# CHAPTER 3

## RESEARCH METHODOLOGY

This chapter will describe (1) the conceptual framework, (2) operational definitions, (3) concepts for determination of treatment seeking pattern of malaria cases, effectiveness of microscopy and dipstick, cost and cost-effectiveness of microscopy and dipstick from the provider and patient perspective, (4) scope of the study, and (5) necessary data and method of data collection for analysis of cost-effectiveness of the above mentioned two technologies.

### 3.1 The Conceptual Framework

The study is designed to analyse the cost-effectiveness of microscopy and dipstick. The effectiveness of microscopy and dipstick is determined by using the indicators namely, accuracy of each technology, percentage of on-site diagnosis, percentage of accurate on-site diagnosis and coverage in terms of geographical and financial accessibility that can be given by each technology. The cost of microscopy and dipstick for the provider are calculated from capital and recurrent costs by activity and the cost for the patient is calculated from direct and indirect costs to the activity i.e. diagnosis of malaria. The details of conceptual framework are shown in Figure 3.1.

There are four main aspects of study in the conceptual framework as shown in Figure 3.1. The first aspect is to determine the treatment seeking pattern of malaria cases. In Sri Lanka, the curative care is mainly provided by western system of medicine through teaching hospitals, base hospitals, district hospitals, rural hospitals, peripheral units and central dispensaries, under the Ministry of Health, by private sector and by individual private practitioners. Apart from western system of medicine, curative services are provided by aurveda and homeopathic practitioners. In addition to these, the patients use quacks, practice self medication by buying the drugs from pharmacies or storing drugs at their homes for future use. This section therefore determines the proportion of malaria cases that use each type of service, the reasons for preferring a particular service, whether the income or socioeconomic status of patients determine the choosing of a particular service and how much do they pay for the service. These information are necessary to determine the percentage of malaria cases that receive on-site diagnosis of malaria by microscopy, and to estimate the percentage of malaria cases would have on-site diagnosis of malaria by dipstick, and to identify the cost components of malaria diagnosis for patients. Finally, this helps to discuss the policy implications of implementation of dipstick in Sri Lanka.

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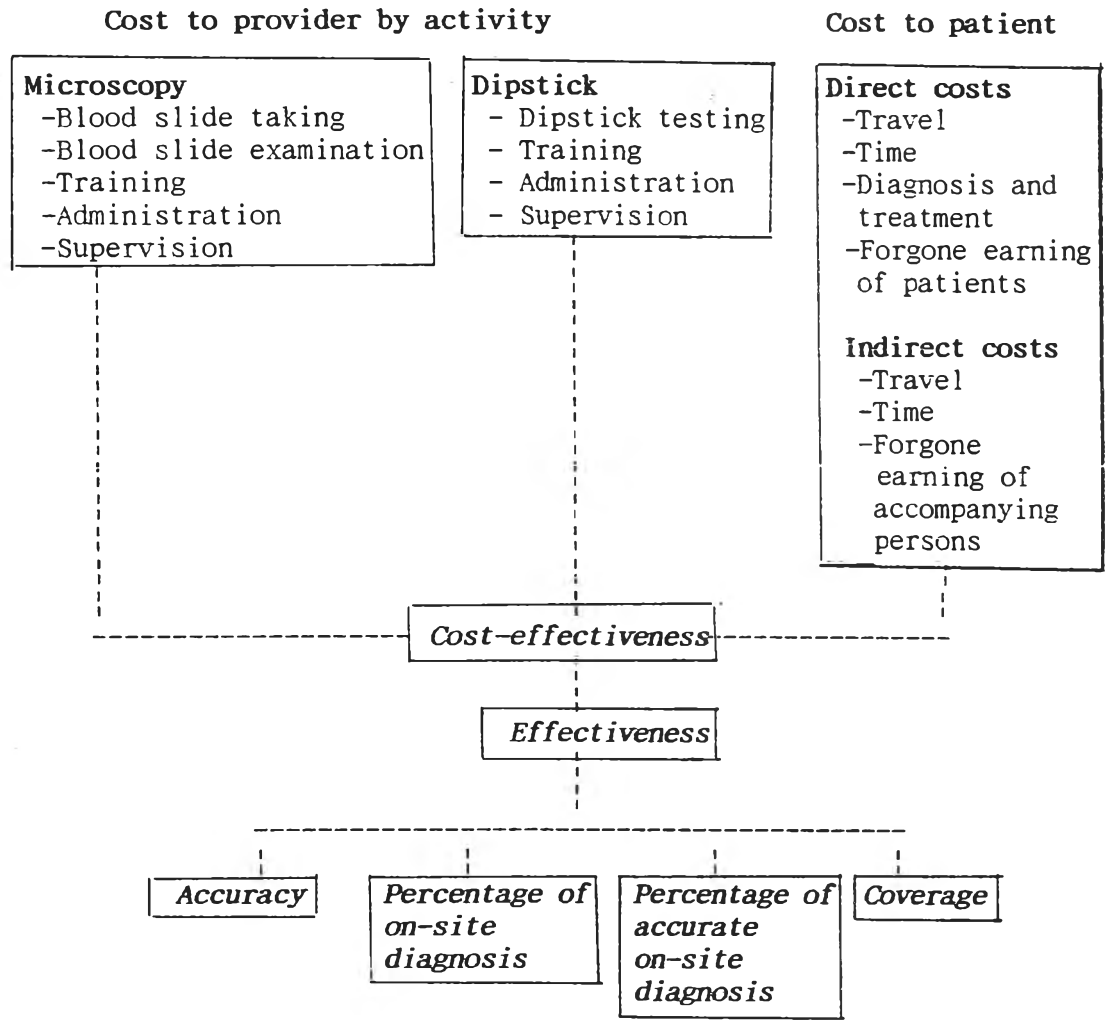
Figure 3.1 The Conceptual Framework




The second aspect of study is to determine the effectiveness of microscopy and dipstick. At present, the health facilities in Sri Lanka use microscopy as a diagnostic test for malaria. Almost all the clinical malaria cases attending at public health facilities are provided microscopic diagnosis but only a portion of them receives on-site diagnosis of malaria by microscopy due to non availability of microscopists at some health facilities. There are two types of services providing microscopic diagnosis of malaria in the public sector. In one service there is a microscopist to examine blood slides at the point of service. The microscopist is supported by a field assistant who takes the blood films from suspected malaria cases.In the other service the blood films are collected from suspected malaria cases and sent to regional laboratory for diagnosis. The blood slides are collected by a field assistant. The blood slides and the results of blood slides are delivered by the post. This system serves only epidemiological objectives. The private sector and individual private practitioners rarely use microscopy.

Four indicators namely accuracy (i.e. sensitivity, specificity, percentage of false positives, and percentage of false negatives), percentage of on-site diagnosis of malaria, the percentage of accurate on-site diagnosis of malaria and coverage are used to determine the effectiveness of microscopy and dipstick. These indicators are calculated under four scenarios which are discussed in section 3.4. The indicators for microscopy are determined using actual data, while the indicators for dipstick are estimated based on the studies carried out in Sri Lanka and in other countries. This analysis of the effectiveness of microscopy and dipstick includes both public and private sectors.

The third aspect of study is to determine the total cost for diagnosis of malaria by microscopy and dipstick. Under this section, the total cost to both public and private providers and cost to patient both at public and private health facilities for microscopy and dipstick are determined. Six types of services of providing microscopy and dipstick are considered in this study. They are (1) public service with microscopy at the point of service $s = 1$, (2) private service with microscopy at the point of service, $s = 2$; (3) public service with dipstick at the point of service, $s = 3$; (4) private service with dipstick at the point of service, $s = 4$; (5) public service without diagnostic technology $s = 5$; and (6) private service without diagnostic technology at the point of service, $s = 6$. The costs to the provider are classified as capital and recurrent costs and are calculated by activity related to microscopy and dipstick. The cost to patient is classified as direct and indirect costs according to the activities, i.e. diagnosis of malaria. The cost items and cost calculations will be discussed in section 3.5.

The fourth aspect of the study is to determine the cost-effectiveness of microscopy and dipstick based on the data mentioned in the above three aspects. This section shows how to calculate cost-effectiveness of microscopy and dipstick under three scenarios i.e. accuracy, percentage of on-site diagnosis, and percentage of accurate on-site diagnosis. The cost-effectiveness of microscopy and dipstick in public and private providers' perspective and patient perspective are discussed.

## 3.2 Operational Definitions

There are some indicators and technical terms used in this study. The definitions of them are given below.

(1) Accuracy (A)
Proportion of all test results which correctly classify individuals as diseased or non-diseased

(2) Sensitivity (SEN)
Proportion of all diseased individuals in whom the test will be positive

(3) Specificity (SPE)
Proportion of non-diseased individuals who will have a negative test

(4) Percentage of false positives (PFP)
Percentage of non-diseased individuals who will have a positive test result

(5) Percentage of false negatives (PFN)
Percentage of diseased individuals who will have a negative test result

(6) Percentage of on-site diagnosis of malaria (POD)
Percentage of malaria cases receive treatment on the result of blood slide examination on the same visit to the health service

(7) Percentage of accurate on-site diagnosis of malaria (PAOD)
Percentage of malaria cases receive correct treatment on the result of blood slide examination at the same visit to the health service

(8) Coverage (C)
Percentage of malaria cases that are geographically and financially accessible to microscopy and dipstick

(9) Recurrent cost
Expenditure on goods and services that do not last for more than one year

(10) Capital cost
Cost for the acquisition of goods and services that usually last for more than a year

(11) Direct costs
The costs to patient in travel, diagnosis and time for diagnosis of malaria itself

(12) Indirect cost
Costs incurred by the persons accompanying the patients. e.g. travel cost, time cost of accompanying person

### 3.3 Determination of Treatment Seeking Pattern of Malaria Cases

The percentage of malaria cases uses a particular health service, the percentage of malaria cases receives on-site diagnosis of malaria by microscopy and dipstick are determined by applying the concept of decision tree. The decision tree is a concept that can be used to analyse the decisions available to the decision maker and the random events of each decision, and the probability of each random

event. The decisions are taken at a decision node and the random events occur at a random node. By using the decision tree concept, the percentage of patients use a particular health service, and the percentage of patients get on-site diagnosis of malaria by microscopy and dipstick can be determined. The costs of patients incurred in diagnosis and treatment of malaria too can be determined through each branch of the decision tree. An analysis made of the decisions and alternative actions available to patients are shown in Figure 3.2.

### 3.4 Measurement of Effectiveness of Microscopy and Dipstick

In the usual practice the microscopy uses examination of 100 oil-immersion microscopic fields per slide in the diagnosis of malaria. The effectiveness of microscopy and dipstick is measured as compared to microscopy with examination of 400 oil-immersion fields which is considered as the gold standard for diagnosis of malaria for this study. As discussed earlier, the indicators used to determine effectiveness are accuracy (sensitivity, specificity, percentage of false positives and percentage of false negatives), percentage of on-site diagnosis of malaria, the percentage of accurate on-site diagnosis of malaria and the coverage which can be achieved by microscopy and dipstick. These indicators are calculated under four scenarios as described below.

#### Scenario 1 Effectiveness in terms of accuracy

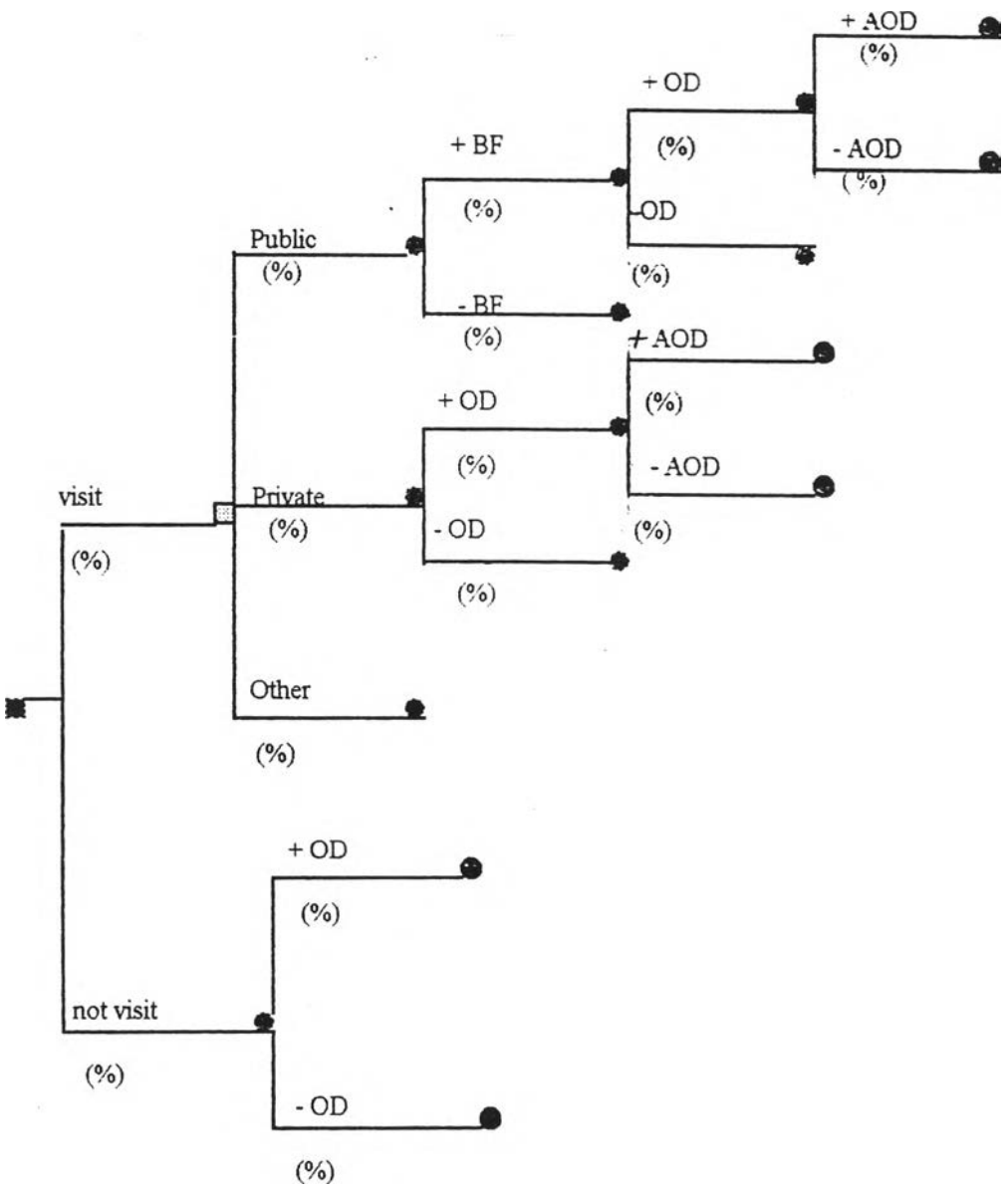
In order to determine the accuracy of one test as compared to the other the results are tabulated as follows.

| | | Gold standard + | Gold standard − |
|---|---|---|---|
| Test results | + | TP | FP |
| | − | FN | TN |

where

TP = True positive (positive test result in a diseased individual)
FP = False positive (positive test result in a non-diseased individual)
FN = False negative (negative test result in a diseased individual)
TN = True negative (negative test result in a non-diseased individual)

Figure 3.2 Decision Tree for Analysing the Decisions of Using a Particular Health Facility and the Resulting Events, i.e. Accurate On-site Diagnosis at Each Facility




where

BF = Blood filming for malaria
OD = on-site diagnosis for malaria
AOD = Accurate on-site diagnosis of malaria

$$A_s = \frac{TP_s + TN_s}{TP_s + FP_s + FN_s + TN_s} \times 100 \quad (1)$$

$$PFP_s = \frac{FP_s}{TP_s + FP_s + FN_s + TN_s} \times 100 \quad (2)$$

$$PFN_s = \frac{FN_s}{TP_s + FP_s + FN_s + TN_s} \times 100 \quad (3)$$

$$SEN_s = \frac{TP_s}{TP_s + FN_s} \times 100 \quad (4)$$

$$SPE_s = \frac{TN_s}{FP_s + TN_s} \times 100 \quad (5)$$

Where

A = Accuracy
PFP = Percentage of false positives
PFN = Percentage of false negatives
SEN = Sensitivity
SPE = Specificity
s = 1,2,3 and 4
- s = 1 is public service with microscopy at the point of service
- s = 2 is private service with microscopy at the point of service
- s = 3 is public service with dipstick at the point of service
- s = 4 is private service with dipstick at the point of service

**Scenario 2 Effectiveness in terms of percentage of on-site diagnosis of malaria**

Assumptions

1. No false positives and false negatives
2. The behaviour of doctors ordering blood checking ($NOD_s$) is not changed for microscopy and dipstick.

$$POD_s = \frac{NOD_s}{RNT_s} \times 100 \quad (6)$$

where

POD = Percentage on-site diagnosis of malaria
$NOD_s$ = Number of patients receive on-site diagnosis by microscopy/dipstick at service s = 1,2,3 and 4
$RNT_s$ = Number of clinical malaria patients attending services s= 1,2,3 and 4.

**Scenario 3 Effectiveness in terms of percentage of accurate on-site diagnosis of malaria.**

Assumptions

1. The doctors behaviour of ordering for blood checking does not change by dipstick or microscopy.

$$PAOD_s = \frac{NOD_s - (FP_s + FN_s)}{RNT_s} \times 100 \qquad (7)$$

where

PAOD = Percentage of accurate on-site diagnosis of malaria

**Scenario 4 Effectiveness in terms of coverage**

$$C_s = \frac{NACC_s}{NMC} \times 100 \qquad (8)$$

where

C = Coverage
NACC = Number of malaria cases accessible to microscopy/dipstick
NMC = Number of malaria cases in the area

To determine the effectiveness of microscopy and dipstick in terms of coverage by the public and private sector, the proportion of malaria patients receive blood tests at those sectors are to be determined. The method of determination of coverage is discussed in subsequent sections.

### 3.5 Measurement of Costs for Microscopy and Dipstick.

The third aspect of study is to determine the cost to both public and private provider and for the patients for microscopy and dipstick in the six services mentioned earlier. The costs are classified by activity related to microscopy and dipstick, and the cost items which are common to both diagnostic tests are not considered for

the analysis. The capital and recurrent costs of each activity is determined for the provider of microscopy and dipstick. The capital costs are the costs of items that are used for more than one year. In this analysis the capital costs are the cost of vehicles, and cost of microscopes and cost of initial training of microscopists and dipstick testers. The recurrent costs are the costs that are used up in a year. The recurrent costs concerned in this study are the costs (1) of personnel, i.e. microscopists, blood slide takers, supervisors and administrators (2) of supplies, i.e. glass slides, stains, dipstick etc. (3) of operation and maintenance of vehicles, i.e. fuel, tyres, registration, insurance, spare parts etc. and (4) cost of in-service training. When calculating the cost of an activity which use personnel with multiple functions, the costs of personnel allocated to that activity is determined based on the time of personnel spent on that activity. When a vehicle is used for several functions, the cost of vehicle allocated to a particular activity is determined on the basis of travelling for that activity. The cost of capital assets for a year is determined by calculating the annual economic cost of that item.

For calculating costs for the patients, the direct and indirect costs of activities related to diagnostic tests are determined. The direct costs are the costs to the patient, i.e. cost of travel to service point, cost of diagnosis of malaria and cost of time spent for attending the service point. The indirect costs are the costs of travel and time of the accompanying person of a patient. The cost of time of a patient or an accompanying person is determined based on the minimum wage rate of a person in Sri Lanka.

In the determination of costs, the real data are used for microscopy. For the dipstick, the costs are estimated based on expert opinion and the related literature.

The malaria control models, model 1 and model 2, developed by Kaewsonthi and others (1996) are used to calculate the total and average cost of microscopy and dipstick for the provider as well as for the patient. The description of the two models are shown in Appendix C.

### 3.6 Measurement of Cost-effectiveness of Microscopy and Dipstick

The fourth aspect of study is to determine cost-effectiveness of microscopy and dipstick in both provider and patient perspective. The cost-effectiveness of microscopy and dipstick in provider perspective is determined under the first three scenarios of effectiveness mentioned in section 3.4. i.e. the accuracy, percentage of on-site diagnosis, and percentage accurate on-site diagnosis.

**Scenario 1 Cost-effectiveness of microscopy and dipstick in terms of accuracy**

Cost-effectiveness of microscopy of scenario 1 at service s = 1 ($CE_{11}$)

$$CE_{11} = \frac{TC_{m1}}{((TP_1 + TN_1)/(TP_1 + FP_1 + FN_1 + TN_1)) \times 100} \quad (9)$$

Cost-effectiveness of microscopy of scenario 1 at service s = 2 ($CE_{12}$)

$$CE_{12} = \frac{TC_{m2}}{((TP_2 + TN_2)/(TP_2 + FP_2 + FN_2 + TN_2)) \times 100} \quad (10)$$

Cost-effectiveness of dipstick of scenario 1 at service s = 3 ($CE_{13}$)

$$CE_{13} = \frac{TC_{d3}}{((TP_3 + TN_3)/(TP_3 + FP_3 + FN_3 + TN_3)) \times 100} \quad (11)$$

Cost-effectiveness of dipstick of scenario 1 at service s = 4 ($CE_{14}$)

$$CE_{14} = \frac{TC_{d4}}{((TP_4 + TN_4)/(TP_4 + FP_4 + FN_4 + TN_4)) \times 100} \quad (12)$$

Where

$TC_{m1}$ = Total cost for microscopy at service s = 1
$TC_{m2}$ = Total cost for microscopy at service s = 2
$TC_{d3}$ - Total cost for dipstick at service s = 3
$TC_{d4}$ = Total cost for dipstick at service s = 4

**Scenario 2 Cost-effectiveness of microscopy and dipstick in terms of percentage on-site diagnosis of malaria**

Cost-effectiveness of microscopy of scenario 2 at service s = 1 ($CE_{21}$)

$$CE_{21} = \frac{TC_{m1}}{(NOD_1 / RNT_1) \times 100} \times 100 \quad (13)$$

Cost-effectiveness of microscopy of scenario 2 at service s = 2 ($CE_{22}$)

$$CE_{22} = \frac{TC_{m2}}{(NOD_2 / RNT_2) \times 100} \times 100 \quad (14)$$

Cost-effectiveness of dipstick of scenario 2 at service s = 3 ($CE_{23}$)

$$CE_{23} = \frac{TC_{d3}}{(NOD_3 / RNT_3) \times 100} \times 100 \quad (15)$$

Cost-effectiveness of dipstick of scenario 2 at service s = 4 ($CE_{24}$)

$$CE_{24} = \frac{TC_{d4}}{(NOD_4 / RNT_4) \times 100} \times 100 \quad (16)$$

**Scenario 3 Cost-effectiveness of microscopy and dipstick in terms of percentage of accurate on-site diagnosis of malaria**

Cost-effectiveness of microscopy of scenario 3 at service s = 1 ($CE_{31}$)

$$CE_{31} = \frac{TC_{m1}}{(((NOD_1 - (FP_1 + FN_1)) / RNT_1) \times 100} \times 100 \quad (17)$$

Cost-effectiveness of microscopy of scenario 3 at service s = 2 ($CE_{32}$)

$$CE_{32} = \frac{TC_{m2}}{(((NOD_2 - (FP_2 + FN_2)) / RNT_2) \times 100} \times 100 \quad (18)$$

Cost-effectiveness of dipstick of scenario 3 at service s = 3 ($CE_{33}$)

$$CE_{33} = \frac{TC_{d3}}{(((NOD_3 - (FP_3 + FN_3)) / RNT_3) \times 100} \times 100 \quad (19)$$

Cost-effectiveness of dipstick of scenario 3 at service s = 4 ($CE_{34}$)

$$CE_{34} = \frac{TC_{d4}}{(((NOD_4 - (FP_4 + FN_4)) / RNT_4) \times 100} \times 100 \quad (20)$$

The cost-effectiveness can not be calculated for services s= 5 and s = 6, since these services have no microscopy at the point of service. But the provider incurs some cost to provide the microscopic diagnosis of the blood films collected at service s = 5 and s = 6. Therefore, the total costs incurred for providing microscopy (indirect microscopy) at those services are calculated in order to see what is the total cost of microscopy and to see what will be the total cost of dipstick at that service if dipstick is introduced at that service.

**Cost-effectiveness of microscopy and dipstick to the patient**

Cost-effectiveness of microscopy to the patient at service s ($PCEM_s$)

$$PCEM_s = \frac{PTCM_s}{(((NOD_s - (FP_s + FN_s))/ RNT_s) \quad x\ 100} \times 100 \qquad (21)$$

Cost-effectiveness of dipstick to the patient at service s ($PCED_s$)

$$PCED_s = \frac{PTCD_s}{(((NOD_s - (FP_s + FN_s)) / RNT_s) \quad x\ 100} \times 100 \qquad (22)$$

where

$PTCM_s$ = Total cost for patient for microscopy at service s
$PTCD_s$ = Total cost for patient for dipstick at service s

Using these concepts, a methodology has been developed to determine the cost-effectiveness of microscopy and dipstick in Sri Lanka. The methodology is discussed in subsequent sections.

## 3.7 The Scope of This Study

This study will be carried out in Sri Lanka and will cover the whole island. The land area of the island is 65,610 sq.km and the estimated mid year population is 17.9 million in 1994. The country has 22 districts but, due to the unstable situation in the Northern, Eastern and North-Eastern parts of the island, four districts in these areas will not be included in the study. Therefore, the study covers only 18 districts in the country.

Population in this study is the public and private health facilities that provide curative care for malaria. The study uses multi-stage sampling technique to select the sample of study units. That is, nine out of the 18 districts are selected randomly and within each selected district the public and private health facilities are selected randomly. All the patients attending these services are included for the data on patients. The sample size is calculated by using the formula

$$n = \frac{Z\alpha^2 \sigma^2}{L^2}$$

where

n = sample size required
$\alpha$ = 95% confidence interval
$\sigma$ = estimated standard deviation
L = Acceptable scientific tolerance

The study tests the below mentioned hypothesis.

1. $H_0 : CE_m(pr) = CE_d(pr)$ for public and private provider
   $H_a : CE_m(pr) \neq CE_d(pr)$ in terms of accuracy, on-site diagnosis and accurate on-site diagnosis
2. $H_0 : CE_m(p) = CE_d(p)$
   $H_a : CE_m(p) \neq CE_d(p)$

where

$CE_m(pr)$ = Cost-effectiveness of microscopy for the provider
$CE_d(pr)$ = Cost-effectiveness of dipstick for the provider
$CE_m(p)$ = Cost-effectiveness of microscopy for the patient
$CE_d(p)$ = Cost-effectiveness of dipstick for the patient

## 3.8 Data Collection

The necessary data, source of data and the tools used to collect these data on treatment seeking pattern, effectiveness of microscopy and dipstick and the cost of microscopy and dipstick are discussed here.

### 3.8.1 Data on Treatment Seeking Pattern

The treatment seeking pattern of malaria cases includes the services where the malaria patients have sought treatment, i.e. public, private, and other health facilities including self medication, the percentages of malaria cases use each service, the reasons for preferring a particular service, and their direct and indirect cost for seeking care at a particular service.

In order to collect data on treatment seeking pattern of malaria cases, the study first identifies the medical services where curative care is provided for malaria. i.e. public, private and other informal health facilities. The list of public and private services can be obtained from the Ministry of Health and at the Medical Council. The other services are identified by interviewing village heads. The numbers of malaria cases attending each service are identified by conducting surveys. The survey includes the collection and examination of blood slides from clinical malaria cases on randomly selected days of the year from randomly selected health facilities. Two monthly fever surveys are carried out to identify the malaria cases which had

not visited any health facility for treatment for malaria. By studying these data the percentage of malaria cases use a particular service can be determined. The data on why a particular service is preferred by patients and the cost of using that service are collected by using a questionnaire.

### 3.8.2 Data on Effectiveness of Microscopy and Dipstick

The effectiveness of microscopy and dipstick is measured by accuracy, percentage of on-site diagnosis, percentage of accurate on-site diagnosis and coverage by microscopy and dipstick.

In order to determine the accuracy, the TP, FP, TN and FN of microscopy and dipstick have to be determined. The TP, FP, TN and FP for microscopy are obtained from the cross-checking laboratory at the NMCP/ HQ. A sample of cross checking laboratory results too is rechecked at Malaria Research Unit in the University of Colombo. The TP, FP, TN and FN for dipstick are obtained by studying the research carried out in Sri Lanka and in other countries, and on expert opinions.

To determine the percentage of on-site diagnosis of malaria by each test, the data on the number of malaria cases attending a particular service ($RNT_s$), and the number of patients get/ would get on-site diagnosis by microscopy and dipstick, ($NOD_s$) at that service have to be collected. Within the public sector, these data for microscopy can be obtained by the records maintained at public health facilities. The percentage of malaria cases that will have on-site diagnosis in the public health facilities by dipstick can be estimated by using some of the data collected for microscopy. i.e. the $RNT_s$ for microscopy and $RNT_s$ for dipstick are the same, but $NOD_s$ for dipstick has to be estimated. The on-site diagnosis that can be given by dipstick ($NOD_s$) in the public sector is estimated by collecting the data on number of blood films collected in the public sector and what percentage of them can be examined on-site if dipstick is available.

To determine the percentage of malaria cases that will have on-site diagnosis by dipstick in the private sector, the private practitioners are interviewed about whether they would like to have dipstick as a diagnostic test for malaria, if so what are the percentages of malaria cases who will be able to buy dipstick at a range of prices of dipstick. Since it is not difficult to obtain the percentage of malaria cases using the private sector, it is possible to estimate the number of malaria cases who will have on-site diagnosis by dipstick in the private sector too.

Based on the data collected on accuracy and percentage of malaria cases having on-site diagnosis, the percentage of malaria cases having accurate on-site diagnosis can be calculated.

To determine the coverage the existing criteria for providing diagnostic facilities for malaria have to be studied. This information can be obtained by discussions with the Director of the NMCP. Based on

this information, the number of medical institutions and the population can be covered by microscopy and dipstick can be determined/estimated for the public sector. In the private sector, the coverage is equal to the percentage of malaria patients that receive on-site diagnosis by each technology. By using this information, the coverage that can be given by microscopy and dipstick can be determined.

### 3.8.3 Data on Costs for Microscopy and Dipstick.

In this section, the data on costs for microscopy and dipstick for the public and private provider and to the patient are discussed. To determine the cost for microscopy at services s = 1,2,5 & 6 and dipstick at services s = 3 & 4 for the provider and for the patient, the cost of activities associated with microscopy and dipstick are to be collected. These activities and the models for calculating cost of each activity, calculating total and average costs of microscopy and dipstick are discussed in section 3.5. The components of cost data for calculating cost of microscopy are obtained from both primary and secondary sources, by using existing records, questionnaires and interviews. Some cost data are derived by using primary or secondary data to calculate the cost of a particular activity.

The cost data for the patients and for the private health sector is collected by using questionnaires. These questionnaires are given in Appendix D and E.

The collected data are tabulated and summarised. The cost-effectiveness of microscopy and dipstick in both public and private provider and patient perspective are summarised as percentages. The patient data on treatment seeking behaviour also summarised as percentages. The tabulation, summarisation and analysis of data are shown in Chapter 4.