compliance of treatment by Sputum smear positive tuberculosis patients. The independent variables used to find out the factors associated with Noncompliance / compliance of treatment, like demographic and socioeconomic factors, access barrier factors, need factors and social barrier factors. Before the study was conducted a baseline data were collected from hospital TB treatment card in order to estimate the study population. Patients diagnosed as containing at least one specimen of acid fast bacilli in the sputum at the time of their presentation and registered for treatment between January 1997 to December 1998 in the hospital were selected retrospectively. Information from the time of their presentation with tuberculosis until 8 months into their treatment was studied. This information was recorded on the standard case record form for each subject in the hospital. Data on clinical outcome for each patient (like completed treatment, not completed treatment, lost to follow up, died or alive) was also recorded in that form, including treatment regimen and adverse reactions. The address of the patients were collected from the record forms and they were interviewed directly at their homes by the researcher himself by using previously designed questionnaire.

4.3 DIAGRAM OF STUDY DESIGN



4.4 TARGET POPULATION

The target population was all tuberculosis patients at the Keshabpur sub district within the district Jessore who were registered for treatment between January 1997 to December 1998.

4.5 STUDY POPULATION

Diagnosed sputum smear positive tuberculosis patients who were registered in the Keshabpur sub district hospital from January 1997 to December 1998 for anti tubercular treatment.

4.6 INCLUSION CRITERIA

- Sputum smear positive (acid fast bacilli) tuberculosis patients registered in the Keshabpur sub district hospital from January 1997 to December 1998 for anti tubercular treatment.
- Patients diagnosed as sputum smear positive tuberculosis from the time of their presentation in the hospital records until 8 months into their treatment were included as study subjects.

4.7 EXCLUSION CRITERIA

- Patient died during treatment within in the study period i. e. between January 1997 to August 1999 was excluded.

4.8 SAMPLE SIZE CALCULATION

Such type of study was never conducted in Bangladesh previously. So this is said to be a pilot study in this country. That is why all sputum positive tuberculosis patients who were treated in the hospital between January 1997 to August 1999 for anti tubercular

treatment were included as the sample. The number of patients treated during that period was 226. Among them 28 (12.4%) patients were found dead (found in the hospital records and by field visits) and 8 (3.5%) patients were untraceable. So 190 patients were interviewed during the study period.

4.9 OBSERVATION AND OUTCOME MEASUREMENT

The Outcome of this study was divided into two variables, which were dependent and independent variables. The following outcome attributes were measured.

4.9.1 DEPENDENT VARIABLES

Noncompliance and Compliance of treatment among sputum smear positive TB patients.

4.9.2 INDEPENDENT VARIABLES

Demographic and Socio-economic factors

- Age
- Sex
- Marital status
- Occupation
- Education
- Religion
- Monthly family income

Access barrier factors

- Longer home to hospital distance
- Irregular visit by the health worker

- Missed appointment for treatment due to absence of doctor/ staffs
- Non cooperation by the hospital authority
- Drug intolerance/adverse effects of drugs

Need factors

- Feeling of clinical improvement/ felt cured during the course of treatment
- Feeling of failure of improvement of clinical symptoms on therapy
- Forgot to take / ingest medicine
- Lack of confidence on hospital treatment
- Therapy by another hospital / physician

Social barrier factors

- Moved residence / Homelessness
- Lack of support from family members to continue drugs

4.10 INSTRUMENT

The questionnaire was used as an instrument for data collection. The investigator developed the content of the questionnaire from previous research^(28, 39) and expert's advice. The questionnaire was formulated to identify the proportion of sputum smear positive TB patients who did not complete the treatment and the factors associated with noncompliance of treatment among those patients. The questionnaire was divided into three parts.

In part one there were seven questions about the demographic and socioeconomic characteristics of the tuberculosis patients, which included age, sex, marital status, educational status, occupation, religion and monthly family income.

Part two consisted of twenty-one questions regarding the factors associated with noncompliance of treatment among the tuberculosis patients. In this section the nature of the questions were open ended, binary and multiple choice types.

Part three consisted of four questions which were result of sputum smear examination at the time of diagnosis, result of sputum conversion at different months after the start of treatment, category of non compliant patients and the result of treatment outcome (patient completed/failed to comply treatment). This information was collected from the hospital TB treatment record forms. By using this questionnaire all relevant and factual information was collected.

4.10.1 VALIDITY OF THE MEASURING INSTRUMENT

In any research validity of the measuring instrument is an important factor. Validity is the degree to which the methods and its measurement process provide precise and correct measurement. In this study content validity was concerned with whether the instrument adequately covered and measured what it was supposed to measure. So the investigator tried to make the research process internally valid by meeting the research objective.

To meet this, a draft questionnaire was developed from related literatures, textbooks and expert experiences. Then items were checked on the basis of study objectives and verification of the content validity of the questionnaire was done from three experts from Thailand. This was maintained by getting the content experts opinion and obtaining score from them. The given score was analyzed by item correlation. The item which had > 0.5 score was accepted to include in the questionnaire. According to the experts suggestions

some items were subtracted and some items were added. The formula used for item correlation was as follows.

Item content (IC) = $\Sigma R / N$.

IC = refers to the correction of items to contents of variables.

R = total score of that item

N = number of experts.

Score +1 = relatively valid item, 0 = not sure and -1 = relatively irrelevant.

4.10.2 PRETESTING OF QUESTIONNAIRE

In this study the questionnaire was pre tested among 25 sputum positive tuberculosis patients who were registered for anti tubercular treatment in the neighboring sub district hospital from January 1997. The purpose of the pre test was to examine the flow of interview questions, the uniformity in information, clarity and variability in response. The pretest questions were reviewed and finalized before conducting the study.

4.11 DATA COLLECTION

Using the questionnaire, which was used as an instrument in this study all necessary data were collected. Data were collected from two sources.

1. From the TB treatment record forms in the hospital where all address of the patients, symptoms of tuberculosis, results of investigations (including sputum examination), treatment regimen given, treatment outcome (completed treatment, defaulted, died etc) were recorded systematically.

2. By face-to-face interviewing the patients at their home settings who were registered in the hospital as sputum smear positive tuberculosis patients between January 1997 to December 1998 for treatment purpose.

The data collection was started from the second week of May and ended on the first week of October 1999. Patients were contacted at their homes with the help of previously collected address from the hospital records. Self- introduction of the interviewer was given and interview was started with religious greetings. Privacy was maintained, purpose and importance of the study was explained and assurance of anonymity was made for critical remarks. Patients were requested to feel free and give complete answer to every question to their own.

To maintain the quality of data collection a number of procedures were established including pre-coded forms and collection of data by the researcher himself.

4.11.1 DATA PROCESSING

Data processing is an important part of the study. After data collection each completed set of questionnaire was checked in order to correct any error in the data. If any error was found the investigator had to go to the field again to correct that error. After the data collection was finished, the data were first coded and edited. Then all data were analyzed by using software computer program SPSS+PC and EPI INFO 6.

4.11.2 RECODING OF THE DATA

Certain variables were considered to be associated with treatment outcome. To see the significant association of these variables, X^2 test (Pearson's chi-square for categorical variables) and Fisher's Exact test (for binary/dichotomous variables) were performed

with those variables. Those variables were re-coded again because former variables had less expected frequency in the cross table for χ^2 test than the needful expected frequency.

They were re-categorized as age 15-29 years = 1, 30-44 years = 2, 45-59 years = 3 and 60-74 years = 4; marital status as single = 1 and married = 2; education as Literate = 1 and Illiterate = 2; occupation as day labor = 1, farmer/agriculture = 2, self business = 3 and house wife = 4; monthly income as 3000- 6000 Takas = 1 and 6001-9000 Takas = 2.

Other variables which were re-categorized were time took by the patients to visit hospital as < 1 hour = 1 and > 1 hour = 2; visit by the health worker as once or twice biweekly and monthly = 1, and never visited = 2; missed hospital appointment as never missed = 1, missed one or more times = 2; problem faced by the patients from hospital authority as felt no problem = 1, felt problem = 2; development of symptom as develop no symptom = 1, develop symptom = 2; support by the family members as support by father/mother/brother/sister and children = 1 and husband/wife = 2.

4.11.3 DATA ANALYSIS

This section is concerned with the summary and planning analysis of the data in order to provide answers to the research questions. The detailed study results were described in Chapter 5.

4.11.4 DATA PRESENTATION

Data presentation was done in contingency tables. The primary outcome noncompliance/compliance of treatment among sputum smear positive tuberculosis patients were summarized in terms of proportion or percentage and the secondary outcome, factors which might affect on the noncompliance of treatment among the

sputum smear positive tuberculosis patients were summarized by descriptive statistics. The quantitative data were summarized in terms of mean, median and standard deviation and the qualitative data as frequency and percentage. Interpretation was done explaining the meaning of outcome and its relationship and significance in p value.

4.11.5 STATISTICAL TEST

The outcome of this study were measured in terms of factors to be the association between the factors and noncompliance of treatment among sputum smear positive tuberculosis patients. Thus the qualitative data were analyzed by chi-square test (Pearson's chi-square for categorical data and Fisher's Exact test for binary/dichotomous data) to assess the statistical significance of the association between the factors of interest and the noncompliance of treatment among those sputum positive tuberculosis patients ($p < 0.05$).

Independent- sample(s) T-Test was used to determine the difference between mean score of difference in respect of distance (in kilometers) from home to hospital among tuberculosis patients who complied treatment and failed to comply treatment. Multiple logistic regression analysis was done to find out the confounding factors associated with noncompliance of treatment among tuberculosis patients.

4.12 ETHICAL CONSIDERATION

In any kind of research dealing with human beings, certain ethical issues must be considered. In this study there was no disadvantage for the patients who were treated previously. Before the study was conducted a written permission was obtained from the district Civil Surgeon with a copy of consent from the local hospital manager after

briefing them about the purpose of the study. The purpose of the study was also clearly described among each patient before the data collection. Each patient was asked for his willingness to take part in the study. Then he was given the right to decide whether to take part in the study or not. Each respondent was assured about the confidentiality of his answers. After obtaining consent from the patient interview procedure was followed at his home by maintaining a good rapport.

The main concern of this study was to determine the reasons / factors of noncompliance of treatment among TB patients as their treatment history was taken retrospectively.

Above all the result of this study was more beneficial than doing any harm for the patients, community and the country.

4.13 LIMITATIONS AND OBSTACLES OF THE STUDY

Due to the limitation of time and budget, this study was conducted in a single sub district hospital in Bangladesh.

Data collection was difficult, as some patients were not found in a single visit, as they were busy with their personal business. So in some cases repeated visits were necessary for interviewing them. Moreover this study might not represent the whole picture of anti tubercular treatment under DOTS Strategy in Bangladesh but could set some suggestions, which could be helpful for making future plan of action in this program.

Some of the patient's reported to have non-compliant to therapy, received treatment from other hospital / physician. But local health authorities were not notified.

In this case over estimation of the number of patients who failed to comply treatment may be done.

Another limitation was that the interviewer knew previously whether a patient had completed treatment or not. For this reason, the interview process was conducted impartially with no leading question to the patient as well as the result of the study was interpreted with caution.

There were chances of recall bias in this study. Keeping in mind the investigator always tried to reduce them by asking factual, relevant, easily communicable and understandable questions to the patients and searched the hospital documents to make correlation's of the patients answers with that documents.

4.14 IMPLICATION OF THE STUDY

- It will be helpful for the authorities concerned to produce a guideline for improving and strengthening the tuberculosis control program by removing the bottlenecks prevailing in the program.
- It will be useful for those managers responsible for planning and implementing the tuberculosis control program.
- The findings of this study will act as a guideline for the authorities concerned to disseminate the information among the population about the hazards of noncompliance of treatment, which will ultimately help to reduce the morbidity and mortality from tuberculosis in Bangladesh.
- It will be useful for health personnel in selecting topics best suited for health education that is an appropriate and effective method to expect better service.