CHAPTER I

INTRODUCTION

1.1 Background

Visceral Leishmaniasis (VL), commonly known as 'Kala-azar' in the Indian sub-continent, is a protozoan disease, caused by *Leishmania donovani* and transmitted by the bite of infected female sandflies. The disease manifests with fever, anaemia, lymphadenopathy, hepatosplenomegaly, alteration in the blood albumin ratio with massive production of antibodies and gradual and severe suppression of cell mediated immunity (Joshi, 1996; Park, 1997). If untreated, VL is lethal in 100 per cent of cases with developed signs and symptoms. Even with treatment, up to 15 per cent mortality is common in some parts (TDR, 1996).

VL has been a public health problem in the world for a long time. About 12 million people from 80 countries are reported to have been infected by the disease with an additional 90 million people at risk. Approximately 400,000 new cases of VL are evidenced per year throughout the world. In Nepal, the first identification of VL dates way back in 1980 in the southeastern Terai region and was believed to be an extension from India across the borders of Bihar province through population movement. However, there are unconfirmed reports of the presence of VL in Nepal even prior to 1980. Subsequently, VL in Nepal extended to several districts and has become one of the important public health problem (Joshi, 1996). There were a total of 378 deaths due to VL reported from all endemic districts of Nepal between 1980-1998 (MOH, 1998). The maximum number reported was 65 deaths in the year 1995. Since the disease is usually fatal if untreated in time, the mortality due to VL is often considered to reflect the seriousness of the problem.

There have been several research conducted to study the epidemiology, vector distribution and biology of VL in Nepal. Devkota (1996) has reported the prevalence of VL to be higher in districts of eastern Terai (lowland or plains); the most affected population reported to be between 15-45 years with male being affected twice more often than females. Although the incidence rate increased from 1.5 per 100,000 population in 1980 to 49.03 per 100,000 population in 1994, the case fatality rate declined from 13.1 per cent in 1982 to 0.46 per cent in 1994 and again rose to 2.98 in 1998 (MOH, 1998; Table 1.1). The rising trend of mortality due to VL is believed to have been associated with delayed reporting of the cases to the health centers (Regmi, 1998).

Twelve districts in the Terai region of Nepal have been identified as VL affected areas (MOH, 1998). The prevalence of the disease is higher in rural areas and people who work in farms, forestry and fishing are at a greater risk, simply because they are exposed to bites from sandflies (Joshi, 1996; Ashford, 1997). While mixed dwellings in bad housing condition, low socio-economic level and malnutrition are considered to be contributing factors for the occurrence of the disease (Devkota, 1996), some experts working in the field of VL control have identified delayed reporting of the case as one of the main causes of increasing deaths due to this disease in the recent years (Regmi, 1998). The internal assessment carried out by Ministry of Health (MOH, 1998) also suggests that there may be a strong possibility of several positive cases not reporting to health facilities, thereby making it difficult to estimate actual prevalence rate of the disease. These observations imply several economic issues such as underutilization of resources used and high opportunity costs associated with them. However, once the disease is reported, the recording system is of high order. Very recently, an early warning reporting system (EWARS) has been established, with eight participating sentinal reporting institutes, most zonal or district hospitals (Ashford, 1997).

The diagnostic procedure in the current system involves clinical examination, followed by a confirmatory test such as bone marrow aspiration, which is invasive in nature and requires laboratory facility. Rapid case detection methods such as the one with k39 dipstick or direct agglutination test show potential use by the health care system, as they have been found very effective elsewhere (Pal, 1991; Sundar, 1998).

Table 1.1 Profile of Visceral Leishmaniasis in Nepal from 1980-98

Year	No. of cases	Incidence/100,000	No. of deaths	CFR (%)
1980	51	1.50	3	5.88
1981	133	3.95	1	0.75
1982	266	7.90	35	13.16
1983	60	1.78	4	6.67
1984	94	2.79	5	5.32
1985	95	2.65	0	0.00
1986	199	9.72	6	3.02
1987	169	6.48	8	4.73
1988	442	17.18	1	0.23
1989	291	9.01	5	1.72
1990	446	12.45	34	7.62
1991	870	17.45	56	6.44
1992	1395	20.96	8	0.57
1993	1368	34.08	5	0.37
1994	1976	49.03	9	0.46
1995	1787	44.60	65	3.63
1996	1571	39.14	55	3.5
1997	1342	33.23	36	2.68
1998	1409	33.88	42	2.98

(Source: MOH, 1998)

1.2 Rationale

Vector control, an essential component of malaria and leishmaniasis control, has become less effective in recent years. There are several reasons for that - poor use of alternative control tools, inappropriate use of insecticides, lack of an epidemiological basis for interventions, inadequate resources, weak management, etc. In addition, "changing environmental conditions, the behavioral characteristics of the vectors, and resistance to insecticides have added to the difficulties" (WHO, 1995). Moreover, in leishmaniasis changes have occurred in the distribution of the disease associated with development impact, urbanization, civil unrest and changed agro-forestry practice (Molyneux, 1998). This may point to the need to look into other avenues for control of vector-borne diseases, including VL, which should be more effective.

Although several cost effectiveness measures have been in use worldwide and many research in this area are in progress, including different types of regimen of drugs in the treatment of the disease (Thakur, 1994), they would also not be very effective if VL patients report to the health centers too late. Delayed reporting of this disease not only affects the health of the infected person, it can also spread the disease in the community, as in most VL endemic areas infected individuals are important reservoir (Park, 1997; TDR, 1998). Moreover, VL in Nepal is believed to be an extension from India across the borders (Joshi, 1996), and Indian VL is considered to be a non-zoonotic infection with man as the sole reservoir (TDR, 1976; Park, 1997). It may be worthwhile, therefore, to carry out early case detection and treatment of those found to be infected (including PKDL[1]) in order to "abolish the human reservoir and control the disease" (Park, 1997). Furthermore, there are no drugs for personal prophylaxis to prevent the disease. Thus, one of the pertinent options left to control VL could be an initiative on nationwide basis, which ensures early case detection[2] and treatment of the disease. Early case detection may be carried out through several different activities, ranging from passive to active case detection programs. Many authors (Kaewsonthi and Attig, 1995; Park, 1997) have considered outreach case detection programs or *community screening* (in which health workers go to community and trace cases) as better alternative in detecting cases of certain disease at the earlier stages. Their argument is, however, based on the fact that these particular disease conditions must have considerably long 'time-lag' between disease onset and usual time of diagnosis. The same argument may hold good in case of VL in Nepal for two reasons. First, if VL is not detected and treated in time, almost cent percent mortality is associated with it. Second, the current knowledge, attitude and practice about VL suggest that there may be a high possibility that VL cases remain undetected for a long time in the communities, contributing to the increasing rate of mortality due to this disease (MOH, 1997; Koirala, 1998; Regmi, 1998). This implies that

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[1] Post-kala azar dermal leishmaniasis, caused by Leishmania donovani, appears one to several years after apparent cure of VL.

[2] The early case detection for visceral leishmaniasis (VL) in this case may be defined as follows (Joshi, 1999b). "A case is said to be detected early when a patient, not having a past history of VL, if presents with fever more than two weeks, may or may not have spleen/liver/limpsnode enlarged on clinical examination, and reported positive in serological test such as k39 dipstick or direct agglutination test (DAT)."

an outreach case detection program may be an option available to ensure early detection of VL cases and, therefore, is worth considering. Devkota (1996), having studied socio-behavioral and epidemiological aspects of VL, has also recommended the need to have a rapid case detection and treatment program in order to control the disease.

However, no information is available as to what extent outreach case detection could be a cost-effective measure to control VL in Nepal. While the above discussed studies, and also the recently introduced EWARS, provide many valuable information on epidemiology, vector distribution and biology of VL, no research on economic assessment on various aspects of the disease has been reported so far. In the current era of cost containment, the benefits have to outweigh the economic input and justification in this regard is overwhelming in favor of such undertaking. As Drummond (1997) argues, the decision on resource allocation should, preferably, be made evaluating both costs and consequences of each alternative available. Some researchers have well established this argument and facilitated the decision making process by carrying out economic evaluation of different alternatives available in a particular disease control program, such as malaria and tuberculosis, the similar infectious disease condition as VL (Kamolratanakul and Dhanamum, 1993; Kamolratanakul and Chunhaswasdiku, 1993). In VL, most of the studies have mainly explored cost-effective treatment regimen or effectiveness of diagnostic tests (Thakur, 1994; Jha, Thakur, 1996). It is important to note here that all of these studies have been instrumental in reallocating the limited resources in order to maximize the welfare of the society at large, thus justifying the efforts put up in carrying out the economic evaluation. However, no study looking at the cost-effectiveness of different case detection programs for VL has been reported so far from Nepal. Thus, an assessment on the costs, benefits and effectiveness of different VL case detection programs needed to be carried out for a better understanding of the economic costs, effectiveness and benefits associated with the monitoring system of disease control.

1.3 Research Question

This study tried to address the following research question:

What is the most cost-effective intervention program that helps to improve earlier case detection for visceral leishmaniasis in Nepal?

1.4 Research Objectives

The *general* objective of this study was:

To identify the most cost-effective option between two alternative interventions (outreach and health facility based detection programs) for early visceral leishmaniasis case detection in Nepal, from the viewpoint of providers and the patients.

The *specific* objectives of this study were as follows:

- To assess and compare the cost-effectiveness ratio of both alternatives being considered
- To make an attempt to translate the effectiveness into monetary term

1.5 Scope of the Study

This study was carried out in Siraha district of Nepal between February-March 2000. The evaluation period was 1998-99 (Nepalese fiscal year 2055/56). The study made use of secondary data generated by a different project on visceral leishmaniasis, which was going on during that time (PI: Joshi A.B., 1999). It also collected primary data to evaluate patient costs. While evaluating the case detection programs, subsequent treatment of detected cases were also included in the cost function.