CHAPTER IV

RESEARCH METHODOLOGY

4.1 Introduction

Research demands a clear statement of the problem and, requires a plan, which builds upon both existing data and the collection of new data, and which answers the original research question(s). IDRC (1991) reported that research is the systemic collection, analysis and interpretation of data to answer certain questions to solve a problem. In order to achieve the objectives of this study, an observational approach was used. Due to the civil conflict situation, other methods of research i.e. cohort and case-control studies would not be feasible to carry out in the study areas. Thus, a cross sectional design was proposed in this study.

4.2 Rationale for the Study Design

The epidemiological approach is basically based upon statistical principles, in the structuring of research design. From this perspective, research can be divided into two approaches: observational and experimental. Table 4.1 helps us to conceptualize the study approach and design of this study.

Table- 4.1: Study Approach and Design

Approach	Designs	
Observational	Descriptive	Cross sectional study
		Organizational surveys
	Analytic	Cohort study
		Case control study

Source: WHO, 1992

Descriptive studies entail the collection, analysis and interpretation of both qualitative as well as quantitative data (WHO, 1992). The distinctive feature of this approach is that its primary concern is with description rather than assessing causation. The descriptive study may be very useful in collecting an information database that can assist in the formulation of the plan; thereby, to address the problem in both areas, those with and; without civil conflict.

The cross sectional studies do collect data at one point of time on the population, which may comprise the whole population or a sample of the total population. The cross sectional design in health system research is used to describe the prevalence by certain characteristics, the pattern of health service utilization and compliance (WHO, 1992).

In order to determine the precise risk factors i.e. time, money, and for administrative purposes the cross sectional study may be relatively better than other research designs. A cross-sectional study aims at quantifying the distribution of certain variables in a study population at one point of time determined by questionnaire. They

may cover for example physical, socioeconomic and behavioral characteristics as well as events that occurred in the population (IDRC, WHO, 1991). Focus group discussions (FGD) can be used at the preliminary stage or at the exploratory stage of a study (Kreuger, 1988). It has been reported that during the FGD, evaluation or development of a particular program or activities can be done (Race, Hotch, Parker 1994). Thus, in order to achieve the objectives of this study, a cross-sectional study design consisting of both qualitative and quantitative methods was used.

4.3 Assessment and Application

4.3.1 Qualitative Measures

Qualitative research methods produce qualitative information, which is often recorded in a narrative form. The qualitative research method involves the identification and exploration of a number of often-related variables that give insight into the nature and causes of certain problems and into the consequences of the problems for those affected (IDRC, WHO, 1991). Basically qualitative data can be obtained through the following ways:

a. Open-ended items on a questionnaire: Not pre-categorized and which are predominantly quantifiable data.
b. Loosely structured interviews: With open-ended questions directed at key informants i.e. individual or group.
c. Observations: Description of individual and group behavior.

d. Focus Group Discussions (FGD): Discussion on selected issues using a list of points to guide the discussion.

While describing qualitative data, we should not forget its major characteristic; it describes data in words rather than in numbers (IDRC/WHO, 1991). Thus, it is useful to summarize the data in diagrams, flow charts or matrices, which help to conceptualize the findings. For the purpose of this study focus group discussions were conducted to understand the problem and to develop the plans to be used by district health facilities.

a) FGD among the heads of the district level administration, health and development offices.
b) FGD among the frontline health workers who are working in DOTS treatment centers and sub-centers.
c) FGD among TB patients both, male and female.

The information collected from FGD was reviewed critically and triangulated with quantitative data to determine the reliability of the information with the assistance of technical support from a researcher, specialized in qualitative research. In addition, the FGDs were also used in the planning process, which address specific objective number 8.

4.3.2 Quantitative Measures

Structured questionnaires that enable the researcher to quantify pre or post-categorized answers to the questions are an example of the quantitative research method. The answers to the questions can be counted and expressed numerically. Quantitative methods are used to quantify the size, distribution and association of certain variables in a study population (IDRC, WHO, 1991). Quantitative data are expressed in numbers and they are presented in different types of frequency tables. When analyzing quantitative data it is important to consider the objectives of our research. Frequently asked questions for research objectives are:

- Describe the variables.

  For example: Distribution of Tuberculosis in certain population.
- Look for differences between groups.

  For example: Differences of TB burden between the area with and without civil conflict.
- Determine the association between variables.

  For example: Association between financial affordability and access and utilization of TB services.

For the purpose of this study, both qualitative and quantitative methods were used to address objectives number one to seven. The diverse nature of civil conflict and independent variables demands the use of both methods. David (2001) noted that examining even a seemingly isolated aspect of something as complex as armed conflict

would require looking at both quantitative and qualitative data. Therefore, both qualitative and quantitative methods have been selected in this study.

4.3.3 Hypothesis

The existing burden of disease, physical availability, financial affordability, acceptability, geographical accessibility and level of civil conflict are not associated with access to and utilization of TB services in the areas with and without civil conflict (Ho).

4.3.4 Population and Samples

TB patients who are receiving their treatment from the district health facilities of the study areas are the population for this study. Due to the restraints of time and resources, the study could not carry out on all TB subjects. Thus, probability sampling was required for this study. The simple random sampling was used to select the study subjects for both questionnaire and study subject. In district level FGD, the participants (district level policy makers) were selected by using the list provided by District public health officers from both study area.

The study areas namely the districts of Dang and Lalitpur have been purposively selected. As earlier mentioned there are many differences between the study districts. However, the National Tuberculosis Center (NTC) has been implementing DOTS program in both districts. As the government declared the Dang as a highly conflict affected area, Dang District has been taken as the conflict area,

Lalitpur has not been recognized as a conflict affected District, thus it has been taken as an area without civil conflict in this study.

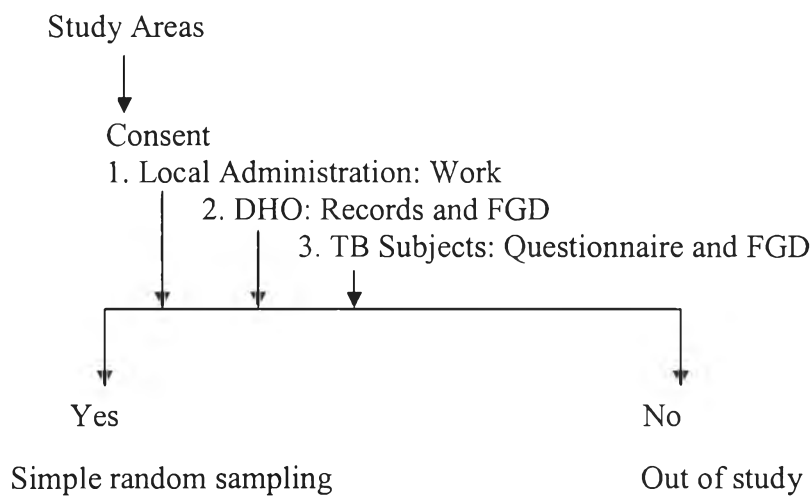
Probability samples are those in which it is possible to ascertain the probability that a unit of the population is included in the sample (WHO, 1992). Random sampling was utilized in this study. Random sampling attempts to guarantee that, each member of the population has an equal chance of being included in the sample (WHO, 1992). Two common methods were used in random sampling a) lottery and b) tables of random numbers. The lottery method was used in this study. A list of study subjects was prepared from District Health Offices of both study areas and numbered consecutively. The numbers were mixed thoroughly and, then, the subjects were selected until the required sample size was achieved. The consent forms with request letters signed by Principal Investigator (PI) were sent to 200 patients in each District. Study subjects responded promptly and properly; out of 200 requests sent, 182 in Lalitpur and 180 in Dang agreed to respond to the questionnaire.

In order to improve the consent from the TB subjects, the support of the Female Community Health Volunteers (FCHV), Maternal and Child Health Worker, Sub-Health Posts, Health Posts, Primary Health Centers and District Health Office was obtained. Figure 4.1, shows the flow chart used to select the sample population in both areas with and without civil conflict.

In both study areas, consent was obtained from the local administration for the entire study, from the District Health Office for a review of their records to determine the prevalence of TB and to identify TB patients, and from the TB patients for

qucstionnaire and FGD. In both areas, questionnaires were completed and FGD were conducted with TB patients. The subjects were those free from psychological illness and not labeled as a criminal by the state. In order to determine the individual status of the study subject, support from the local administration, health facilities and families was acquired.

Figure-4.1: Sampling Procedure in Study Areas



For the purpose of this study, the sample size was calculated by using Epi-info 6^{th} version. From the main screen, Stat-Calc was selected. After that the sample size and power were used to calculate the sample size for each specific objective. In order to acquire the bigger sample size following process has been utilized:

Table-4.2:Sample Size

Variables (% without conflict: with Conflict)	Sample Size by Using Different Power			
	80	85	90	95
Burden (55.5:34.6)	97	110	126	154
Physical availability (50:30)	103	116	134	***163***
Financial affordability (55:25)	47	53	60	73
Acceptability (60: 30)	48	54	62	75
Geographical accessibility (50:25)	65	74	85	102
Civil Conflict (60:25)	36	40	45	***54***

Since there are no existent data of the given proportions had to be hypothesized for each variable (Table 4.2). Stat-Calc calculated the maximum sample size as 163 for physical availability in which we hypothesized as 50 percent in the non-conflict area and 30 percent in the conflict area. The maximum number demonstrated in the table 4.2 was used as a minimum required sample size for each of the study areas. Thus, minimum 163-sample size in each study area had been taken in the study. In order to manage for missing data, 10 percent subjects were added to the study; making the sample size 180 subjects in each study areas.

Following statistical formula have been used by Epi-Info.

$$n = \frac{[\, p_u (1 - p_u) + p_e (1 - p_e)\,]^* (z_1 - \alpha/2 + z_1 - \beta)^2}{(p_u - p_e)^2}$$

From the above-calculated sample sizes TB subjects were selected and requested to participate in the FGD and questionnaire survey.

4.3.5 Instrumentation

Instrumentation deals with the systematic collection of information about the objects i.e. people, phenomena etc. of the study and the settings in which they occur. Although cross-sectional studies can be regarded as variants of other epidemiological designs, they have the distinguishing characteristics of always involving measurement of disease prevalence rather than incidence (Harvey, 1989). Direct interviews with structured questionnaire and focus group discussions will be used as the study instruments in the study.

An interview using a written questionnaire is a well-known instrument and will be used in this study. Most of the questions will be close-ended: however, some open-ended questions will be presented to acquire the respondent's views. Interviewers will be used to gather the data in a timely fashion. The instrument, itself, has an effect on the subject and can produce a distorted response (IDRC/WHO, 1991). In order to deal with a possible interviewer bias, the printed structured questionnaires were used in the study and following steps were followed in the study.

a) Objectives and variables will be taken as a starting point.
b) Formulating question: formulation of one or more questions that will provide information needed for each variable.
c) Sequencing of the question.
d) Formatting of the questionnaire.
e) Translation of the questionnaire into Nepali language.

The subject questionnaire was prepared and pre-tested before its use in the study areas. Simple questions over 30 minutes were asked to the study subjects of study areas. The prevalence study was made in both study areas. In order to determine the prevalence of Tuberculosis in the study areas, secondary data was used. Records from the District health facilities were searched to calculate the prevalence of TB. In regards to maintaining quality assurance, the records of TB patients from the private clinics and from I/NGOs were also used in this study. The records were obtained with the approval of the District administration offices of both Districts.

Focus group discussions were conducted with the TB subjects, and with three other groups. A focus group discussion is a group discussion with 6-12 persons guided by a facilitator, during which group members talk freely and spontaneously about a certain topic (IDRC/WHO, 1991). Focus group discussions assist us to formulate the appropriate questions, to supplement the information about the problem. For the purpose of this study; a) preparation of FGD, b) conduction of session, c) analysis of results, and c) report writing steps were adopted.

The following framework was used during FGD in the study areas. A total of eight focus group discussions (4 in Dang and 4 in Lalitpur) were conducted during the study.

Frame Work of FGD in Study Areas

Issue: Access to and utilization of health services in the areas with and without civil conflict in Nepal: A case of TB services through district health facilities

Number of participants: 7-8 people

Total Time: 120 to 160 minutes

Number of FGDs: 4 in each area: with 2 for TB Patients(1male and 1 female). One FGD, involving the chief of the local administrative office, health office and development offices and one for front line health workers of the DOTS treatment Center and Sub-Centers.

Ending: 5 minutes

1. Thanks from facilitator.

Male and female study subjects were separated for FGD and one facilitator, one reporter and one recorder was assigned during the discussion of each FGD. Persons form the same localities were included in the reporting and recording. Moreover, the same set of guiding questions and process were utilized in each FGD. Recording and picturing except written reporting were made only after obtaining consent. Training and guiding questions were provided to the facilitators and reporters of focus group discussion.

In order to implement the instruments in both areas, process and related documents were submitted to local administration. Formal approvals were obtained from local administrations and strong coordination was made with District health facilities. Good rapport with the community, strong coordination with District health

officials, civil societies and administrative approval from local administration were taken as the most necessary aspects of the study.

4.3.6 Hypothesis Testing

Testing hypotheses is an essential part of this study. In order to formulate such a test, usually some theory has been put forward, either because it is believed to be true or because it is to be used as a basis for argument, but has not been proved.

The question of interest is simplified into two competing claims / hypotheses between which, we have a choice; the null hypothesis, denoted H0, against the alternative hypothesis, denoted H1. These two competing claims / hypotheses are not, however, treated on an equal basis. For the purpose of this study special consideration is given to the null hypothesis. The null hypothesis relates to the statement being tested, whereas the alternative hypothesis relates to the statement to be accepted if / when the null hypothesis is rejected. The final conclusion once the test has been carried out; is always given in terms of the null hypothesis. We either 'reject H0 in support of H1' or 'do not reject H0'; we never conclude 'reject H1', or even 'accept H1'. For the purpose of this study, content validity reviewed by experts was used to ensure the quality. It is well understood that there is very close connection between the confidence intervals and test of hypotheses. Multiple testing was required; thus to test the significance a P-value of less than 0.05 for univariate analysis and less than 0.05 for multivariate analysis was calculated.

4.3.7 Variables

Variable is a term that comprises with characteristics of a person, object or phenomenon that can take on different values. Some variables are expressed numerically and others as categories. Numerical and categorical variables are often used in research (IDRC/ WHO, 1991). For the purpose of this study, both numerical and categorical variables were used. In order to ensure that everyone understands exactly what has been measured and to ensure that there will be consistency in the measurement, it is necessary to clearly define the variables and indicators of variables. For the purpose of the study, the following variables and indicators were used:

a. Dependant Variables:

1. Access to case detection refers to the percentage of people who can visit to District health facilities for microscopy on three occasions, Utilization based upon case detection, refers to percent of suspected cases who do visit to District health facilities for microscopy on three occasions.

2. Access to cure refers to 85 percent of diagnosed cases who can receive daily TB drugs Utilization of cure refers to 85 percent of diagnosed cases.

b. Independent Variables:

Variables	Indicators
1. Burden	Prevalence, number of diagnosed TB cases during the past five years as percentage of population and symptom of TB.
2. Physical availability	1) Percent of patients that has knowledge about TB service, availability of microscopes, Percent of patients that has knowledge about TB drugs. 2) Infrastructure: Separate checking room.
3. Financial affordability	1) Percent of population reporting problem with affordability. 2) Number of days worked by lowest paid government worker to get TB treatment.
4. Acceptability	1) Satisfaction with health services (in last visit), 2) Number of female health worker, and 3) Percent of people who first visit DOTS treatment Center or Sub-Center
5. Geographical accessibility	1) Percent of population distanced 30 minutes or more to DOTS treatment Center or Sub-Center. 2) Available means of transportation to go DOTS treatment Center or Sub-Center
6. Conflict	1) Percent of people affected by conflict, 2) # of Mass campaign organized, 3) # of Curfew declared,

4) # of Closure declared.

5) # of Casualties took place,

6) # of Killings happened

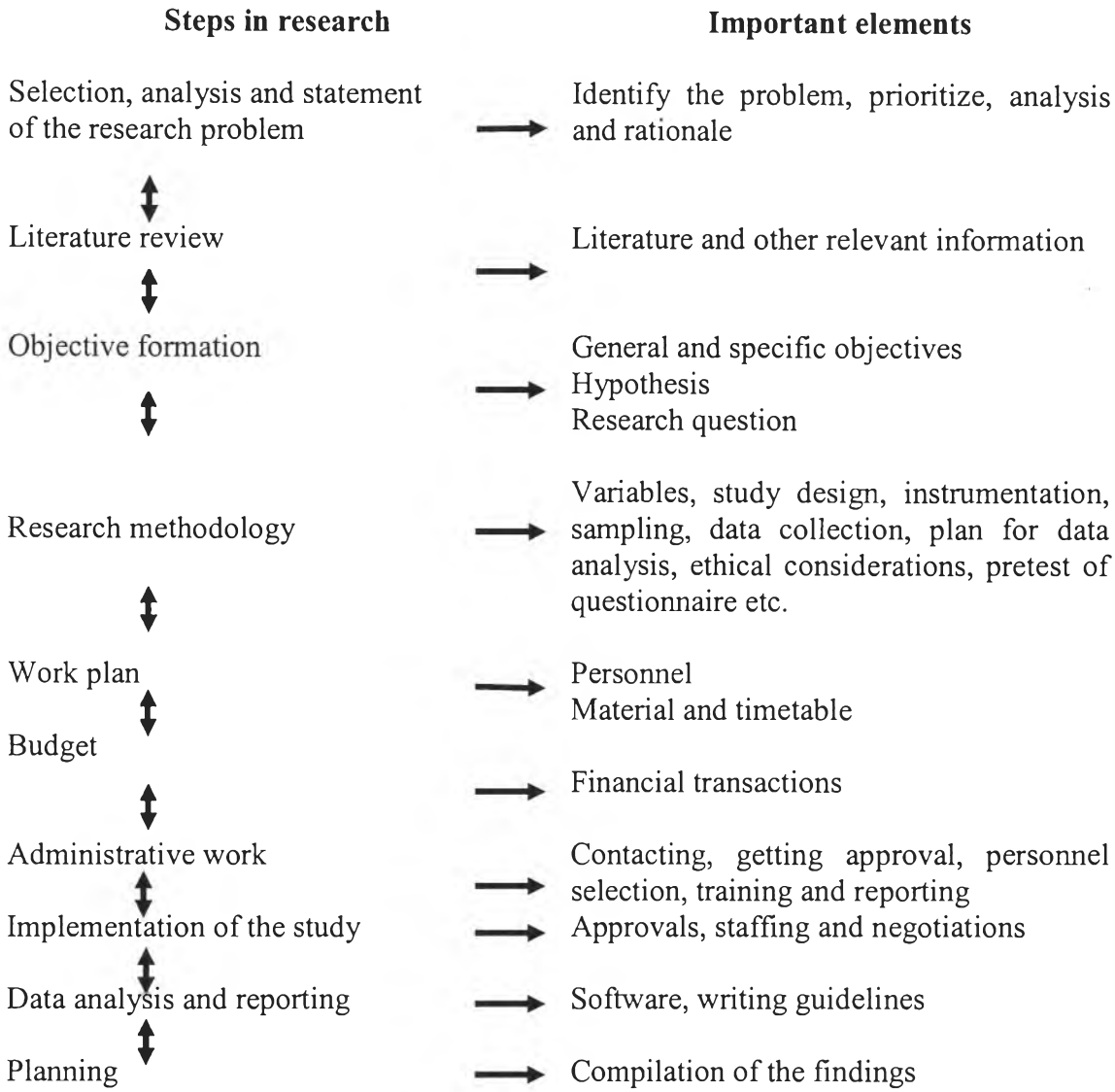
(Source: Lee, 2001, Sanhueza, 2000, Marc 2001, Stebbing 1999, DoHS 1997, Collier 2001, and NTC 2001).

The indicators mentioned in number 7 were only related with the armed conflict between His Majesties Government of Nepal and The Communist Party of Nepal, Maoist.

4.3.8 Procedures

The study process, as a whole, can be divided into three major stages a) designing, b) implementing and c) analysis. After analysis, study can play an important role to implement the study findings by impacting on the decision-making sectors. Records from different District health facilities were used to determine the prevalence of TB in the study areas. Statistical formula was used to determine the prevalence of TB. For the purpose of this study, the flowchart shown as the Figure 4.2 was used as the research procedure:

Figure- 4.2:Steps in Research



(Modified from IDRC, WHO 1991)

In order to recognize the study a copy of the proposal was submitted to the Nepal Health Research Council (NHRC) and received their Ethical Approval. At the beginning of the study a formal meeting with the National Tuberculosis Center was organized. The presentation was made during the meeting and the NTC members were asked for their comments. No comments on the study process emerged from the

meeting. Introductory meetings with Local Administration Offices and District Health Offices of both study Districts were conducted. Due to the civil conflict situation and the absence of a local government, formal approval from the District administration offices was obtained.

The questionnaires were pre-tested in Surkhet District, an area with conflict and in Banke District, an area without conflict. The pretest was done one month prior to the study. With the support from the staff of the Social Awareness Center (SAC), the PI conducted the pre-testing in both Districts. Twenty questionnaires were administered in each District. The accuracy of the language, simplicity, and cultural aspects of the questionnaire were reviewed by local researchers who have knowledge on both local language and culture. A simple modification was suggested by local researchers. Likewise, in order to ensure the quality of guiding questions for FGD, one FGD in each of the above-mentioned Districts was organized. The pre testing of FGD was organized for front line health workers. The samples, according to the calculated sample size, were collected from both District health facilities. Complete information i.e. addresses of the local health officials, administrative officials, hotels, communication stations, and journalists were taken from both study areas. The current situation of the study subjects were also explore with District TB Leprosy Assistant (DTLA).

The required research personnel i.e. interviewer and facilitators were hired. A committee comprised of principal investigator, a locally available researcher and the Chief of DHO hired the required personnel through interviews. A 3-day (including one day practical and field visit) training programs were organized in each District. The

training program included the following: facilitation skills, primary health care, Tuberculosis, objectives, questionnaire, report writing and management.

Eight focus group discussions were conducted at 3 different levels a) FGD with District level policy makers, b) Front line TB workers who are working in DOTS Treatment Centers and Sub-Centers c) TB patients (1 male and 1 female group). The same sets of guiding questions were used in all FGDs. Reports of each FGD in each District were compiled separately and triangulated. For the purpose of reliability, researchers who are the experts in qualitative research verified the reports and FGD process compiled by reporter and recorder. After completing the FGD, structured questionnaires were implemented in both Districts. After completing the data collection, data were gathered in one place and given ID numbers. After finishing a process a plan for each district was prepared and recommended to be used by district health facilities.

4.3.9 Data Analysis

In a cross sectional study, methods for comparing disease prevalence are outlined first then analytic techniques useful for comparing distributions explained (Harvey, 1989).The following steps were utilized in the data analyses:

Steps in Data Analysis

1. Preparation for analysis	Compile field reports, inventory of data and check computer output
2. Describe Variables	Frequency distribution, figures and means
3. Cleaning the quantitative data	In line with objectives
4. Analyze the qualitative data	Verbatim
5. Statistical analysis	Objectives, study design and variables
6. Report writing and presentation	Complete format of report writing, presentation, discussions for planning the interventions.

For the purpose of this study both qualitative and quantitative data were used. The quantitative data were analyzed by using SPSS computer software. Using Prevalence study, Chi-Square Test and Logistic Regression, the data were analyzed. The following table helps us to understand the data analysis

Table-4.3: Framework of the Study

Specific Objectives	Indicators	Research Tools	Statistical Calculation
To identify the prevalence of TB, in areas with and without civil conflict.	Prevalence	Secondary	Prevalence study
To explore the differences in physical availability determining access to and utilization of TB services in areas with and without civil conflict	% of population that has access to information on services and drug, # of infrastructures and # of health personnel	Direct questionnaire and FGD	Chi-square Test
To explore the differences in financial affordability determining access to and utilization of TB services in areas with and without civil conflict	% of population reported problem of affordability, # of days worked by lowest paid government worker to get TB treatment	Direct questionnaire FGD	Chi-square Test
To explore the differences in acceptability determining access to and utilization of TB services in areas with and without civil conflict	Satisfaction with health commodities, # of female health worker, % of people who visits District health facilities first	Direct questionnaire FGD	Chi-square Test
To explore the differences in geographical accessibility affecting access to and utilization of TB services in areas with and without civil conflict	% of population distanced 1 hours or more to District health facilities, # means of transportation available	Direct questionnaire FGD	Chi-square Test
To explore the differences between perception of TB subjects about civil conflict, which might influence their decision in not using the TB services in areas with and with out conflict.	% of people affected by conflict, mass campaign, curfew, closure, casualty, and killings	Direct questionnaire FGD	Chi-square Test
To explore the strength of Associations between the factors related to access to and utilization of TB services in areas with and without civil conflict.	Association with access to and utilization of TB services	Direct questionnaire	Logistic regression

The records from the District health facilities prevalence study were the primary data source, supplement by the data from the private health clinics and I/NGOs providing TB treatment for the prevalence study. The denominator of the prevalence study will be the total populations of both study Districts.

4.3.10 Validity

In all research design a primary and most important concern is on the conclusion of the study is valid and reliable. Validity means that the conclusions are true. Like wise reliability means that someone else using the same method in the same circumstances should be able to obtain the same findings (IDRC, 1991). Since this is a descriptive study, information was collected from the sample and findings were used to make conclusions about the population. The major threats are associated with sampling and data collection. Content validity review by experts was utilized in the study. Likewise a pretest of questionnaire was used to increase the reliability of the data. Following major threats are reported in different research a) confounding factors, b) history, c) differential subject loss in group, and d) instrumentation (IDRC, WHO, 1991). In order to deal with above-mentioned threats following strategies were taken in the study: a) proper randomization, b) before and implementation measurement, c) careful design and d) pre testing and e) knowledge of the environmental events.

4.3.11 Ethical Issues

It has been well understood that in an every research we need to consider whether our research procedures are likely to cause any physical and or emotional harm or not. The following considerations were taken to address the ethical issues in this study.

1. Obtaining informed consent of the participants before any part of the study begins.
2. Not exploring sensitive issues before a good relationship has been established with the informants.
3. Ensuring the confidentiality of the data obtained.

For the ethical clearance and national record of the research and its sustainability, a copy of dissertation proposal was submitted to NHRC.

4.4 Limitations

Every research has certain kinds of limitations. In order to acquire the justifiable information every researcher need to have a clear understanding of the different limitations of the research.

4.4.1 Methodological Limitations

Cross sectional study design may not explore the causes of the problem; it can only explore the situation as a snapshot. The number of study subjects and study areas can prove the limitation to generalization in national settings. FGD provided the in depth understanding on the problem; however, each focus group may not be appropriate to generalize the findings. The questionnaire has several limitations an important limitation in this study is short response may lack the cross-checking of the findings. Likewise the studies cannot explore the incidence that could be a limitation of this study.

4.4.2 Ethical Limitations

His Majesties government of Nepal has declared the state of emergency and mobilized the Royal Nepal Army nation wide. The fundamental constitutional rights of the people become limited in the country especially for civil conflict affected areas. During the focus group discussion participants were felt insecure. Due to the highly

uncertain situation participants preferred not to walk in the group because for security reason did not allow group meetings.

4.4.3 Resource Limitations

Due to the conflict situation research team could not carry the heavy materials in the field and the local market i.e. hotels and groceries were almost dismissed. Thus both money and material were the limitations of the study. In civil conflict areas nobody willing to go in and conduct the study, thus the human resource limitations was also a prominent limitation of this study. In order to mitigate the above-mentioned limitation close information back up with District administration, patients, local level researchers, journalist, health workers and civil societies were managed.

4.5 Sustainability

It is well accepted that very few public health focused research studies are being conducted in Nepal. At the central level Nepal Health Research Council (NHRC) is working as a coordinating body. However due to lack of it's networking at the peripheral levels, NHRC faces problems in lunching and monitoring research work. To overcome this difficulty local governments' i.e. DDC, Municipalities and VDC can also be mobilized to sustain the research efforts in the future. For the eventual sustainability after completing this research, a financial proposal will be submitted to potential international funding agencies for the wider implementation of this research in Nepal.