CHAPTER III

RESEARCH METHODOLOGY

3.1 Research Design

This is a retrospective cohort study for CD4+ cell and for quality of life to analyze the outcome of antiretroviral therapy among HIV/AIDS patients in Nepal and comparison between those receiving treatment and without treatment in terms of well-being. The total patients taking antiretroviral therapy in Nepal in both Non-DAART and DAART methods will be the study subjects. 42 people living with HIV without ART will be from PLWHAs in Maiti Nepal hospice.

3.2 Site of Study

This study was carried out in Kathmandu valley. The sites of the study were the Surkraraj Tropical and Infectious disease hospital, Teku Kathmandu (Teku Hospital) and Maiti Nepal. Teku Hospital is distributing antiretroviral drugs to 25 patients with HIV/AIDS, Who are on self administered therapy. Whereas Maiti Nepal, is giving directly observed antiretroviral treatment to its patients with HIV/AIDS in its own hospices. The 42 People living with HIV/AIDS in Maiti Nepal without treatment were people were selected

3.3 Population and Sample

Since the total population of patients taking ART was included in the study, therefore there was no sub sampling. The control group was selected from PLWHAs living in Maiti Nepal hospice.

3.3.1 Inclusion criteria

- The patients above 18 years administering ART in either HAART or DAART setting with informed consent and those not falling in exclusion criterion would be included in the study
- The patients with available data on health status, CD4 etc for the last 15 months will be included.
- The patients not taking any form of ART will be included in the study as control group

3.3.2 Exclusion criteria

- The HIV/AIDS patients taking ART for prevention of mother to child transmission or for post exposure prophylaxis will be excluded in the study.
- Children below 18 years will be excluded in the study.

3.4 Sampling Method

The total HIV/AIDS patients considering inclusion/ exclusion criteria were included in the study. The total respondents will be 84 in which 25 are the patients in HAART method under Teku Hospital and 17 are the patients receiving DAART in

Maiti Nepal and 42 people living with HIV in hospices of Maiti Nepal will be included in the study.

3.5 Sample Size

The sample size of the study was based on the total patients with HIV/AIDS currently under ART in Nepal. The total patients with HIV under ART in Nepal are 42; no treatment was selected on 1:1 ratio.

3.6 Research Instrument

The study will apply a quantitative method to asses the respondent's information. The data was collected using structured questionnaires by Face-to-face interviews (takes place when the interviewer asks the questions and notes the answers on questionnaire sheets). The retrospective data on health status, baseline CD4 level etc were assessed from existing records and reports.

The structured questionnaires consisted of 5 parts as follows.

Part 1: Socio Demographic Characteristics of the respondents

Part 2: Knowledge on HIV/AIDS and Treatment

Part 3: Using anti-retroviral treatments

Part 4: Source of information on HIV treatment

Part 5: Well being

3.6.1 The Patient Data were collected from

- Clinical, laboratory and virological evaluation before and during ARVT
- Initial ARV regimen and consequent changes
- Monitoring for efficacy and safety
- Clinical and immunological outcomes

3.7 Validity and Reliability

To develop research instrument, related literatures were reviewed and conceptual framework was developed accordingly. The questionnaires were adapted from previous studies in respect of well being in HAART and DAART settings. The questionnaire was adapted from NASAH (NGO in Africa) for socio-demographic characteristics, knowledge about HIV, adherence and side-effects of treatment (www.sigmaresearch.org.uk) and WHO (QOL for people living with HIV/AIDS)

The questioners were modified as per Nepalese setting. After the field test, question number 27 was omitted in final set of questionnaire since patients said they have difficulties answering the questions.

3.8 Method of Data Collection

The questionnaires was prepared in English for ethical review and translated in Nepali for field interview. The study would be carried out in the duration of 2 weeks in January-February of 2005.

3.8.1 Selection of Interviewers

The health workers from Maiti Nepal and Teku Hospital were used to conduct the interview to prevent the respondent's unwillness to discuss subjects which are sensitive, confidential, or culturally shameful to someone who they don't know.

3.8.2 Training of the Interviewers

The interviewers (Health workers) were trained on the objectives and concept of the study. They were also oriented to conduct interviews properly and to collect data with minimum errors or mistakes.

The interviewers were supervised by the researcher to ensure that quality control procedures were closely implemented and followed.

3.9 Data Analysis

The data will be processed using the SPSS version 11.5 statistical software. The researcher begin entering data on computer one day after collection to ensure the synchronization of the study activities. The errors that were made during data collection were cleaned and rectified.

3.10 Major Goals of Analysis

3.10.1 Compare symptoms and well-being between treated patient within and without DAART.

Example: The proportion of subjects with rash will be compared according to type of ARV treatment. This comparison involves categorical independent and dependent variables, so the chi-square test will be used.

3.10.2 Compare symptoms and well-being between treated and non-treated patients.

Example: The average well-being score will be compared according to treatment status. In this comparison, the independent variable is categorical (dichotomous) and the outcome variable is continuous, so the independent-samples t-test will be used.

3.10.3 Identify association of treatment status with other independent variables.

Example: Non-DAART and DAART with age; independent-samples t-test will be used.

3.10.4 Identify association of other independent variable with symptoms and QOL

Example: The average symptoms and well-being score will be compared with social support and since it is continuous variable, so independent-samples t- test will be used.

3.10.5 CD4 Cell count and the comparison of the two years data

For each subject in the dataset, the baseline CD4+ count was subtracted from the one-year CD4+ cell count, to create a new variable equal to the subject's change in CD4+ over time. My goal was to ascertain whether the mean change in CD4+ count differed with treatment status. Therefore, I used the independent-samples t-test technique to compare the mean of this new variable in the group with treatment to the corresponding mean in the group without treatment. Within the treatment group, I ran an additional independent-samples t-test to compare the mean of this variable in the DAART group to that in the Non-DAART group. (I would have used the paired t-test if my goal had been to ascertain whether the mean one-year CD4+ count differed from the mean baseline count among all subjects, without respect to treatment status.)

3.11 Ethical Considerations

In accordance to the Deceleration of the World Medical Association in Geneva, every effort to protect the right of the research subject was made. The ethical conduct was maintained throughout the study. Informed consent was sought from the study population during the field data collection. HIV/AIDS is very sensitive issue. Therefore confidentiality of the information is the one of the most important issue. The research ensured strict confidentiality, and the study subjects were not identified by name on the questionnaire.

The ethical clearance for this study was approved from Chulalongkorn University Ethical Review Committee and Nepal Health Research Council.