CHAPTER 1

INTRODUCTION

1.1 Background

Despite considerable efforts, malaria is still the most prevalent and the most devastating parasitic disease in the tropics. It is a public health problem today in more than 90 countries, inhabited by a total of some 2,400 million people. Worldwide prevalence is estimated to be of the order of 300-500 million clinical cases and the mortality to be in the range of 1.5 to 2.7 million deaths each year. It threatens about 40% of the world's population, undermining the health and welfare of families, endangering the survival of children, debilitating the active population and straining both countries' and people's scarce resources by excessive public health costs, low productivity and impaired growth (World Health Organization [WHO], 1993).

Since malaria varies throughout the world, there is no single formula for its control in all countries or situations. The key is competent local action. The ultimate goal of malaria control is to prevent mortality and reduce morbidity and social and economic loss, through the progressive improvement and strengthening of local and national capabilities.

Evans (1992), citing the World Bank Report (1991) stated that many developing countries had experienced a period of economic stagnation since the early 1980s and this, combined with a dramatic reduction in private sector lending to developing countries, restricted the ability of governments to raise revenue. Yielding to the pressure by international lending agencies to make structural adjustments to their economies, there had been a reduction in the size of the government sector with corresponding incentives to stimulate an efficient private sector. Accordingly, government expenditure fell in many countries. At the same time the demand for health care continued to rise, partly as a result of population growth, but also

because of the epidemiological transition. While non-communicable diseases, which are often technology-intensive and expensive to treat are replacing communicable diseases as the major causes of mortality and morbidity among the more affluent groups in the developing countries, the latter diseases have not been controlled and remain dominant causes of ill health among the less affluent. Governments have, therefore had to face increasing pressure on their health budgets and growing dilemmas about the types and quantity of care to provide.

Resistance of *Plasmodium falciparum* to drugs has probably has become the most important threat to effective control of the disease. Asymptomatic cases appear to play a major role in the persistence of malaria in endemic foci and are difficult to eradicate. Although Giemsa-stained thick blood film examination is still the best technique for malaria diagnosis now available it is time-consuming and labor intensive, especially when the parasites are infrequent in the blood or are absent at the time of testing (Tanpradist and other, 1995). Waiting time for proper diagnosis and treatment in remote areas is costly for patients and their families, and most of them are poor. Although rapid on-site diagnosis allows immediate radical treatment, reducing presumptive drug wastage as well as reducing waiting time, morbidity and mortality, it is necessary to make the radical drugs available at the same site. This means putting these drugs into a greater number of hands, some with meager training. It also calls for extension of drug distribution networks, more extensive quality assurance systems, careful monitoring of drug usage and of outcomes (Indaratna and Kidson, 1995).

Malaria has been identified as the most important public health problem in Myanmar. In the first People's Health Plan (PHP) covering the period from 1978 to 1982 malaria was the first priority disease out of 51 diseases. For the second PHP from 1982 to 1986 it stood as the second priority disease next to diarrhoeal diseases. It is still in a priority list in the third PHP for 1986 to 1990 and the first National Health Plan (NHP) for 1991 to 1992. The incidence of malaria remained more or less stable with little yearly fluctuations up to 1987. The number of positive cases increased from 66,643 (Annual Parasite Incidence 1.74/1000 population) in 1987 to 94,736 (Annual Parasite Incidence 2.43/1000 population) in 1988. The Annual

Parasite Incidence in 1993 was 2.7/1000 population. Since 1985 there has been a progressive increase of reported malaria deaths from 8.2/1000 population to 12.6/1000 population in 1991. The reported deaths in 1993 were 9.8/1000 population. The falciparum malaria accounted for more than 80% of the cases and falciparum vivax ratio increased year by year. About 36% of the total population in the country reside in areas regarded as high risk. The prevalence of malaria is high with intense and there is poorly developed health infrastructure in some areas. Fifty five percent of the population reside in areas of low risk where the prevalence is low, transmission is sporadic and the health infrastructure is well developed. The remaining 9% stay in urban areas (the large cities of Yangon and Mandalay) where malaria transmission has never been detected or established (Vector Borne Diseases Control Program, 1993). Blood slide examination and positive rate from the same report are shown in Table 1.1

Table 1.1: Blood Slide Examination and Positive Rate

Year	Total Examined	Active Case Detection (ACD)	Passive Case Detection (PCD)	Other	No. Slide Positive (%)
1991	1,038,248	473,936	544,526	19,883	126,967 (12.23)
1992	899,237	425,565	458,007	14,665	125,710 (13.98)
1993	746,166	350,567	378,775	16,824	116,724 (15.64)

Source : Vector Borne Diseases Control Program, Annual Report 1993.

1.2 The Problem

Because of the continuous intensification and spread of resistance to antimalarial drugs among parasites which poses a serious threat of increased severity of disease and death, the problem is qualitatively becoming more difficult to manage. Quantitatively, the number of foci of intense malaria transmission is increasing because of changing environmental conditions in areas of intense economic development and the spread of malaria to areas previously free of disease, as millions of people move into malarious areas to claim land, seek transmission wealth or escape civil disturbances and war (WHO, 1993).

Among the major problems faced by malaria control programs is lack of both financial and technical resources for implementing their malaria control programs in many countries. In many parts of the world where malaria endemicity is comparatively low, especially in Asia and Latin America, malaria control programs persist in promoting incomplete presumptive treatment for febrile patients and sometimes their relatives, and radical treatment only for slide-confirmed cases. However, since slide confirmation of malaria may take many days, this practice is not conducive to good patient care and usually it is not even epidemiologically sound or cost-effective. The principle should be that patients everywhere who are suspected of having malaria must receive full treatment without delay.

The global definition based on assumption of malaria if the patient presents with fever that has no other clear cause, either alone or with accompanying symptoms lacks both sensitivity and specificity. The case definition of malaria cannot be uniform throughout the world. It will vary according to how malaria is perceived by the populations in different areas, by its local pattern of transmission and its disease consequences. It will also be influenced by logistic factors, including the level of the health service at which diagnosis is made and the methods available for treatment (WHO, 1993).

It is seen from Table 1.1 that the slide positive rate in Myanmar is around 12 % to 15 %. If presumptive treatment is given to all the cases from whom the slides have been taken, it

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is apparent that the proportion of those who have been given treatment unnecessarily is considerable, assuming the standard and quality of microscopy is reliable. Apart from the wastage of drugs there can also be other problems of drug resistance, missing or delayed treatment for other illnesses misdiagnosed as malaria. Although it is undeniable that it is a safe approach when the interruption of disease transmission is desirable, other factors just mentioned should also be taken into consideration. In endemic areas most cases of malaria are diagnosed on clinical grounds without laboratory confirmation of parasitaemia. The diagnosis is based on presence of fever or history of fever. Since fever is a nonspecific symptom and can be due to many acute illnesses, many patients thus treated may not have malaria (Genton and others, 1994). Clinical finding are insufficiently specific to identify which cases with or history of fever have or do not have malaria. In highly endemic areas persons with fever should be treated for malaria even when signs of another causing illness are present (WHO, 1992).

In the absence of laboratory support better clinical judgment based on criteria strong enough to predict the occurrence of attack of malaria is needed. Misdiagnosis of malaria can result in either giving anti-malarials to a person without malaria or missing another disease presenting with similar clinical features; both outcomes are not without costs. Giving drugs unnecessarily means waste of resources or exposing the patient to the side effects of the drugs without any benefits. Missing of other serious diseases associated with fever can result in severe morbidity or mortality.

1.3 Rationale

The four basic technical elements of the Global Strategy for malaria control are: to provide early diagnosis and prompt treatment; to plan and implement selective and sustainable preventive measures including vector control; to detect early, contain or prevent epidemics; to strengthen local capacities in basic and applied research to permit and to promote the regular assessment of a country's malaria situation, in particular the ecological, social and economic determinants of the disease. Implementation of the Global Strategy should affect many current practices by changing the way in which the malaria problem is

addressed. With regard to disease management it should improve diagnosis and treatment , especially for severe and complicated malaria, by focusing early diagnosis and prompt treatment on those at most risk (WHO, 1993).

Early diagnosis and adequate treatment are basic elements of any malaria control program. This will shorten the duration of disease, prevent the development of complications and prevent the great majority of deaths from malaria. Despite the problems of drug resistance, falciparum malaria remains potentially curable affliction. Access to early diagnosis and treatment should be seen not only as a component in any malaria control program, but as a fundamental right of all populations affected by malaria. Determination of a patient's clinical signs and symptoms not only is an acceptable basis for the management of malarial disease, but can produce effective and standardized medical care.

The capacity to assess patients presenting with acute febrile illnesses is required at every level of the health services. Algorithms and treatment guidelines are recommended and they should be developed and tested under local conditions. Diagnostic criteria for febrile illness should be developed in an integrated format to cover the broad range of diseases that can manifest with fever in defined age groups.

In the absence of microscopy, reliance will have to be placed more on the clinical criteria strong enough to predict attacks of malaria. Although diagnostic techniques are becoming better and more precise, it is undeniable that clinical judgment still can not be neglected. By identifying and determining both the sensitivity and specificity of relevant clinical features it is expected that malaria could be diagnosed or excluded more accurately where microscopy or other more advanced procedures are not available. In addition, a methodology for estimating costs and outcomes of introducing a diagnostic procedure or process should also take into consideration those that can result from their inherent properties (i.e. sensitivity and specificity) to make the picture more complete. Presumptive treatment may be potentially inappropriate in areas with great seasonal variation in incidence of malaria.

It is true that the signs and symptoms of malaria are nonspecific and to have a set of criteria to diagnose it accurately on clinical grounds alone seems impossible. But attempts should be made to determine how and to what extent the diagnosis can be improved, based on the available clinical features, and what will be the possible economic implications in terms of costs and consequences. If presumptive treatment is to be given only after screening by a set of clinical criteria, one can avoid giving drugs unnecessarily and thereby saving costs. As more and more patients are seeking care in the private sector, the diagnostic capability in this sector could potentially be enhanced by providing the guidelines for case management based on the findings of this study. At a time when microscopy or other advanced diagnostic facilities cannot be made available to the remote areas and where private practices are prevalent, it is expected that this alternative approach may be more effective and cost saving.

1.4 Research Questions

1.4.1 To what extent can the clinical diagnosis of malaria be improved using a set of clinical criteria in comparison with the existing approach in giving presumptive treatment to fever cases ?

1.4.2 What will be the costs and consequences of using these clinical criteria in comparison with current approach in presumptive treatment ?

1.5 Objectives of the Research

1.5.1 General Objective

To determine how precisely malaria can be diagnosed based on a set of clinical criteria, and the ways to estimate costs and consequences of introducing and using them in comparison with existing approach in presumptive treatment.

1.5.2 Specific Objectives

1. To specify clinical symptoms and signs of malaria to be included in the clinical criteria by reviewing literature.

2. To develop a set of clinical criteria for diagnosis of malaria using an logistic regression model.

3. To determine sensitivity and specificity of the developed clinical criteria by comparing with results of a gold standard (microscopy).

4. To develop an approach for determining benefits (costs saved) of using the clinical criteria in selecting cases for giving presumptive treatment.

5. To develop an approach for determining additional costs of introducing and using the clinical criteria in selecting cases for giving presumptive treatment.

6. To calculate benefit cost ratio from the benefits and costs determined.

1.6 Expected Benefits of the Study

From this study it is expected that the approach developed will enable the control program to determine ways to evaluate costs and consequences of introducing criteria to diagnosis malaria on clinical grounds. As the approach is to be based on the inherent or technical properties of a diagnostic process or procedure this study may provide a supplementary means of evaluating a diagnostic procedure or process or test.