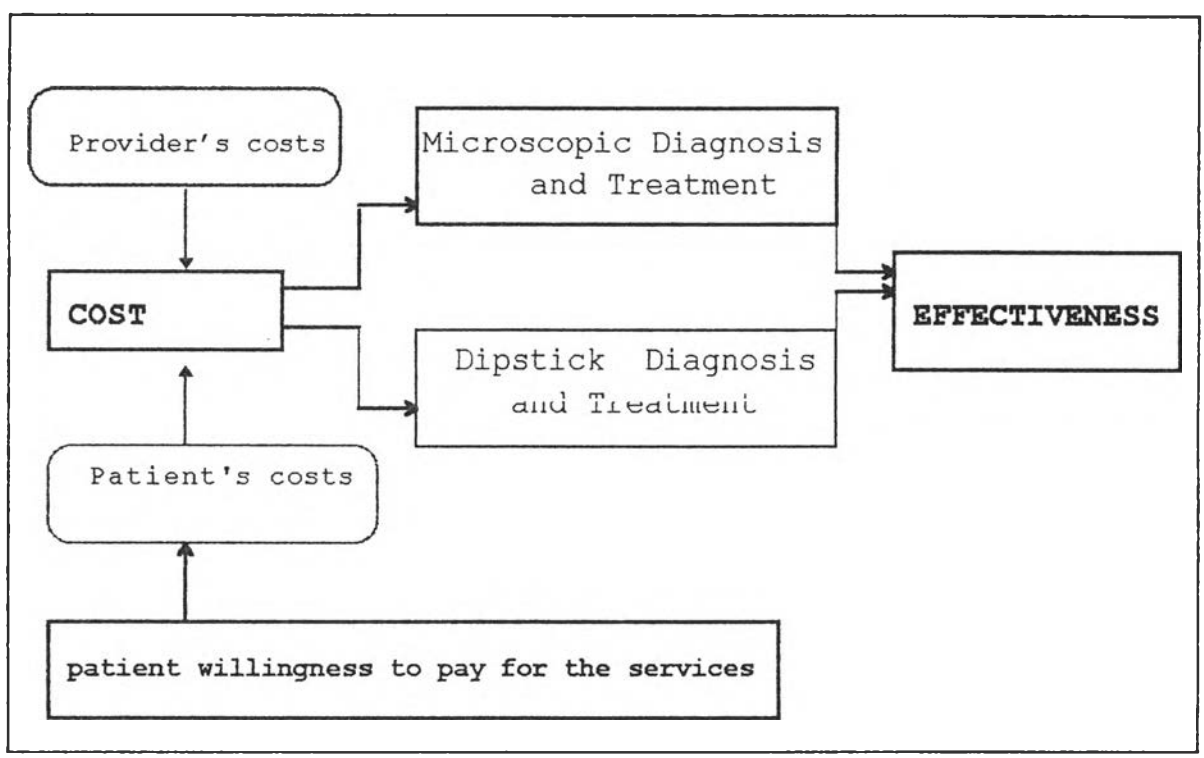
CHAPTER 3

RESEARCH METHODOLOGY

3.1 Conceptual Framework

The broad concerns of the research are presented in Figure 3.1. The current focus is the costs of provider and patient for diagnosis and treatment of malaria. For diagnosis and treatment of malaria in the malaria control project, both the provider and patient incur costs for the services rendered. The provider incurs direct and indirect costs for providing the said services and the patient incurs costs for seeking diagnosis and treatment in the MCP.

Figure 3.1 Relationship between Costs and Effectiveness of Two Diagnostic Methods for Diagnosis, and Treatment of Malaria.



The provider incurs costs for providing diagnosis and treatment of malaria at the formal service points.

The itemized cost will be included in this study. The costs of patients for seeking diagnosis and treatment are also put into this study considering that although it is free of charge at this moment they have willingness to pay for it if the service time extends to out of office hours. The factors to be considered for their willingness to pay in this study are as shown in the following equation. The ability to pay is not included in this study considering that it is not suitable to determine only by patient's interview leaving many variables which are necessary to be observed.

Willingness to Pay (WTP) = f(I,SI,QC,Tr,Oc,Sex,Edu)

I = Income of household per annum;
SI = Perceived severity of the illness;
QC = Perceived quality of malaria clinic;
Tr = Traveling time to arrive the clinic
Oc = Patient's occupation
sex = Sex different of patients
Edu = Education level of patient

Income of household : It is assumed that income of household per month/annum may affect the willingness to pay for seeking diagnosis and treatment in the MCP, *ceteris peribus*.

Perceived severity of the illness : It is assumed that if the patient suffers from severe illness, he/she will be willing to pay for the better quality of services so that to be shorten the duration of his/her suffering, *ceteris peribus*.

Perceived quality of service : It is assumed that patients will have willingness to pay for the better quality of services rendered for their illness, *ceteris peribus*.

3.2 Operational Definitions

Diagnosis and treatment : Diagnosis is firstly clinical, confirmed where possible by examination of the patient's blood leading to correct radical treatment for specific species of malaria parasite.

Existing diagnostic technology : Confirmatory diagnosis of malaria by using microscopic examination of the patient's thin and thick blood film.

New diagnostic technology : Confirmatory diagnosis of malaria by using dipstick paper (ParasightF, Becton

Dickinson Tropical Disease Diagnostics)testing of the patient's periphery blood.

Willingness to pay : A maximum amount of money to pay for diagnosis and treatment services by a person when he/she has an attack of fever(perceived as malaria).

Provider costs : Costs incurred by the malaria control project for diagnosis and treatment of malaria.

Patient's costs : Costs incurred by the patient for seeking diagnosis and treatment in the malaria clinics of the malaria control project.

Economic analysis : Economic analysis encompasses cost analysis of the existing system and cost effectiveness analysis of the two types of diagnostic method.

Effectiveness : Correctly detected and completely treated cases of malaria by using either microscopy or dipstick technology.

Perceived severity of the illness : Patient's own statement as mild, moderate and severe according to their sufferings.

3.3 Research Design

This is a methodological study for prospective application to the malaria control project in Myanmar. This methodology will be focused on(i)descriptive cross sectional study of the internal costs of existing diagnosis and treatment in the malaria control project by using available national data and appropriate hypothetical data, plus patient willingness to pay for these services using primary data to be derived from patient interview in the future, and (ii) projection of the costs of existing and new diagnostic techniques by using available epidemiological data and hypothetical data, together with sensitivity analysis.

3.3.1 Study Area

Malaria clinics of the malaria control project, which are established in 14 states/divisions. In each state/division there is one malaria clinic under the

administrative and technical guidance of the malaria control project, Myanmar.

3.3.2 Study Population

Patients attending the malaria clinics in the malaria control project for seeking diagnosis and treatment of malaria. Eligible criteria for patients to be interviewed are as follows.

Inclusion criteria : The patients attending the malaria clinics with the following criteria.

1. Ability to answer the interview questionnaire.
2. Age between 18 to 60 years old , both male and female(according to the working age group in Myanmar).

Exclusion criteria : The patients attending the malaria clinics with the following criteria.

1. Unconscious and semi-conscious patients.
2. Patients who need immediate referral to the other health facilities.
3. Patients who are unwilling to participate the interview.

3.3.3 Sampling Technique

Selection of the patient for interview will be done by multistage sampling:

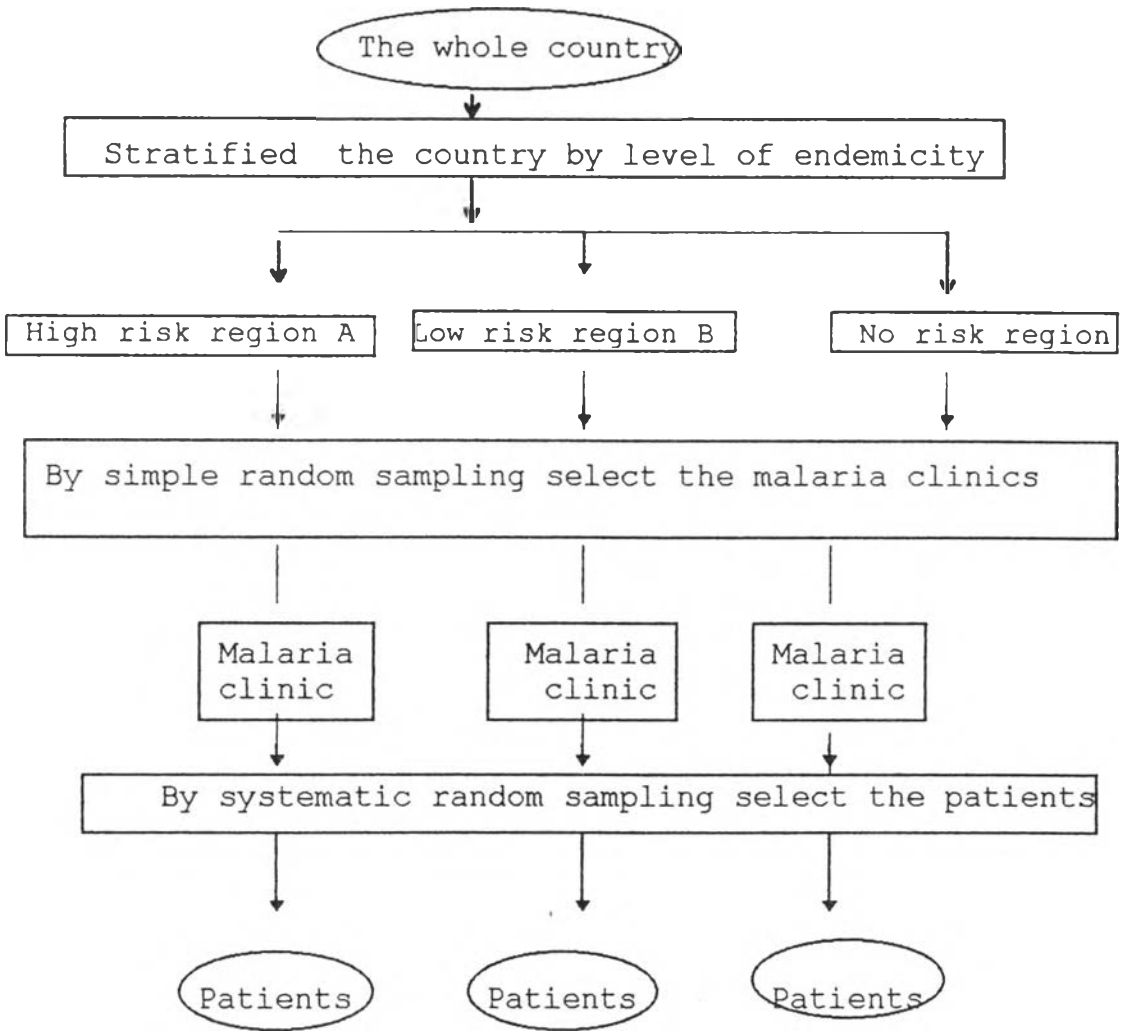
(1) Stratified sampling of the whole country. According to the level of endemicity, there are three malaria risk regions in Myanmar. Here, risk is based on level of annual parasite incidence (API).

A- High risk region
B- Low risk region
c- No risk region

(2) Simple random sampling for selection of malaria clinic as a sampling unit from each stratified region.

(3) Systematic random sampling for selection of patients attending the selected malaria clinics.

Figure 3.2 Steps Showing Selection of Patients for Interview



3.3.4 Sample Size Calculation

The required sample size for patient to be interviewed is calculated by using the following formula.

$n = z^2 * \delta^2/e^2$
n = Required sample size
z = 1.96
δ^2 = Variance
e = Margin of error

3.3.5 Study Variables

1. National budget on malaria control

2. National budget on malaria control for diagnosis and treatment section
3. Total malaria control budget of study area
4. Malaria control budget for diagnosis and treatment section of study area
5. Total training budget for laboratory technicians
6. Malaria morbidity/mortality per 100,000 population
7. Number of microscopes used for blood slide examination per annum
8. Expected number of RDT used for diagnostic examination per annum
9. Estimated % of false negatives (all species) from negative slides reexamined
10. Estimated % of false positives (all species) from positive slides reexamined
11. % of Pf cases being treated by 1st line drugs per year
12. % of Pf cases being treated by 2nd line drugs per year
13. % of Pf cases being treated by 3rd line drugs per year
14. Average time (minutes)for a technician to examine a blood slide of a patient with microscope and provide diagnosis
15. Average time (minutes)for a technician to examine the blood of a patient with RDT and provide diagnosis
16. Average travel costs, incurred by patients, per visit
17. Average travel costs, incurred by accompanying persons per visit
18. Average food costs, incurred by patients, per visit
19. Average food costs, incurred by accompanying persons per visit
20. Average materials cost per slide examined with microscope
21. Average materials cost per slide examined with RDT
22. Number of microscopes used for blood slide examination
23. Average cost of microscope
24. Average annual deprecation cost of microscope per year
25. Average cost of RDT kit per test
26. Average number of visits, by positive cases per malaria infection to non formal services prior to attending formal services
27. Average number of visits, by positive cases per malaria infection to private medical services prior to attending formal services

28. Average number of visits, by positive cases, per malaria infection to formal services
29. Average number of visits, by non positive cases per malaria infection to private medical services prior to attending formal services
30. Average number of visits, by non positive cases per malaria infection to private medical services prior to attending formal services
31. Average waiting time (minutes/hour) per visit for microscopic result and treatment at services
32. Average waiting time (minutes) per visit for RDT result and treatment at services

3.4 Data Collection

Because collection of real data is not feasible at this moment, hypothetical data are developed for analysis in this methodological study. This study mainly focus on the development of design so to be applicable in the study area.

3.4.1 Sources of Data Collection

(1) Total and average costs incurred by supply organization (MCP) (later to collect from the project documents, but only to use hypothetical data during this time-bound study period.)

(2) Costs incurred by patients (later to collect from the patient interviews, but only to use hypothetical data during this time-bound study period.)

(3) Projection of costs for using RDT will be based upon theoretical information (e.g. average time for an RDT at service), existing country data (e.g. exchange rate against the US$, population of the study area etc.)and the project documents (e.g. number of Pf cases per year, number of blood slides taken, national malaria control budget etc.)

3.4.2 Development of Structured Questionnaires

For patient interviews, the structured questionnaires including general information, cost information and their willingness to pay for the services are to be developed for immediately applicable in the study area. Appendix 4.

3.5 Data Analysis

3.5.1 Cost Component

The costs of diagnosis and treatment for malaria control are made up of two main categories: those falling on the government, and those falling on the patient, his/her family and the community. For the costs falling on the MCP, secondary data are to be collected from project documents, and the computed data are also to be applied. The data to be included are budget allotment and its functional allocation, the current value of laboratory equipment and antimalarials and the derived costs such as depreciation of laboratory equipment, building will be used. Primary data from patient interviews will be collected in future by using a structured questionnaire being developed in this methodological study.(Appendix 4). At this moment, hypothetical data from existing studies will be applied for analysis.

(I) *classification of costs* by inputs

Inputs of the MCP for diagnosis and treatment is classified into capital and recurrent costs. Those that are used up in the course of a year and are usually purchased regularly are included in the recurrent costs while those that last longer than one year are in the capital costs.

Table 3.1 Inputs for Diagnosis and Treatment in the Malaria Control Project(199..ear)

Category	Amount	Type of Data
♦ Capital		
Vehicles		Secondary data
Equipment		Secondary data
Buildings-space		Secondary data
Training-nonrecurrent		Secondary data
Subtotal, Capital		
♦ Recurrent		
Personnel		Secondary data
Supplies		Secondary data
Vehicles-maintenance		Computed data
Building- maintenance		computed data
Training-recurrent		Secondary data
Subtotal, Recurrent		
Total		

Source: Adapted from Creese and Parker(1994)

Note: 1.Personnel:Salaries and wages, along with other expenses for personnel.
2. Supplies: Material used up in the course of the year as direct inputs into the principal activities performed by the MCP. For example,antimalarials,reagent for tests,bloodslides,lancets, dipstick paper, stationary.
3. Equipment:It includes microscopes.
4.Training(recurrent): On-the job training, orientation course and short course for micriscopy/RDT for diagnosis and treatment of malaria are to be included.

(ii) The *unit cost* will be calculated thus:

$$\text{Unit Cost} = \frac{\text{Total Cost (TC)}}{\text{Quantity (Q)}}$$

A unit cost is a kind of simple average:cost per unit of output. This will be applied to some sorts of things in the analysis of the MCP.

Example: cost per case diagnosed, cost per case treated , cost per case diagnosed and treated.

(iii) The *economic cost* of major items such as a microscope will be computed as follows:

Current value : Amount to purchase a microscope at the present time.
Useful life : The expected number of years that the microscope can be useful after being purchased.
Discount Rate : To find out the discount rate used by the government.
Annualization factor: Use a standard table

$$\text{Annual economic cost} = \frac{\text{Current value}}{\text{Annualization Factor}}$$

To compare this economic cost with corresponding financial cost.

To compare this economic cost with corresponding financial cost.

$$\text{Financial cost} = \frac{\text{Current Value}}{\text{Useful Life}}$$

(iv) The *estimation of future cost* by the ingredients approach.

It involves translating the general description of malaria program is to be costed into specific resource requirements:itemizing in detail the amount and type of equipment, the quantity and types of drugs, and so forth. For each item an appropriate price is identified and the cost calculated by multiplying the quantity by the price and summing the results.

Patient costs are costs external to the MCP for seeking diagnosis and treatment of malaria. The tools for collecting these data are structured questionnaires. (Appendix 4). By using structured questionnaire, patient interviews at randomly selected malaria clinics of the MAP are to be conducted according to schedules. Supposing 100 patients at each malaria clinics(say, A B and C) areas to be interviewed and findings will be summarized as follows. Here, assuming hypothetical data and actual epidemiological data are used for calculation of costs by a Software package being developed by Somkid Kaewsonthi and Alan G. Harding at the Centre for Health Economics (CHE).

For collection of data and information such as costs of seeking diagnosis and treatment, and patients response to willingness to pay and amount to pay, interview with sample population (randomly selected patients) at the randomly selected malaria clinics will be conducted according to the schedule(see Table 3.2).

Table 3.2 Patient Costs for Seeking Diagnosis and Treatment in the Malaria Control Project

Category	Cost Items	Type of data
Direct cost	Drug cost	Primary data (patient interview)
	Laboratory cost	Primary data (patient interview)
	Travelling cost	Primary data (patient interview)
	Food cost	Primary data (patient interview)
Indirect cost	Time cost(absence from work)	Primary data (patient interview)

(v) *Willingness to pay* for diagnosis and treatment

To measure how much patients are willing to pay for the service in the MCP can be assessed by asking them directly using structured questionnaires. The factors influencing the WTP for seeking diagnosis and treatment in the MCP are explored in accordance with the structured questionnaires, and regression analysis will be applied for further analysis and interpretation. Regression analysis is a statistical technique that attempts to explain movements in one variable, the dependent variable, as a function of movements in a set of other variables, called independent(or explanatory).

Multiple regression equation of willingness to pay for independent variable is as follows:

$Y = f(Xi);$

$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \ldots\ldots\ldots + \beta_k X_k + \varepsilon_i$

Where Y_i = dependent variable(willingness to pay for diagnosis and treatment)

X's = independent or explanatory variables e.g. education level, severity of illness etc.

β_0 = regression intercept

β_i = partial regression coefficients, for i=1,...k

ε_i = error term
i = 1,2,.....N

The coefficient β_1 measures the change in Y associated with a unit change in X_1 on the assumption that all other values for the remaining explanatory varibles are held constant. Likewise the coefficient β_2 measures the change in Y associated with a unit change in X_2. Regression analysis will be done by using microTSP software. Scores are to be given to the study variables.

Sex: Male (1), female (2)

Marital status: single(1), married (2), widow(3)

Education: less than 4 years of schooling(1) between 5 to 10 years of schooling(2)more than 10 years of schooling (3)

Household income: less than 3600 kyats per year(1)between 3601 to 50000 kyats (2) between 5001 to 10000 kyats (3) more than 10001 kyats(4)

Occupation: private (1), public (2),self-employed(3) dependent(4), other(5)

Perceived severity of illness: mild(1), moderate(2), severe(3)

Perceived quality of service: poor(1), fair(2), good(3)

Traveling time: less than half hour(1), between half hour and 3 hour(2), more than 3 hour(3)

3.5.2 Effectiveness Component

The indicator for effectiveness in this study is correctly detected and completely treated cases. Because there may be different situations of malaria in Myanmar, three scenarios are to be developed in this study. The first one may be idealistic case but the latter two are to be applicable in the real situation.

Scenario-1 (The Best Case)

Assumptions

1. There are no false positives and false negatives.
2. There is no known parasite resistance to antimalarials.

Scenario-2 (The Intermediate Case)

Assumptions

1. There are false positives and false negatives.
2. There is no known parasite resistance to antimalarials.

Scenario-3 (The Worst Case)

Assumptions

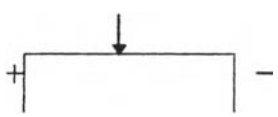
1. There are false positives and false negatives.
2. There is known parasite resistance to antimalarials.

Scenario-1 (The Best Case)= c

Scenario-2 (The Intermediate Case)= d

Scenario-3 (The worst Case)= a

False positive/False Negative



Drug Resistance		
+	++ a	b +-
-	-+ c	d --

3.5.3 Software Package Application for Calculation of Costs

To facilitate the calculation of costs a software package being developed by Somkid Kaewsonthi and Alan G. Harding at the Centre for Health Economics(CHE) for comparative analysis of the costs of existing and new diagnostic technologies will be applied. The detailed description of the software model applied in this study is given in Appendix 4.

3.5.4 Cost-effectiveness Calculation

$$\text{Cost-effectiveness Ratio} = \frac{\text{Costs}}{\text{Effectiveness (Intermediate Outcome)}}$$

In this study, the indicator for effectiveness is correctly detected and completely treated cases.

		Gold standard: Malaria	Gold standard: Non-malaria
Diagnostic Test	Positive	TP (a)	FP (b)
	Negative	FN (c)	TN (d)

True positive(TP):A positive test result in a diseased individual.

True negative(TN) :A negative test result in a non-diseased individual.

False positive(FP):A positive test result in a non-diseased individual.

False negative(FN):A negative test result in a diseased individual.

Sensitivity% = (a/a+c) X100

Specificity% = (d/b+d) X100

Accuracy% = (a+d/a+b+c+d) X100

Prevalence% = (a+c/a+ b+ c+d) X 100

Sensitivity :It is the pick-up rate of a diagnostic test. The proportion of all diseased individuals in whom the test will be positive.

Specificity :The proportion of non-diseased individuals who will have a negative test.

Table 3.4 Cost-effectiveness Analysis of Alternative Diagnostic Technologies

Alternatives	costs	Effectiveness	Cost-effectiveness Ratio %
RDT			
Microscopy			