Project Credit No.: 4461-IN

Project Implementation Plan

NATIONAL VECTOR BORNE DISEASE CONTROL SUPPORT PROJECT

UNDER WORLD BANK

ON MALARIA CONTROL & KALA-AZAR ELIMINATION

(2008-2013)

MALARIA

KALA-AZAR

NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME
Directorate General of Health Services
Ministry of Health and Family Welfare
22, Sham Nath Marg, Delhi 110 054
www.nvbdcp.gov.in
June, 2008

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Abbreviations and Acronyms

ABER	Annual Blood Examination Rate
ACD	Active Case Detection
ACT	Artemisinin-based combination therapy
ANM	Auxiliary Nurse Midwife
API	Annual Parasite Incidence
BCC	Behavior Change Communication
CAS	Country Assistance Strategy of the World Bank
CS	Country Strategy
CHC	Community Health Center
COMBI	Communications for Behavioral Impact
CMP	Common Minimum Program of Government of India
CPAR	Country Procurement Assessment Report
DALY	Disability-Adjusted Life Year
DBS	Domestic Budget Support
DC	Direct Contracting
DDC	Drug Distribution Centre
DDT	Dichloro Diphenyl Trichloroethane
DEA	Department of Economic Affairs, Government of India
DFID	Department for International Development, Govt of UK
DO	Development Objective
DPs	Development Partners
DPIP	District Program Implementation Plan
EAP	Externally Assisted Projects
EMCP	Enhanced Malaria Control Programme
EPW	Empowered Procurement Wing
EMP	Environment Management Plan
FMG	Financial Management Group
FTD	Fever Treatment Depot
GOI	Government of India
GTZ	Gesellschaft fur Technische Zusammenarbeit (Germany)
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
ICB	International Competitive Bidding
ICDS	Integrated Child Development Services
ICMR	Indian Council of Medical Research
IEC	Information, Education and Communication
IDA	International Development Association
IDR	In-Depth Review
IMNCI	Integrated Management of Newborn & Childhood Illnesses
IMR	Infant Mortality Rate
IPC	Inter-personal Communications
IRS	Indoor Residual Spraying
ITN	Insecticide Treated (bed) Nets
JMM	Joint Monitoring Mission
KFW	Kreditanstalt fur Wiederaufbau (Germany)
LLIN	Long lasting insecticidal nets
MDGs	Millennium Development Goals
M & E	Monitoring and Evaluation
MIES	Monitoring Information and Evaluation System

MIS	Malaria Indicator Survey
MOHFW	Ministry of Health and Family Welfare
MOU	Memorandum of Understanding
MPO	Modified Plan of Operation
MTR	Mid-term review
MRC	Malaria Research Centre
NACO	National AIDS Control Program
NCB	National Competitive Bidding
NFHS	National Family Health Survey
NGO	Non-Governmental Organization
NIMR	National Institute of Malaria Research
NHSRC	National Health Systems Resource Center
NMCP	National Malaria Control Programme
NMEP	National Malaria Eradication Programme
NPIP	National project implementation Plan
NRHM	National Rural Health Mission
NS	National Shopping
NVBDCP	National Vector Borne Disease Control Programme
PCD	Passive Case Detection
PDO	Project Development Objectives
PBF	Performance Based Financing
Pf	*Plasmodium falciparum*
PHC	Primary Health Center
PIP	Program Implementation Plan
PPP	Public Private Partnerships
PRI	Panchayat Raj Institutions
Pv	*Plasmodium vivax*
RCH	Reproductive and Child Health
RDK	Rapid Diagnostic Kit
RPRG	Regional Programme Review Group
SAG	Sodium Antimony Gluconate
SSG	Sodium Stibo Gluconate
SOP	Standard operating procedures
SP	Sulphadoxine-Pyrimethamine
SA	Social Assessment
SC/ST	Scheduled Caste/ Scheduled Tribe
SDR	Special Drawing Rights
SOE	Statement of Expenses
SPAR	State Procurement Assessment Report
SPIPs	State Program Implementation Plans
SWAp	Sector Wide Approach
TA	Technical Assistance
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VBD	Vector-borne disease
VCP	Vulnerable Community Plan
VCRC	Vector Control Research Centre
VGHP	Vulnerable Group Health Plan
WB	World Bank
WHO	World Health Organization

Chapter 1

Situational analysis

Introduction

The Vector-borne diseases (VBDs) are a cluster of infectious diseases transmitted by mosquitoes and other vectors. India's population suffers from a significant disease burden from these diseases, in the form of morbidity and mortality from malaria, kala-azar (Visceral Leishmaniasis), lymphatic Filariasis (LF), Japanese Encephalitis (JE), Chikungunya and Dengue. There are considerable variations in epidemiology of these vector borne diseases on account of ecology, vector bionomics, economic, socio-cultural and behavioral factors. The high risk areas for VBD are generally rural, tribal and urban slums inhabited by the poor, marginalized and vulnerable groups with limited access to quality health care, communication and other basic amenities.

The National Vector Borne Disease Control Programme (NVBDCP) is an umbrella programme for prevention & control of vector borne diseases and an integral part of the India's National Rural Health Mission (NRHM). The National Health Policy (NHP) of 2002 has set goals for achieving reduction of mortality due to malaria, dengue and JE by 50% by the year 2010 along with efficient morbidity control; eliminating Kala-azar by the year 2010; and elimination of Lymphatic Filariasis by 2015.

The NVBDCP envisages a well informed and self-sustained, healthy India free from vector borne diseases with equitable access to quality health care and the Programme activities are in tandem with the NHP and NRHM goals as well as the Millennium Development Goal of halting and reversing the incidence of malaria and other vector borne diseases by the year 2015 towards reduction of poverty.

The proposed World Bank supported project for malaria control and kala-azar elimination will be implemented within the overall policy and program framework of the NVBDCP. However, the project will focus on supporting efforts to prevent and control malaria and eliminate kala-azar from the most endemic districts. This approach makes World Bank support more strategic and better targeted as malaria contributes to highest morbidity and mortality rates among the VBDs while kala-azar is known to affect the poorest of the poor residing in inadequate and unhygienic housing conditions.

1.1 Burden and distribution of Malaria and Kala-azar in India

1.1 a. Malaria Situation

Among the VBDs, malaria continues to pose a major public health threat. Malaria due to *Plasmodium falciparum (Pf)* is particularly prone for complications including death, if not treated early. During the past few

years, the Indian surveillance system has been reporting around 2 million cases of malaria every year. Increasing proportion of P*f,* which currently stands at about 45% of total reported cases, is a major cause of concern.

India is estimated to contribute 77% of cases in the South East Asia (SEA) region of the WHO though only 66% of SEA population actually lives in India. Within India, about 80% of malaria burden is confined to 20% of population residing in high risk areas. States like Orissa, Jharkhand and Chhattisgarh lead the country in incidence of malaria while the case fatality rates are highest in Arunachal Pradesh, Assam, Meghalaya& West Bengal. All these high burden states have a very high proportion of tribal population. Even though, the number of cases and deaths attributable to malaria, have declined significantly during last decade, there is however, increase in *P. falciparum* proportion out of total malaria positive cases. During 2006, 1.78 million malaria positive cases were reported with 1704 deaths. In 2005, the figures were 1.81 million cases with 963 deaths. The malaria cases and Death in the country for the last 3 years is enclosed at **Annexure 1**.

1.1 b. Kala-azar Situation

After decline to negligible number of cases due to collateral benefits of indoor residual spray on the vector *Phlebotomus argentipes*, Kala-azar resurged in the state of Bihar in sixties and by seventies the disease got firmly established in endemic form in the state of Bihar followed by West Bengal, Jharkhand and Uttar Pradesh. Currently, kala-azar is endemic in 52 districts from the states of Bihar (33 districts), West Bengal (11 districts), Jharkhand (4 districts) and Uttar Pradesh (4 districts) located in the eastern parts of the country. The state of Bihar contributes 70-80% of the total disease burden in the country.

The four endemic states reported 39,178 cases and 187 deaths due to kala-azar in the year 2006. While the disease mostly affects poorest socio-economic groups primarily living in rural areas, among these 4 states about 129 million populations are estimated to be at risk of acquiring kala-azar. The year wise cases and deaths are presented in **Annexure 2.**

The data available with NVBDCP suggests an increasing trend in the reported cases of Kala-azar since 2003. This increase may partially be due to intensification of active case search in affected areas.

The NHP (2002) envisages elimination of Kala-azar by the year 2010. The Govt. of India is also a signatory to Tripartite Memorandum of Understanding (2005) along with Nepal and Bangladesh, on elimination of Kala-azar from the South-East Asia Region by 2015 by reducing the annual incidence of Kala-azar to less than one per 10,000 population at sub-district level in Bangladesh and India and at the district level in Nepal.

The following matrix summarizes the transmission mechanisms of malaria and kala-azar, their health effects and geographical dispersion:

Type of Vector Borne Disease	Description of the Vector and Causative Agent	Description of the Infection and health impact	Geographical dispersion
Malaria	Vector: *Anopheles* mosquitoes, which breed in clean water and feed during the night Causative Agent: *Plasmodium* parasites. Among different species of the parasite, *falciparum* causes most severe form of malaria with higher mortality risk. The other commonly reported species in India is *vivax.*	One to two weeks or more after a person becomes infected, first symptoms appear. Typically, malaria produces fever, headache, vomiting and other flu-like symptoms. The parasite infects and destroys red blood cells resulting in anemia. Infections with falciparum may cause cerebral malaria with fits/convulsions and loss of consciousness, and often death. Malaria in pregnancy poses a substantial risk to the mother, the fetus and the newborn infant.	Of all reported malaria cases in India during 2006, about 90% were in 11 States: Orissa, 22%; Jharkhand, 11%; Chhattisgarh, 10%; West Bengal, 10%; Gujarat, 10%; Madhya Pradesh, 6%; Uttar Pradesh, 6%; Karnataka, 5%; Assam, 4%; Rajasthan, 3% and Maharashtra, 3%.

Type of Vector Borne Disease	Description of the Vector and Causative Agent	Description of the Infection and health impact	Geographical dispersion
Kala-azar (Visceral Leish-maniasis)	Vector: Female P*hlebotomus argentipes* (sand-fly). The sand-flies breed in the presence of organic debris, making homes with mud walls plastered with cow dung ideal for breeding. These sand-flies feed on blood (usually in the evening and at night) and can travel about a radius of a few hundred meters around its habitat.	Kala-azar is a slow progressing disease and often recognized late. Kala-azar infection is manifested in two forms. Initial infection leads to acute disease, i.e. Kala-azar. Later on, skin manifestations of Kala-azar infection, known as Post Kala- azar Dermal Leishmaniasis (PKDL), may appear after variable periods ranging up to a few years.	Practically all cases of Kala-azar reported in 2006 are from three States: Bihar, 70%; Jharkhand, 21%; and West Bengal, 9%.

Type of Vector Borne Disease	Description of the Vector and Causative Agent	Description of the Infection and health impact	Geographical dispersion
	Causative Agent: *Leishmania donovani*, a parasite mainly residing in bone marrow, spleen and liver. No intermediate host is known in India (i.e. humans are the only hosts). *P. argentipes* is the only vector responsible for Kala-azar in India	Kala-azar is characterized by irregular bouts of fever, darkening of the skin substantial weight loss, enlargement of the spleen and liver, and anemia. If left untreated, the case fatality rate can be as high as 100% within two years. Patients with PKDL are not in danger of dying from the disease, but are contagious	

1.2 Malaria Control in India

The National Malaria Control Programme (NMCP) started in 1953 and subsequently changed in 1958 to National Malaria Eradication program. Since then there have been many achievements as well as set backs in the program. The incidence of malaria reached to all time low of 0.1 million cases in 1965. However, this has subsequently increased to 6.47 million cases in 1976. The Modified Plan of Operation (MPO) launched in 1977 in response to reemergence of malaria in the country successfully brought down annual incidence of malaria from 6.47 million (0.85 million *P. falciparum*) in 1976 to 2.18 million cases (0.65 million P. falciparum) by 1984.

Modified plan of Operation (MPO), 1977 envisaged a major strategic shift by integrating malaria program with the primary health care delivery system and changing the concept of blanket Indoor Residual Spraying (IRS) to selective IRS by stratifying the areas based on number of cases reported per 1,000 population in a year [the Annual Parasite Incidence (API)]. IRS was limited to areas reporting API of 2 and above.

The Urban Malaria Scheme (UMS) was launched in 1971 with the objective to control malaria by reducing the vector population in the urban areas through recurrent anti-larval measures complemented by detection and treatment of cases through the existing health services. The scheme was sanctioned for 181 towns spread over 17 states and two union territories. However, it has so far been implemented in 131 towns only covering a population of 101.1 million in 2005

The Enhanced Malaria Control Project (EMCP) was implemented with the support of the World Bank during 1997 to 2005 with the objectives of creating an enhanced and more effective malaria control program focusing on the tribal areas with high disease burden and supporting the introduction of mix of cost-effective and sustainable strategies. The Project was implemented in 1045 Primary Health Centers (PHCs) in 100 districts of 8 states (Andhra Pradesh, Chhattisgarh, Gujarat, Jharkhand, Madhya Pradesh Maharashtra, Rajasthan and Orissa) predominantly inhabited by tribal population. In the EMCP areas, the number of cases have declined from 1.17 m in 1997 to 0.76 m in 2005 (44% decline) and deaths from 522 to 301 (42%). The *Pf* cases reduced from 0.71 m to 0.51 m (28%).

India adopted WHO- RBM strategy and was successful in bids during the GFATM Round IV. Under GFATM, NVBDCP is supporting malaria control in the states of Assam, Arunachal Pradesh, Meghalaya, Tripura, Nagaland, Mizoram, Manipur, West Bengal, Jharkhand and Orissa.

1.3. Kala-azar Control in India

Kala-azar has been endemic in India for a long time and earliest outbreaks date back to early nineteenth century. With the implementation of successive National Malaria Control operations from 1953, the disease declined to negligible proportions due to collateral benefit of IRS. However, withdrawal of IRS from some erstwhile malaria endemic areas resulted into a gradual build up of vector population that ultimately led to resurgence of kala-azar in seventies initially in 4 districts of Bihar. Slowly the disease started spreading to other areas in Eastern India.

Concerned with the increasing incidence of Kala-azar, the GOI launched a centrally sponsored Kala-azar Control Program in the year 1990-91. The initial success of the program resulting in a significant decline in Kala-azar morbidity could not be sustained by the states. An expert committee chaired by the Director General of Health Services reviewed the program in 2000 and recommended the feasibility of eliminating Kala-azar from India and the NHP (2002) has endorsed this recommendation and set a goal for eliminating Kala-azar by 2010.

1.4 Program Constraints

The NVBDCP is also affected by the generic constraints of public health system in India such as large number of vacant staff positions, weak program management capacities, delays in procurement, ineffective distribution of supplies, weak financial management, and insufficient supervision and monitoring. Further, non- engagement and lack of oversight of private sector plays an important role in the diagnosis and treatment of malaria and Kala-azar cases.

1.4.1. Key Program Constraints – Malaria

a) Technical

- Rapidly emerging chloroquine resistance in *Pf* and insecticides resistance in vectors.
- Incomplete treatment or poor treatment compliance.
- Use of irrational anti-malaria drug regimens by the public and private sector.

b) Operational

- Inadequate surveillance and case detection in large number of states. Six states record ABER of less than 5%.
- Heavy work load imposed by active surveillance on the microscopists increases the backlog and thereby resulting in delayed reporting of blood smear collected from patients currently suffering from fever.
- Due to shortage of microscopy centers, the Health Workers carry blood smears to the PHC/ CHC once a week and collect the report in the subsequent week. This again delays the treatment as well as early confirmation of an outbreak.
- Delays in reporting of blood smears, treatment and referral to hospitals increases the risk of severe malaria and consequent complications.
- Inadequate strategies for delivery of services in remote and inaccessible areas where there is severe shortage of public health outreach services[1].
- Despite existence of good program guidelines innovations such as social marketing for rapidly up-scaling ITNs usage has not taken place.
- Weak coordination with Integrated Disease Surveillance leading to overload of information and poor or delayed local response to suspected outbreaks.
- Shortage of male Multi Purpose Workers (MPW) for routine surveillance activities in Blocks/PHC plays an important role in detecting the malaria cases.
- Inability of states to buy Malathion 25% and Synthetic Pyrethroids for IRS operations in DDT resistant areas (since it is a decentralized item).
- Non-cooperation/ apathy of community towards IRS and insufficient demand for diagnostic and treatment services.
- Inadequate entomological monitoring in states with highest burden of malaria due to inability of states to fill the posts of entomologists.
- Inadequate supervision and monitoring including National Anti Malaria Management Information System (NAMMIS).

c) Management

- Frequent delays in release of program funds to the endemic districts by states.
- Delays in procurement of supply of goods (drugs, insecticides, laboratory commodities etc).
- Delays in payment of seasonal staff who undertake the IRS operations.
- Non-submission of statement of expenditure (SOE's) & utilization certificate (UCs) by the States thus hampering release of funds by the GOI.

[1] Several malaria high endemic states have shortage of sub-centers as per national norms. For example, the states of Arunachal Pradesh and Assam have only half of the required sub centers while Orissa, Nagaland and West Bengal have about three fourths.

- Inadequate attention to mosquitogenic conditions by local self-government as well as private corporate sector and weak coordination between concerned authorities resulting in man made malaria

1. 4. 2. Key Program constraints – Kala-azar

a) Technical

- Active Case Search which is done only through Kala-azar fortnight is labor intensive and generally the yield of cases is very low.
- Continued dependence on Napier's Aldehyde test for diagnosis of Kala-azar except in pilot districts.
- There is an emerging trend of poor response to first line drug Sodium Stibo Gluconate (SSG) in North Bihar which is also toxic when the prescribed regime for 28 days treatment is strictly followed.
- Despite clear guidelines from GOI, indiscriminate use of medicines and incomplete treatment are common among both public as well as private sector health service providers.
- Treatment protocols are not followed properly. Treatment cards recommended for use under the Programme often are not filled adequately.
- Detection of Post Kala-azar Dermal Leishmaniasiss (PKDL) and its treatment are not satisfactory. The treatment is prolonged and patients have no motivation to follow the treatment since they do not suffer any ill health except for the skin problems.
- Coverage and quality of IRS is unsatisfactory.
- Emergence of HIV-Kala-azar and TB-Kala-azar co-infections.

b) Operational

- Political commitment exists but insufficient monitoring of control interventions and resource utilization; variable absorption capacity of states in relation to utilization of funds/commodities.
- A large number of patients receive treatment through private sector which does not report these cases and treatment outcomes to the government. Though Kala-azar is included under the notifiable Diseases in Bihar, enforcement has been ineffective.
- A large number of patients do not complete the recommended 28 days treatment because of poverty, side effects of medicine and weak supervision by the health care providers.
- Limited social mobilization due to inadequate BCC efforts with low resource allocation.

c) Management

- Non-receipt of funds by the Districts/PHCs due to administrative delays or non-release of funds by states.
- Non-submission of SOEs & UCs by the States thus hampering release of funds by the GOI.

Chapter 2

Key Findings and Recommendations of Joint Monitoring Mission (JMM) of NVBDCP

At the behest of GoI, a Joint Monitoring Mission (JMM) led by WHO which included over 30 national and international experts undertook a comprehensive review of NVBDCP during the months of January and February 2007 and made important recommendations on policy and strategy. Further, the NVBDCP in collaboration with Indian Council of Medical Research has undertaken in-depth reviews (IDR) of malaria and Kala-azar interventions in 2006. This section summarizes the key findings and recommendations of the JMM and IDR.

2.1. Current Policies for Malaria Control

2.1. a. Case Management

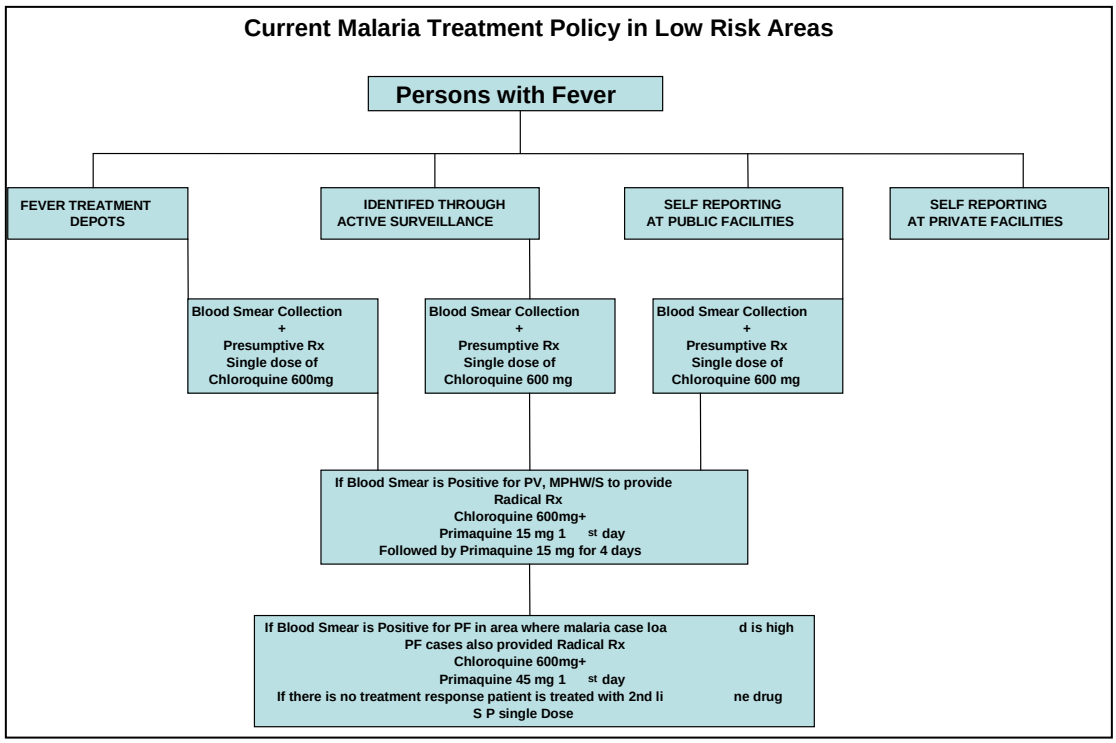
The current policy for malaria diagnosis and treatment in the public sector varies according to whether a given area is classified as a low malaria risk area or a high-risk area. Primary health centers are classified as *high malaria risk areas* if any of the following applies (otherwise it is classified as *low risk area*):

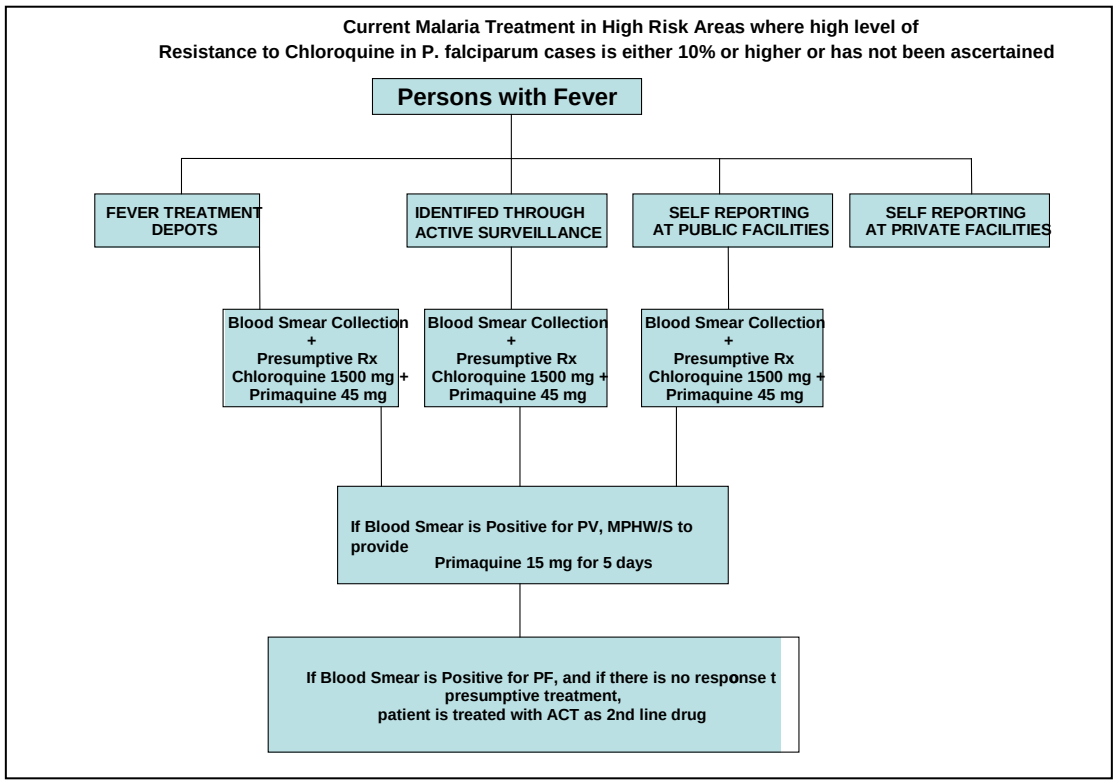
- Deaths due to malaria have been reported (on clinical diagnosis or microscopic confirmation).
- The Slide Positivity Rate (SPR) has doubled during the last three years, provided the SPR in the second or third year reaches 4% or higher; or the average SPR of the last three years is 5% or higher.
- Of all reported malaria cases the proportion of *P. falciparum* proportion is 30% or higher, provided the SPR is 3% or higher during any of the last three years.
- Any area having a focus of Chloroquine-resistant *P. falciparum*.
- Agglomeration of migrant labor in endemic/receptive and vulnerable areas.

High-risk areas are further divided, for the purposes of malaria diagnosis and treatment, between those areas where a high (greater than 10%) level of resistance to chloroquine in *P. falciparum* cases has been ascertained and those areas where such high level of resistance has not been ascertained. However, it has been very difficult to successfully undertake and complete a large number of studies on drug resistance as such studies require a lot of effort, especially for ensuring follow up of enrolled patients.

The following flow-charts summarize current malaria treatment policies;

(i) low-risk areas and (ii) high-risk areas where chloroquine resistance levels greater than 10% has been ascertained; and high-risk areas where levels of chloroquine resistance has not been ascertained.


Current Malaria Treatment Policy in Low Risk Areas
Persons with Fever
FEVER TREATMENT DEPOTS
IDENTIFED THROUGH ACTIVE SURVEILLANCE
SELF REPORTING AT PUBLIC FACILITIES
SELF REPORTING AT PRIVATE FACILITIES
Blood Smear Collection + Presumptive Rx Single dose of Chloroquine 600mg
Blood Smear Collection + Presumptive Rx Single dose of Chloroquine 600 mg
Blood Smear Collection + Presumptive Rx Single dose of Chloroquine 600 mg
If Blood Smear is Positive for PV, MPHW/S to provide Radical Rx
Chloroquine 600mg+
Primaquine 15 mg 1 st day
Followed by Primaquine 15 mg for 4 days
If Blood Smear is Positive for PF in area where malaria case loa d is high
PF cases also provided Radical Rx
Chloroquine 600mg+
Primaquine 45 mg 1 st day
If there is no treatment response patient is treated with 2nd li ne drug
S P single Dose


Current Malaria Treatment in High Risk Areas where high level of
Resistance to Chloroquine in P. falciparum cases is either 10% or higher or has not been ascertained
Persons with Fever
FEVER TREATMENT DEPOTS
IDENTIFED THROUGH ACTIVE SURVEILLANCE
SELF REPORTING AT PUBLIC FACILITIES
SELF REPORTING AT PRIVATE FACILITIES
Blood Smear Collection + Presumptive Rx Chloroquine 1500 mg + Primaquine 45 mg
Blood Smear Collection + Presumptive Rx Chloroquine 1500 mg + Primaquine 45 mg
Blood Smear Collection + Presumptive Rx Chloroquine 1500 mg + Primaquine 45 mg
If Blood Smear is Positive for PV, MPHW/S to provide
Primaquine 15 mg for 5 days
If Blood Smear is Positive for PF, and if there is no response t
presumptive treatment,
patient is treated with ACT as 2nd line drug

Some of the recent changes in the national drug policy (2007) include:

- Discontinuing the presumptive treatment for fever cases with chloroquine
- Reducing the chloroquine resistance levels for deciding use of ACT from 25% to 10% as recommended by WHO
- Giving flexibility to states to decide on extent of areas to be covered (clusters of blocks) with ACT once chloroquine resistance levels of more than 10% are noted
- Introducing 14 day radical treatment for confirmed cases of P.*Vivax*

The Technical Advisory Committee (TAC) GoI has approved the use of Artesunate combination drugs (ACT) as first line treatment to all confirmed *P. falciparum* cases in 50 districts under World Bank project and districts under GFATM support Intensified Malaria Control Project

It is pertinent to note that a large number of fever cases are treated in the private sector where the practices are variable and the cases are not reported to the programme.

2.1. b. Current practices in Vector control

a. *Indoor Residual Spray (IRS)* - At present, IRS is being carried out during the disease transmission season (May to November) without undertaking micro stratification. Every year two rounds of sprays are to be carried out with DDT/ Synthetic Pyrethroids. The IDR review (2006) has shown that both the coverage and quality is ineffective to reduce mosquito density.

b. *Bednets* - Insecticide Treated Nets (ITNs) have been distributed in the EMCP (1997- 2005) areas and NGOs were contracted to impregnate these nets once every 6 months. The use of ITNs however was observed to be inadequate (IDR review 2006) due to multiple factors, such as social cultural and operational problems to re impregnate the nets.

c. *Larvivorus Fish* - The use of larvivorus fish and larvicide's have not contributed to a significant reduction of mosquito density.

d. *Environmental engineering* - Has been equally ineffective in motivating communities to improve environment sanitation especially in municipalities.

2.2. Recommendations on Malaria Control

i) Review and update the policy for malaria diagnosis and treatment

The Joint Monitoring Mission noted that the present policy for malaria diagnosis and treatment in public sector is not appropriate to the current context. The key policy issues relate to the *diagnosis and treatment of P. falciparum malaria.* Drug sensitivity studies show that resistance to

chloroquine in *P. falciparum* cases is widespread in India[2] . The share of *P. falciparum* malaria has been increasing in India since 1980s, and is currently about 45 percent of reported malaria cases. At present different treatment policies are applied in different parts of the country based on the chloroquine resistance level, so that ACT (artemisinin+sulfadoxine-pyremethamine) is used as first line treatment for *P.falciparum* malaria only in clusters of PHC areas, where reported chloroquine resistance is above 25%. The experience from other countries such as Cambodia, Thailand and Vietnam indicates that a rising share of *P. falciparum* malaria is a sign of chloroquine treatment failure, and that this trend can be reversed by treating all *P. falciparum* cases with Artemisinin-based Combination Therapy (ACT).

Furthermore, millions of fever patients who do not have malaria are given presumptive treatment with a single, sub-curative dose of 10 mg/kg chloroquine (600 mg in adults) by the government health services. This can increase drug pressure, cause unnecessary side-effects, is wasteful and reduces confidence of the public in the services. Progressively, all fever patients suspected of malaria should be tested to confirm the diagnosis of treatment before treatment is given. The JMM recommended discontinuation of presumptive treatment with chloroquine 10 mg/kg.

According to JMM, several important changes in the policy on diagnosis and treatment of malaria are required; the most important of these include the following[3]:

(i) Use ACT as the first line treatment for all confirmed falciparum malaria cases. Introduce this policy in a phased manner to cover nation-wide – according to a prioritized plan including diagnostics, training, quality assurance, supply chain management and information to the public.

(ii) Reform the surveillance of malaria by expanding the coverage of passive case detection. The target should be prompt blood slide or RDK test for all suspected malaria cases. Strengthened and expanded PCD should help the programme to achieve the target of about 10% annual blood examination rate. Active Case Detection (ACD) should be restricted to pockets of problem areas particularly areas with poor access to PCD or used during focal outbreaks.

(iii) Testing all suspected malaria cases[4] before treatment: The main challenge in terms of training, logistics and funding for implementing the

2 Since 2001, 64 studies of resistance to chloroquine have been conducted following WHO protocol. Only five of these 64 studies found that the level of resistance to chloroquine was less than 10%. Seventeen studies showed levels of resistance between 10% and 25%, and 42 studies showed levels of resistance greater than 25%. WHO recommendation is to use 10% as the cut off level for drug resistance.

[3] National Vector Borne Disease Control Programme: Joint Monitoring Mission Report, February 2007

[4] Precise guidelines on criteria for suspicion of malaria should be prepared by NVBDCP at central level according to following principles: Malaria should be suspected in patients who present with fever or anemia living in malaria- risk areas (e.g. PHC) or having visited an endemic area within the last month. A malaria-endemic area could for example be defined as

new treatment policy is confirming malaria diagnosis by blood slide or RDK. In poorly accessible areas, this will have to be done by an HRP2-based RDK, Use of RDKs should be prioritized in health facilities where blood slide results cannot be obtained within 24 hours and falciparum malaria is common. Based on experiences in the north-east, the national programme must now estimate the commodities, training, supervision and quality assurance needs for each state for introducing ACT. Once rough State-wise needs estimation has been done by a desk study, states and districts should be prioritized, with the *Pf* incidence as the main criterion. The prioritized states and districts should receive full national level support to roll-out the new treatment regimen in the government facilities and private sector according to an agreed plan. An implementation plan including clear objectives, targets, timelines, and appropriate process and output indicators for monitoring should be developed for rolling out the new treatment policy nationwide. Funding should be mobilized (as part of the overall programme funding) to complete the roll-out of the new case management strategy nationwide through public and private sectors within 4 years.

(iv) Presumptive treatment for malaria should be discontinued in all settings incrementally to be replaced by treatment based on confirmed diagnosis of malaria.

ii) Importance of improving malaria diagnosis and treatment in the private sector

In India, a large proportion of fever patients seek treatment from private health care providers. According to the in depth review, in Orissa, for example, about 50 percent of fever patients sees a private provider, and in urban areas the percentage is substantially higher. The diagnosis and treatment of malaria in the private sector is not subject to any regulation or oversight, and the quality of diagnosis and treatment services varies widely. Many private providers have not been trained and do not have the national guidelines. Most of the practitioners do not have access to reliable laboratory facilities. The JMM report recommends that following the introduction of ACTs in the government health system, all private providers (including pharmacies, drug vendors and quacks should be targeted to enable them to follow the national treatment guidelines.

iii) Effective Vector control

Effective vector control is necessary for controlling malaria and other VBDs. Entomological surveillance and monitoring of vector resistance to insecticides are below par and there is a shortage of trained entomologists. As a result, in most States, there is no stratification of districts according to eco-epidemiological characteristics for deploying appropriate vector control measures. Government criteria for deployment of Indoor Residual Spraying (IRS) and ITNs overlap, and the States and districts are not clear whether to apply one of these or both in areas of intense transmission. According to

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having had an SPR above 1% at some period during the latest 3 years. In non-endemic areas, tests for malaria should also be carried out on members of the family of a confirmed malaria case, if they have fever or anemia and on patients belonging to any unusual cluster of fever cases.

the in depth review in 2006, the coverage and quality of IRS are low in most areas. The coverage of ITNs varies widely among the States, from high in Assam to almost zero in Rajasthan (in depth review 2006). The low ITN coverage rates in many forested and urban areas reflect a lack of promotion and poor access. There are also new technological developments for vector control such as Long-lasting Insecticidal Nets (LLINs) which need to be introduced in India. The current spray pump will need to be gradually replaced by compression Pumps, which is faster, better and can be managed by one person only.

2.3. Current Policies for Elimination of Kala-azar

India is committed to the elimination of Kala-azar which includes the elimination of PKDL. According to the National Health Policy (2002), kala-azar is to be eliminated by 2010. The elimination programme has been accorded a priority and it is a centrally sponsored scheme. There is no formal written policy on kala-azar though national strategy document has been prepared. On Kala-azar the programme is guided by the recommendations made by the Technical Advisory Committee (TAC) which reviews the programme periodically as requested by NVBDCP.

The major thrusts of the elimination program are (1) Early diagnosis and complete treatment (2) Disease surveillance and (3) IRS with DDT in the affected districts. The diagnosis is made by aldehyde test which is used as a screening test and confirmation by parasitic diagnosis through aspiration of the bone marrow or splenic puncture examination. Bone marrow aspiration and splenic puncture are invasive procedures that can be done only in well equipped hospitals since they are associated with the high risk of complications. The programme is using SSG as the first line drug. It is recommended as a course of 28 days duration and the medicine has to be given parenterally. Amphotericin B is recommended as the rescue drug. Passive case detection is supported by kala-azar fortnights organized once in an year for active search. Indoor residual spraying with DDT is recommended as two rounds in the affected districts.

2.3. a. Case Management

According to IDR (2006), over 60% of kala-azar patients approach the private sector for diagnosis and treatment. For diagnosis, rk39 dipstick is the state-of-the-art technology which is available in the private sector. In Bihar which is most endemic, patients at public facilities are tested by "rk 39" through an outsourcing mechanism or by referral to a private provider. Some government doctors doubt the efficacy of the first line drug Sodium Antimony Gluconate (SAG), in use to treat kala-azar, because of observed treatment failure. In Bihar's northern districts, SAG resistance is reported in about 60% cases.

There are often delays in diagnosis and treatment due to lack of access, inability to afford, lack of information on treatment availability, and wage loss during hospitalization or treatment at home. NGOs have not been

widely involved for case detection and treatment. The national guidelines for treatment of kala-azar are not strictly followed even in the public sector.

Even though cases of Post Kala-azar Dermal Leishmaniasis (PKDL) are reservoir of the parasite the programme gets very little information on cases of PKDL since this is difficult to diagnose and treat. There is yet no standard treatment of PKDL. Although guidelines have been produced by the national programme capacity development needs considerable improvements and the guidelines often do not reach the end users. In the absence of district plans for kala-azar elimination, the program implementation occurs on an *ad hoc* basis.

2.3. b. Surveillance and reporting

The reporting of kala-azar is based on passive case detection supplemented by additional case finding during the kala-azar fortnight. During the Kala-azar fortnight kala-azar cases are identified by house to house search and using serology tests. The labour intensive kala-azar fortnight in November 2006 detected very few cases. It had overlapped with EPI campaign and there was no IEC prior to or during the fortnight. Further, there is no vector surveillance, and studies on vector behavior, bionomics and susceptibility are lacking. Only a small proportion of the health care providers have been trained on kala-azar surveillance.

Some districts have started to include the reports from selected private institutions. This carries the risk of double reporting in the absence of a system for identification of patients through line listing and individual patient treatment cards.

The registers and records of kala-azar cases were inadequate and provided sketchy information which was often confusing. Consequently, the reporting and feedback are unsatisfactory.

2.3. c. Vector Control

Data from the recent IDR indicate that the average coverage of IRS is 50% for 1st round and only 20% for 2nd round. However uniform and complete IRS coverage was only 7%. The JMM observed that the preparation for IRS was inadequate in Bihar. The micro-plans for IRS are not being prepared and there was no advance planning to train spray squads. There is no contingency plan if the IRS round overlaps with other mass campaigns such as Polio.

The storage facility for insecticides at the Block PHC level was reasonable. However, the spraying equipments were inadequate and poorly maintained. There is no vector surveillance, study on vector behaviour, bionomics or susceptibility. There is a shortage of entomologists or insect collectors at the state level in Bihar.

2.3. d. Recommended actions on Kala-azar Elimination

- Diagnosis and treatment of kala-azar should be offered free of cost at the point of delivery in the government and private sectors. Additional

incentives to assist kala-azar patients to mitigate the loss of income during kala-azar treatment should be explored.

- The programme should ensure practice of uniform standards in the public and private sector through training, effective dissemination of national treatment guidelines, oversight of diagnosis and treatment by private providers and establishing working public private partnerships.
- The existing effective interventions (e.g. 'rK39', miltefosine) and new tools (paromomycin) should be introduced as appropriate and an action plan to achieve a high coverage by these tools (target to be set by the NVBDCP) should be achieved.
- The passive case detection system should be strengthened through line listing, data management, timely reporting and feedback. This should be supplemented through sentinel surveillance and periodic surveys using IDR 2006 data as the base-line.
- Vector control should be planned well ahead of the IRS operations (at least 3-4 months). In 2008 the plan should be based on regular annual studies on vector behaviour, bionomics and level of susceptibility of the vector. The programme should consider 'covering hot spots' in an intensive manner through focal spraying.
- The NVBDCP should monitor the quality of insecticide, and equipments used for IRS and assist the states to maintain adequate capacity for implementing, and monitoring coverage and quality of IRS.

Chapter 3

Over view of National Vector Borne Disease Control Project (2008-09 to 2013-14)

The NVBDCP is responsible for prevention, control, and elimination of vector borne diseases in the country and the program operates under the overarching framework of the NRHM. The proposed World Bank supported '**National Vector Borne Disease Control Project'** will help NVBDCP to implement evidence based interventions for control of malaria and elimination of kala-azar covering districts with highest burden of these diseases in a phased manner.

The project will be implemented over a five-year period, from 2008/09 to 2012/13, a large portion of which coincides with the 11th Plan period (2007/08 to 2011/12) of GoI. This implementation plan is a result of extensive consultative process with active participation of the States, non-governmental organizations (NGOs), civil society, the World Bank, WHO, GFATM, and other Development Partners currently supporting the control of vector-borne diseases in the country.

3.1 Guiding Principles

The MOHFW is keen to bring about a paradigm shift in the strategies for the control/elimination of vector borne diseases and the proposed project will support such shift within the policy framework of NRHM.

The program's paradigm shift would include the following principles:

- The national policies and strategies will be driven by evidence and allow flexibility to the states and districts to implement these policies as per their specific needs and capacities.
- States will evolve their programs within the national policy framework according to environmental and social conditions.
- Central budget allocations will be based on state and district plans and not just population-based norms. The state plans will be drawn up based on log frame.
- High priority will be given to strengthening program management at state and district levels and supportive supervision at sub district level. Provided the states are willing to fill an agreed proportion of critical program staff, Centre will support the remaining staff.
- State plans will prioritize high burden areas while maintaining vigil in low endemic areas and ensure better harmonization of surveillance and service delivery with initiatives supported under NRHM such as integrated disease surveillance.
- There will be stronger focus on program performance based on log frame that links outcomes and outputs to program inputs and processes.
- The responsibility of implementing the malaria control and Kala-azar elimination programme will be of the staff deployed by the states for

provision of general health services as a part of NRHM. The staff at all levels will be technically supported and supervised by the staff hired for doing VBDC work.

- The State Health Departments will focus on activities where they have core competency and partner with other departments or non-government agencies/private sector for the remaining.
- The NVBDCP will ensure uniformity in application of best practices by non-governmental/private partners.

3.2 Project Objectives

The Objective of the project is to:

- Reduce Malaria morbidity by 25% by 2013 (Base Year 2007)
- Reduce Malaria mortality by 50% by 2013 (Base Year 2007); &
- Achieve Kala-azar elimination by 50% of sampled blocks during the project period.

3.2.1. Malaria

In Phase one, 50 districts where the new malaria treatment policy is applied

- By the end of second year of implementation, more than 50 % of clinically suspected malaria cases tested for *P. falciparum* either by rapid diagnostic kits or microscopy within 24 hours from the time the fever patient reports to the government health services. This percentage may go up to 80% after 3 years of implementation.
- All confirmed *P. falciparum* cases, except pregnant women in their first trimester will receive correct Artimisnin Combination Therapy (ACT) within 24 hrs of diagnosis by government health services.
- The minimum Annual Blood Examination Rate (ABER) from passive case detection including cases detected by using RDK and those detected by private sector will be 10%.

In high endemic Sub Centers (API >5 in at least two of last 5 years) where IVM is applied

- At least 80% of individuals slept under Insecticide Treated Nets (ITNs) during previous night in the bed net targeted areas. As far as possible LLINs will be used.

  OR
- At least 80% of targeted areas covered with quality spray uniformly and completely as per program norms.

3.2.2. Kala-azar

- At least 50 % of sampled blocks which at base line have not achieved the elimination goal of less then one Kala-azar case per 10,000 persons will achieve the elimination goal.
- At least 80 % of diagnosed kala-azar cases complete standard treatment.

- At least 80% of houses in identified Kala-azar endemic areas covered uniformly and completely with effective insecticide spray.

3.3 Project Strategies

3.3.1 Malaria Control

1. Phased implementation of new policies focusing on high burden districts;

a. The NVBDCP has introduced new drug policy (2007) for malaria diagnosis and treatment.
b. Apart from 106 districts in North-eastern States, Jharkhand, Orissa, West Bengal which are already covered by GFATM support for malaria, 93 districts in the country with high *Pf* malaria incidence have been selected for the proposed project. Selection criteria was based on *Pf* more than 25%, *Pf* cases more than 1000 per district, Slide falciparum rate (SFR) >0.5 (Data from 2004-05-06 formed the basis for selection of districts).
c. Implementation is proposed in 50 districts in first phase accounting for 60% of national *Pf* cases in 6% population, another 43 districts in second phase i.e 3rd year onward accounting for additional 10% of *Pf* cases and 30 % population.

2. Improved access to malaria case management;

a. All project districts will first be stratified according to the risk of *Pf* malaria in each PHC block/ sub centre.
b. In PHC blocks with Slide Falciparum Rate (SFR) >= 2%, all reported fever patients will have an RDK for *Pf,* except in areas where a microscopy result can be available within 24 hours.
c. In other PHC blocks, microscopy will be used as the first diagnostic procedure and RDK will be used for inaccessible locations for high risk patients and during e emergency. Such selective use of RDKs will make diagnosis of *Pf* malaria more cost-effective.
d. All confirmed Pf malaria cases will be treated with ACT.

3. Supporting innovations in malaria surveillance;

a. Active case detection is proposed at the time of an outbreak. Options for active case detection will be used e.g. as a part of fever surveillance in partnership with IDSP. Active case detection will also be considered in high risk P falciparum areas that are inaccessible.
b. In project districts, surveillance will be primarily based on the examination of blood samples from suspected malaria cases i.e., Passive Case Detection (PCD).
c. In the first phase, States will set tentative annual targets for the number of patients to be tested in PCD (e.g. at least 10% in highly endemic areas); when more experience gained in implementation, NVBDCP will prepare norms adapted to different epidemiological situations.
d. In the first phase, blood slides will be collected from all patients suspected of malaria, whether or not an RDK test is also given. This is important since the RDK to be used is only specific for falciparum malaria. This will also help to ensure quality control of the two methods.
e. It is likely that by 3rd year RDKs sensitive to Pf as well as Pv will be available. At this time the recommendation on microscopy for diagnosis of malaria will be reviewed and appropriate strategy adopted.

f. The project will introduce a sentinel surveillance system in the NVBDCP to monitor hospital admissions and deaths attributable to malaria at selected representative sites including those from government and in the private sector.
g. Periodic surveys of health facilities and households, and LQAS in endemic areas are proposed in order to support and validate M&E.

4. Monitoring of anti-malarial drugs and insecticides efficacy;

a. Monitoring of therapeutic efficacy of SP and ACTs will be undertaken so that effective drugs continue to be used in the treatment of *Pf* malaria.
b. To maintain the use of effective drugs and get the desired impact, at least five units will monitor the quality of medicines and insecticides at different sites in the country.
c. One unit in each State will be responsible for quality assurance of diagnosis.
d. There will be an independent inspection agency monitoring the quality of pharmaceuticals by testing random samples. To restrict the use of unregulated use of Artesimine monotherapy by the private sector, there will be a rapid assessment of Artesiminin monotherapy use, its data on production sale, stock at medical shops etc shall be done by hiring the services of National Institute of Malaria Research [NIMR (ICMR) institution].

5. Integrated vector Management;

The project will implement an IVM strategy to use the mix of best available options for vector control.

5.1. Indoor Residual Spray;

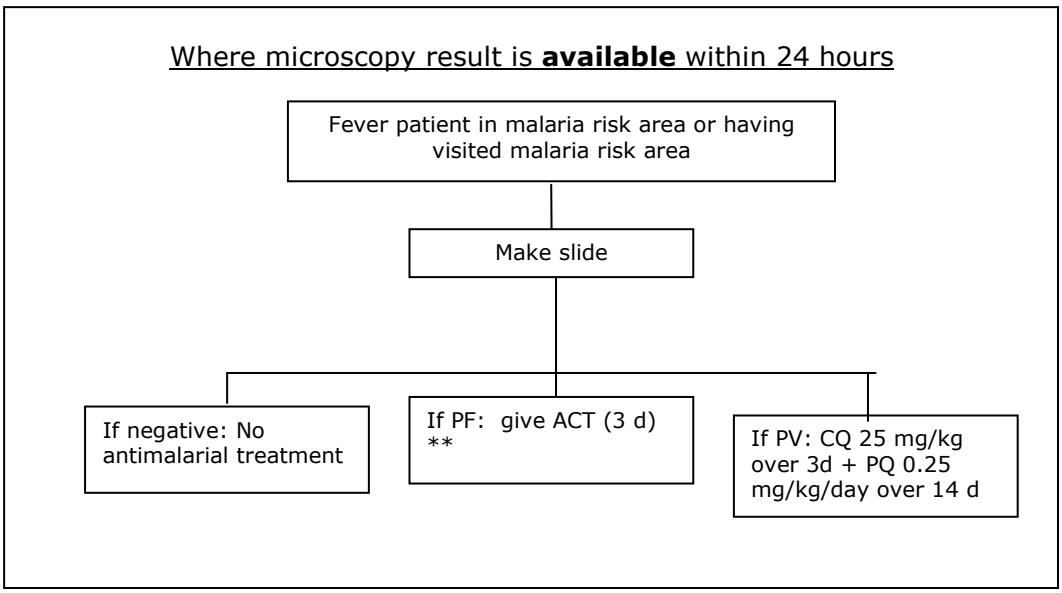
1. The project will support improvements in the effectiveness of vector control operations in high burden districts for *Pf by* introducing micro-stratification of districts as per national guidelines based on; epidemiological and ecological data, to delimit areas and populations which would be targeted for selected interventions, i.e. IRS or ITNs.
2. The program will systematize insecticide rotation for IRS to lessen the risk of insecticide resistance and ensure the implementation of good pesticide management practices consistent with WHOPES.
3. The use of IRS will be restricted to those high risk areas where ITNs are unacceptable for the population or there is other evidence for superior effectiveness of IRS and for the control of epidemics with a focus on quality and completeness of IRS coverage.

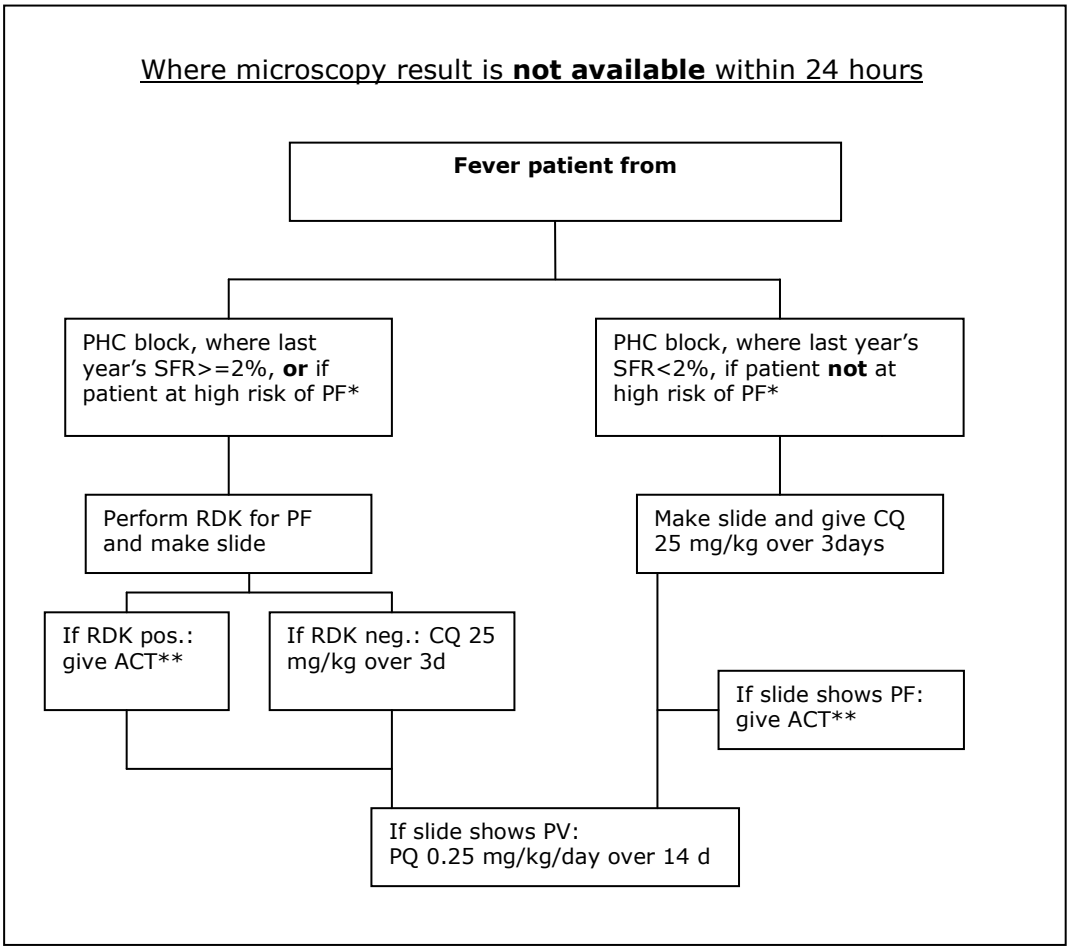
5.2. Introduction of Long Lasting Insecticidal Nets (LLINs);

1. Thrust of the project in the period will be on promoting the use of Long Lasting Insecticidal Nets (LLINs). Areas consistently reporting high Annual Parasite Incidence (API) in all age-groups (indicating intra-domiciliary transmission) will be given priority in this regard, with a target of achieving 80 percent coverage in all the villages of the sub centre selected for LLINs.
2. This will require effective Behavior Change Communication (BCC) strategies for proper use of the net and demand generation. LLINs would, in the first years, normally be distributed by the public sector free of charge (possibly through performance contracts with NGOs, self help groups).

3. It is expected that a progressively larger proportion of nets will be distributed through public-private initiatives (social marketing/social franchising), with the government providing a partial subsidy, depending on household economy in a given area.
4. LLINs will be introduced as pilot in 1–2 districts in five states in 2nd year of project and later scaled up. The first year of project will set logistic arrangement, training and distribution mechanism of LLINs.
5. Until LLINs are widely available re- impregnation of ITNs will be carried out on regular basis for which the project funds shall be utilized.

Based on the recommendations of Technical Advisory Committee (TAC) and the Joint Monitoring Mission, Government of India has summarized the policy on malaria control. An algorithm has been developed to summarize the use of RDK, microscopy and treatment of malaria in a cost effective way. This algorithm forms the basis for planning the programme and for implementation of the program in the high burden states.





ACT= artemisinin-based combination therapy; CQ= chloroquine; PQ=primaquine

**Patient at high risk of PF* (when living in area, where last year's SFR<2%). Like the patient visited PF endemic area, or belongs to aggregated labor force or household with recent PF case

** Pregnant women in 1st trimester: Quinine per os for 7 days. The possible addition of newer combination drugs for higher effectiveness needs to be considered (viz. WHO treatment guidelines).

3.3.2 Strategies for Kala-azar Elimination

1. Improving access to and use of services for elimination of Kala-azar;

a. Improving Kala-azar case management;

- The project will improve access to better-quality and more specific diagnosis and treatment of kala-azar patients, mainly by introducing rapid diagnostic dipsticks in the government health services (for appropriate diagnosis of the disease), and the use of effective new first-line drugs such as Miltefosine. In districts where new first line drugs have not been introduced, SSG treatment will be given observing all precautions and measures to reduce side effects provided that the resistance to SSG is less

than 10%. Where the resistance exceeds 10% level, SSG will be replaced by rescue drug Amphotericin B. Non responsive patients will also be treated with rescue drugs. These measures will be accompanied by staff training and intensive monitoring of each case for supervised treatment so that treatment is complete and effective.

- The project will use surveillance of 'hot spots' for early detection and complete treatment.
- Interventions to be supported for complete treatment will include development of a system for individual treatment boxes for each patient, a patient retained treatment card and supervised treatment.
- In addition to improving services in the government sector, the NVBDCP will seek to establish public-private partnerships with private health care providers wherever feasible.

b. Strengthening of Kala-azar surveillance;

- Passive case detection will be strengthened through reporting and information system at different levels of health care as well as the use of treatment cards
- Reporting by the private sector will be a part of the information system
- Sentinel sites will be established in the public and private sectors to obtain detailed and accurate information on Kala-azar.
- Periodic household surveys and LQAS will be done to support and validate disease surveillance.

c. Effective Vector Control;

- Integrated Vector Management (IVM) approach will be used in areas as per NVBDCP programme policies and would comprise of selection of the mix of interventions from amongst IRS, personal protection including the use of ITNs, improved housing of the poorest and the most affected.
- Insecticide Residual Spray with DDT will be the main control tool for reducing sand fly and human contact. In districts where malaria is reported and DDT resistance is a concern, pyrethroids or other alternatives for DDT can be considered.
- Indoor DDT spraying in all cattle sheds and human dwellings is proposed. NVBDCP has mapped Kala-azar areas through GIS mapping for focused IRS interventions. This system shall be updated and applied to economize insecticide consumption.

d. Monitoring of Kala-azar drugs and Insecticide efficacy;

- New drugs and diagnostics are proposed to be used in the elimination of Kala-azar. It is proposed to do the monitoring of therapeutic efficacy of Kala-azar drugs and pharmaco vigilance to assess side effects of drug used
- Quality assurance of Rapid Diagnostic kits used for Kala-azar will be established
- The insecticide resistance will be monitored to ensure that appropriate and effective insecticides are used in the programme.

e. Supporting interventions for Kala-azar:

- The project will support piloting of interventions, backed by expanded BCC efforts to educate the public in endemic areas and to motivate infected persons to seek treatment from qualified providers at an early stage of the disease.
- Because many kala-azar patients are very poor, the program will support innovations such as cash subsidies to patients, to compensate for the loss of income during kala-azar in-patient treatment.
- The Catholic Relief Agency services shall be utilized by programme to improve Kala-azar case management services covering 3-4 districts in the state of Jharkhand.

The Kala-azar programme shall be implemented in 16 districts in the state of Bihar selected for first year of the project. After gaining experience, the remaining number of districts shall be expended in phased manner in the state of Bihar, West Bengal and Jharkhand.

CHAPTER 4

Detailed Project Description

The project would support NVBDCP to implement evidence based interventions for control of malaria and elimination of Kala-azar covering districts with highest burden of these diseases in a phased manner. Support for strategic planning and institutional development will also be provided to endemic districts and states in evolving programs relevant to their needs and implementing them effectively. There will be special emphasis on strengthening monitoring and evaluation systems to assess the impact of innovations to improve service delivery.

The project will be implemented over a five-year period, from 2008/09 to 2012/13, a large portion of which coincides with the 11th Plan period (2007/08 to 2011/12). The broad outlines of the project were drawn in a document produced by the Directorate of VBDCP, the "Draft Concept Note for the Proposed Enhanced Vector-Borne Disease Control Program, 2005-2010", which evolved through a consultative process led by the Directorate and with active participation from the States, non-governmental organizations (NGOs), civil society, the World Bank, WHO, GFATM, and other Development Partners currently supporting the control of vector-borne diseases in the country. The main program characteristics envisaged by the NVBDCP are:

The program will use evidence-based national policies and strategies for prevention and control of vector borne diseases.

- The States and districts will be given adequate flexibility to plan and implement the national policies and strategies as per their specific needs, environmental and social conditions and capacities.
- Central budget allocations will be based on state plans (which in turn are based on district plans) and not just population-based norms.
- There will be a stronger focus on program performance. Every state plan will be driven by a clear log frame that links outcomes and outputs to program inputs and processes. States will ensure similar emphasis in their district plans.
- State plans will prioritize high-burden areas while maintaining vigil in low and non- endemic areas, and will ensure better harmonization of surveillance and service delivery with other initiatives supported under NRHM such as the Integrated Disease Surveillance Program (IDSP).
- High priority will be given to strengthening program management at state and district levels and supportive supervision at sub-district level.
- The State Departments of Health and Family Welfare, in addition to implementing national policies and strategies for prevention and control of vector-borne disease, will partner with other departments or NGOs/private sector to improve access and quality of care.
- The state NVBDCP will play a greater role and assume the responsibility of oversight to seek uniformity in the application of best practices by NGOs and other private health care providers.

The following table summarizes the key innovations being put in place by the project and some remaining concerns and issues:

Intervention and Current Status	Agreed Change in Policy/Program	Comments/ Challenges
Malaria Case Management		
➢ Presumptive chloroquine treatment no longer effective for increasing falciparum malaria (Pf) prevalence ➢ Community-level diagnosis based on microscopy not available or delayed in rural and tribal areas	➢ Confirmed Pf cases to be treated with ACT, a highly effective drug regimen ➢ Rapid diagnostic test kits to be introduced at community level and used to confirm Pf within 24 hours of reporting of fever	➢ ACT treatment requires new training and supervision ➢ Higher commodity costs ➢ Need to assure adequate supply and storage in remote areas ➢ Need to assure quality of drugs and medical supplies in booming global market
Malaria Vector Control		
➢ Mosquito control traditionally with insecticide spraying in houses (IRS). Effectiveness has declined due to vector resistance	➢ Program will replace over time most IRS with use of long-lasting insecticidal mosquito bed nets (LLINs). Delivery free to villagers	➢ LLINs not yet widely accepted by beneficiaries in many districts– need strong behavior change activities ➢ LLIN production in India still limited. Need to develop market
Kala-azar Case Management		
➢ Increasing resistance to currently used injectable medicines for Kala-azar which also have significant side effects ➢ Current tests to diagnose Kala-azar are not very specific	➢ New oral drug – miltefosine – which is safer and more effective to be introduced in districts where there is high resistance to current drugs. ➢ New Rapid Diagnostic Test for Kala-azar test kits to be used to improve diagnosis ➢ Successful strategies from TB program to be used to increase patient compliance	➢ New strategies will require better implementation in some of weakest districts ➢ Miltefosine must be closely monitored as it can be toxic to pregnant women and small children ➢ Adequate supplies and logistics must be assured in difficult areas ➢ New technologies are higher in cost and may result in low quality imitators which must be kept away from program
Kala-azar Vector Control		
➢ *Kala-azar vector, the sandfly, poorly covered*	➢ DDT application to be strengthened with	➢ New strategies require additional staff

Intervention and Current Status	Agreed Change in Policy/Program	Comments/ Challenges
with DDT	new approaches in identified high risk prevalence areas ➢ Training and supervision of control workers to be improved ➢ Collaboration with local housing and sanitation programs to be increased ➢ New innovative IVM strategies like use of Insecticide treated nets	support and better monitoring and supervision in weaker locations
Overall Program Management		
➢ Current program implemented in many states ➢ Widespread implementation with little attention to capacity or preparation ➢ Weak monitoring ➢ Slow introduction of expert advice	➢ Project will focus on states with more affected districts ➢ Project will introduce district level readiness filters prior to implementation ➢ Strengthened HMIS plus focused sample and survey reviews ➢ Biannual technical reviews	➢ New processes need to be scaled up. Project will expand in two phases with major progress review before two years ➢ Additional staff support needed for implementation. Project will finance local staff, mobility, and training which will eventually be adopted into government system

4.1 Malaria control and Kala-azar elimination

The main objectives, activities and reforms planned by NVBDCP for malaria control and Kala-azar elimination supported by the project are summarized below:

4.1.1 Malaria Control

1 *Phased implementation focusing on high burden districts*

The NVBDCP will introduce the new policy for malaria diagnosis and treatment recommended by the 2007 Joint Monitoring Mission (JMM) in a phased manner, prioritizing States and districts with high Pf burden. Apart from 106 districts in North-eastern States, which are already covered by GFATM support for malaria, 93 districts in the country with high Pf malaria incidence have been selected for the proposed project.

2 Improved access to malaria case management

All project districts will first be stratified according to the risk of Pf malaria in each PHC block. In PHC blocks with Slide Falciparum Rate (SFR) >= 2%, all fever patients will have an RDK for Pf, except if a microscopy result can

be available within 24 hours. In other PHC blocks, an RDK will only be used for patients at high risk. This selective use of RDKs will make diagnosis of PF malaria more cost-effective. The proposed changes will have important implications for the commodities to be procured by the program, especially RDKs, and ACTs, and in terms of training, M&E, and quality assurance.

3 Supporting innovations in malaria surveillance

In surveillance, the project will support efforts to de-emphasize the collection of blood samples through outreach workers through house to house visit –i.e., Active Case Detection (ACD). Such collection will be restricted to high-risk areas with weak curative services, and when there is suspicion of an outbreak. In project districts, surveillance will be primarily based on the examination of blood samples from suspected malaria cases i.e., Passive Case Detection (PCD). In the initial phase, States will set tentative annual targets for the number of patients to be tested in PCD (e.g. at least 10% in highly endemic areas); when more experience has been gained NVBDCP will prepare norms adapted to different epidemiological situations. In the initial phase, blood slides will be collected from all patients suspected of malaria, whether or not an RDK test is also given. This will ensure continuity in surveillance and support quality control of the two methods of confirmatory diagnosis. After two years, the policy of blood slides on all fever cases where RDK is performed will be reviewed. By then it is likely that RDKs sensitive to PF as well as PV will be available. In addition, the project will support introduction of a sentinel surveillance system in the NVBDCP to monitor hospital admissions and deaths attributable to malaria at selected representative sites including those from government and in the private sector, and periodic surveys of health facilities and households in endemic areas.

4 Monitoring of anti-malarial drugs and insecticides efficacy

The project will support nation-wide actions to update and strengthen monitoring of therapeutic efficacy of anti-malarial medicines, insecticide resistance and quality of medicines to contain the problems of drug and insecticide resistance and ensure their efficacy. Monitoring of therapeutic efficacy of SP and ACTs will be undertaken so that effective drugs are used in the treatment of malaria. To maintain the use of effective drugs and get the desired impact, at least five units will monitor the quality of medicines and insecticides at different sites in the country. One unit in each State will be responsible for quality assurance of diagnosis. In addition, there will be an independent inspection agency monitoring the quality of pharmaceuticals by testing random samples.

5 Enhancing effectiveness of existing vector control

The project will support improvements in the effectiveness of its vector control operations in high Pf high burden districts by introducing micro-stratification of districts according to revised national guidelines based on epidemiological and ecological data, to delimit areas and populations which would be targeted for selected interventions, i.e. IRS or LLINs. Furthermore, the program will systematize insecticide rotation for IRS to lessen the risk of insecticide resistance and ensure the implementation of

good pesticide management practices. The use of IRS will be restricted to those high risk areas where LLINs are unacceptable for the population or there is other evidence for superior effectiveness of IRS and for the control of epidemics with a focus on quality and completeness of IRS coverage.

6 Introduction of Long Lasting Insecticidal Nets (LLINs)

An important thrust of the program during the project period will be promoting the use of Long Lasting Insecticidal Nets (LLINs). Areas consistently reporting high Annual Parasite Incidence (API) in all age-groups (indicating intra-domiciliary transmission) will be given priority in this regard, with a target of achieving 80 percent coverage. The success of this thrust will require effective Behavior Change Communication (BCC) strategies for proper use and demand generation. Current BCC activities lack focus in objectives, media, messages and target audiences; there is a lack of clear articulation of the behaviors to be changed and most BCC activities are input based with limited attention to desired outcomes. A BCC strategy and Action Plan will be prepared. LLINs would, in the first years, normally be distributed by the public sector free of charge (possibly through performance contracts with NGOs), but it is expected that a progressively larger share of nets will be distributed through public-private initiatives (social marketing), with the government providing a partial subsidy, depending on household economy in a given area.

4.1.2 Kala-azar Elimination

1. Improving access to quality Kala-azar diagnosis and treatment services in endemic district

The project will support to achieve the goal of eliminating Kala-azar by 2010 focusing on 46 districts in the three States that account for practically all Kala-azar cases in India (Bihar, Jharkhand, and West Bengal). Specifically the project will provide inputs to improve access to better-quality and more specific diagnosis and treatment of Kala-azar patients, mainly by introducing Rapid Diagnostic Test for Kala-azar dipsticks in the government health services (for appropriate diagnosis of the disease), and the use of effective new first-line drugs such as miltefosine and new emerging drugs. These measures will be accompanied by the required staff training and intensive monitoring of each case.

2. Improving quality of Kala-azar case management in private sector

In addition to improving services in the government sector, the program will seek to establish public-private partnerships with private health care providers whenever feasible.

3. Supporting supply-side interventions for Kala-azar

The project will support piloting of supply side interventions, backed by expanded BCC efforts to educate the public in endemic areas and to motivate infected persons to seek treatment from qualified providers at an early stage of the disease. Because many Kala-azar patients are very poor, the project will support innovations such as cash subsidies to patients, to compensate for the loss of income during Kala-azar inpatient treatment.

4. Behavior Change Communication

A three pronged BCC strategy is proposed for the NVBDC program: This includes: (a) decentralized BCC activities financed by NVBDCP; (b) central BCC activities implemented by a professional media agency to be financed by the project; and (c) social mobilization activities with specific focus on promoting LLINs to be implemented by NGOs or social marketing agencies having strong field presence financed by the project. The decentralized locale specific BCC activities are detailed in the operational guide for anti-malaria month campaign. This PIP provides a clear roadmap for initiating and implementing structural and institutional framework for implementation as well as institutional arrangements and monitoring and evaluation processes along with a budget template. However, random state visits undertaken during the project preparation suggest that the implementation capacities across the states vary widely. The project will provide consultant support at state and national levels and the primary focus will be on interpersonal communication and group discussions to inform community based institutions like Panchayat Raj and self help groups, and vulnerable populations about new diagnostic and treatment services made available at village level. A professional media agency will be selected following QCBS process at national level to undertake formative research, develop and pre-test multi-media campaign and undertake media buying for a nation-wide campaign with strong focus on endemic states. The project also provides for hiring Services of NGOs and social marketing agencies having strong field presence will be used to undertake social mobilization of beneficiaries in villages selected for LLIN intervention.

5. Training

The focus will be on competency based and inclusive training. The program has well defined operational guidelines for each cadre of staff and a well defined training plan supported by clear operational guidelines. Under the project additional consultant support for training has been provided at national and state levels to ensure effective planning and oversight for decentralized training activities. National & State trainers for malaria and Kala-azar have been trained at Bhubaneswar (Orissa) and Patna (Bihar) during December 2007 and early part of 2008 by a team of experienced national and international experts and this opportunity has been used to update the training modules. The national, state trainers in addition to training the core vertical contractual staff proposed under the project (such as malaria and Kala-azar technical supervisors and the district VBD officer and consultant) will also monitor the quality of training. One dedicated NVBDCP focal point has been identified for each project state who will be regularly visiting the state to provide technical oversight for decentralized activities and for trouble shooting. Further, an independent agency will be monitoring the physical progress of decentralized training including compliance with the program guidelines. The proposed early implementation review by the World Bank (after 18-21 months) will also assess the competencies of the staff at different levels.

4.2 Project Components and Sub-Components

For achieving the objectives, the project will have the following components and sub-components

Component I. Improving Access to and Use of Services for Control of Malaria;

a. Sub Component: Improving malaria case management
b. Sub Component: Strengthening Malaria Surveillance
c. Sub Component: Effective Vector Control

Component 2. Improving Access to and Use of Services for Elimination of Kala-azar;

a. Sub Component: Improving Kala-azar Case Management
b. Sub Component: Strengthening Kala-azar Surveillance
c. Sub Component: Effective Vector Control

Component 3. Policy and Strategy Development, Capacity Building and Monitoring and evaluation;

a. Sub Component: Policy and Strategy Development
b. Sub Component: Program Management and Capacity Building
c. Sub Component: Monitoring and Evaluation

The first two components would include activities implemented by the Directorate of the NVBDCP, as well as activities implemented by the States (on the basis of approved annual state action plans) but financed by the central government, either in the form of in-kind transfers or cash transfers through state health societies. Component 3 contains inputs to strengthen the management support. The project design incorporates recommendation of the quality enhancement review to focus on two priority diseases malaria & Kala-azar and to implement scale-up phases with a mid course review.

Besides the above three components, the document will also address issues on Financial Management Plan, Procurement Arrangements, Impact Evaluation, Safeguard Policies and GAAP.

4.3 Project Cost

Project costs are shown in two tables. The first shows the total project costs including the three components and their subcomponents, as well as an unallocated amount. Because of joint costs across project subcomponents, it is not always possible to break down costs across different subcomponents within a component.

The unallocated amount Rs. 1460 million has been retained in the project costs as a contingency to allow more rapid scale up of the distribution of commodities for malaria control and Kala-azar elimination, such as LLINs. It is also a contingency to allow the project to support costs of NGOs partnerships and efforts to improve quality of services in private practice

and also support the implementation in other malarious districts, in case GFATM funding is not available and provided that fiduciary arrangements are acceptable to the World Bank.

Components/Sub-Components	Costs (US$ Million)	Cost (INR Million)
Component 1: Improving Access to and Use of Services for Control of Malaria	**119.5**	**4780.0**
Sub-Component 1.a.: Improving Malaria Case Management	45.0	1800.0
Sub-Component 1.b.: Strengthening Malaria Surveillance	5.9	236.0
Sub-Component 1c.: Effective Vector Control	68.6	2744.0
Component 2: Improving Access to and Use of Services for Kala-azar Elimination	**41.9**	**1676.0**
Sub-Component 2.a.: Improving Kala-azar Case Management	40.0	1600.0
Sub-Component 2.b.: Strengthening Kala-azar Surveillance	1.5	60.0
Sub-Component 2c.: Effective Vector Control	0.4	16.0
Component 3: Policy and Strategy Development, Capacity Building and Monitoring and Evaluation	**52.1**	**2084.0**
Sub-Component 3.a.: Policy and Strategy Development	23.1	924.0
Sub-Component 3.b.: Capacity Building and Program Management	24.2	968.0
Sub-Component 3.c.: Monitoring and Evaluation	4.8	192.0
Total Baseline Project Cost	**213.5**	**8540.0**
Unallocated Amount*	**36.5**	**1460.0**
Total Project Cost	**250.0**	**10000.0**

* The refund of the Project Preparation Facility (PPF) advance of US 1 million will be financed from this unallocated amount.

The second Table (below) presents the agreed cost estimates for standardized costs of contractual staff, mobility, and training at state and district level. These costs will be reviewed by NVBDCP and the World Bank at the time of project implementation and may be revised if needed. They will be revisited again at the time of the early implementation review after 18 months of project implementation.

A. Standard Cost for a Project District	Unit Cost/INR	No. of Units	Total Cost INR million	Total Cost USD million
Contractual Staff*	123000	12	1476000	36900
Mobility	15000	12	180000	4500
Training (Per annum)			1,785,000	44625
Total			**3441000**	**86025**
B. Standard Cost for a Project State	**Unit Cost/INR**	**No. of Units**	**Total Cost INR**	**Total Cost USD**
Contractual Staff*	212500	12	2550000	63750
Mobility	50000	12	600000	15000
Training (Per annum)			60000	1500
Total			**3210000**	**80250**

*As approved by EFC
Calculation: US $ @ INR40

Chapter 5

Malaria Control

5.1 *Project Component 1: Improving Access to and Use of Services for Control of Malaria [Rs 4780 million]*

This component includes activities to be implemented by the Directorate of NVBDCP in the Project States of Andhra Pradesh, Chhattisgarh, Jharkhand, Madhya Pradesh and Orissa during the first 2 years of project covering a total of 50 districts. After mid course review by World Bank (18 -21 months), the project implementation shall be extended in another 43 districts in 8 states (5 states above+Gujarat,Karnataka and Maharastra). The World Bank shall provide drugs, diagnostic kits, lab consumables, insecticides, long lasting insecticide treated nets (LLINs), lab consumables, computer hardware and software, furniture, training, IEC/BCC materials. Support for supervision and integrated vector control will also be provided to remaining 43 districts covered under the project in phased manner. The districts covered under malaria project are enclosed. It comprises three sub-components:

- Sub-Component 1.a: Improving Malaria Case Management [Rs. 1800 million]
- Sub-Component 1.b: Strengthening Malaria Surveillance [Rs. 236 million]
- Sub-Component 1.c: Effective Vector Control [Rs. 2744 million]

5.1.1 Sub-Component 1.a: Improving Malaria Case Management

- The NVBDCP will introduce the new policy for malaria diagnosis and treatment, in a phased manner in project districts. While prioritizing States and districts with high P*f* burden, 93 districts in the country with high malaria incidence have been selected for implementation of the new policy and related reforms. This will be in addition to 106 districts already covered by GFATM. During the first two years, the new malaria case management policy will be implemented in 50 prioritized high Pf burden districts in five states of Andhra Pradesh, Chhattisgarh, Jharkhand, Madhya Pradesh and Orissa and an effective implementation model shall be developed.
- Access to early diagnosis of *Pf* based on RDKs will be implemented in 50 districts during the first two years to develop and refine implementation models while only minimal inputs (training to Lab technicians, MTS, VBD Consultant etc.) will be provided to the remaining 43 districts.

After the implementation review by experts and the World Bank, the new model will be implemented in remaining 43 districts from the third year to cover the total 93 districts in project.

This sub-component will also include:

- Training and improved supervision with special focus on application of new tools for effective diagnosis and treatment of malaria;

- Behavior change communication to promote appropriate treatment-seeking and adherence; promotion of appropriate case management in the private sector;
- Innovations such as social marketing/franchising for private sector involvement.
- The household surveys planned under the project will provide data on access.

Detailed sub-components are described below:

1.a. a) Early diagnosis and complete treatment

- To reduce morbidity and mortality due to malaria the best means is to detect early and provide complete treatment.
- Presumptive treatment will be discontinued but all fever cases in the high endemic areas will be attended by health worker and will be immediately tested for *P falciparum* by RDT Kit. A Blood slide shall also be made for microscopy.
- All positive *Pf* patients will receive ACT (other than pregnant women). All P *vivax* will be given Chloroquine and Primaquine (*for 14 days*) according to national treatment policy.
- Provision of RDT and ACT will be prioritized in areas which do not have access to microscopy in 24 hours and in tribal areas.
- Private sector partners would be identified for Malaria diagnosis and treatment and efforts will be made to provide the diagnosis and treatment according to national standards.

The activity schedule for the first year is presented in Table-1.

Table – 1 Activity Schedule for the first year

Result	Indicator	Activity	Time Schedule	Responsibility
At least 30 % Malaria cases are diagnosed and treated within 24 hours of reporting	% of *P falciparum* +ve patients treated within 24 hours of reporting	Develop district action plan for the followings:	Nov 08	District, state
		Identify areas for use of RDT & ACT	Nov 08	District, state DMO
		Map the high risk areas, Calculate need	Jan 09	SPO,NVBDCP
		Train staff	Jan 09	State NVBDCP
		Supply RDT ACT;	Feb 09	Centre
		Use RDT ACT Provide Complete treatment of PF & PV	Ongoing	District, CHC & PHC

Result	Indicator	Activity	Time Schedule	Responsibility
Severe cases treated at referral centers Case fatality is less than 10%	% of case fatality	Referral centers identified and mapped	Sept 08	MO PHC, District
		Health workers are trained to identify severe cases	Jan 09	MO PHC, District
		Staff at referral centers are trained to treat severe malaria cases including reserved beds for severe malaria	Feb 09	Hospital, MO PHC, District
		Centers are equipped with medicines needed	Feb 09	State NVBDCP
Introduction of RDT and ACT	No. of RDT , ACT used	Health staff and VHW are trained in its use	Jan 09	NVBDCP State/ districts
		RDT – ACT are procured	Dec 08	NVBDCP
		RDT- ACT stored and distributed with safety	Jan 09	NVBDCP
		RDT – ACT is supplied to all health workers in PHCs	Feb 09	NVBDCP/ state / district
		RDT- ACT use reported with adverse reaction if any	Continued process	District
Strengthening microscopy		Microscopy centers identified and LTs trained for strengthening correct malaria diagnosis	Jan 09 Continued process	Regional Offices

A detailed log-frame will be developed based on lessons learnt during the first three months of implementation.

1.a. b) *Microscopy*
The activity schedule for the first year is presented in Table-2.

Table -2 Activity schedule for the first year

Result	Indicator	Activity	Time schedule	Responsibility
Adequate Microscopy centers are established in the districts	No. of microscopy centers functional in private sector and government	Listing the labs for microscopy	Oct 08	District
		Invite proposal from pvt. Sector	Oct 08	District, state
		Short list the labs	Dec 08	District, state
		Train the technicians	Jan 09	District
		Sign the MOU	Jan 09	District, state
		Monitor results and service quality	Ongoing	State , NVBDCP
		Review the arrangements	April 09	NVBDCP
Apex microscopy centre established	Functioning apex lab.	NIMR is strengthened for Quality assurance by way of staff and equipment	Jan 09	NVBDCP/ NIMR

5.1.2. Sub-Component 1.b: Strengthening of Malaria Surveillance

Surveillance will be primarily based on the examination of blood samples from suspected malaria cases, i.e., Passive Case Detection (PCD). Initially, tentative annual targets for the number of patients to be tested in PCD, e.g., 10% in highly endemic areas, will be set by the project districts. After gaining some experience, NVBDCP will prepare norms adapted to different epidemiological situations. At present RDKs sensitive both for Pf and Pv will not be introduced by the programme since conclusive evidence is awaited. To ensure continuity in surveillance and support quality control of the two methods of confirmatory diagnosis, blood slides will be collected initially from all patients suspected of malaria, whether or not an RDK test is given. After two years, the need for taking blood-slides will be reviewed. It is hoped, that at the end of second year, RDKs sensitive to both Pf and Pv will be available.

Active case detection will be undertaken in high risk areas where the outreach is poor. Various options will be tried to net fever cases in collaboration with IDSP. Active case detection will also be done when there is a clustering of fever cases in the community or there is concern about malaria outbreak. For fever surveillance, the health care provider would

contact key informants in the village. The information on fever cases will be reviewed and analyzed to diagnose unusual fever activity or clustering of cases.

In addition to active case detection and passive case detection, the project will support introduction of a sentinel surveillance system for PCD to additionally monitor hospital admissions and deaths attributable to malaria at selected representative sites, in both public and private sectors. These sentinel sites in each district, 2-3 hospitals/health centres with high malaria case load (these can be private or mission hospital) for recording of all in - patients with malaria and malaria related death shall be introduced as per criteria developed. The criteria shall be developed by NVBDCP and put in place within six months of project implementation with the help of experts, WHO and the World Bank. The Periodic health facility and household surveys will be carried out to supplement the information obtained from surveillance. The household and health facility surveys done by NIMR in 2006 will serve as benchmark.

1.b. a) Malaria Outbreaks

Fever surveillance will play a key role in early detection of malaria outbreaks, initiation of prompt action such as IRS, testing by RDK for *P falciparum* and immediate treatment. Rapid response teams will initiate surveillance including entomological surveillance in situations where there is clustering of fever cases reported by IDSP or malaria staff. Active collaboration with IDSP program will ensure District surveillance team to undertake corrective measures jointly.

Epidemic response teams will take action when;

a. High reporting of fever cases is captured from Internal reports and IDSP
b. Sentinel, sites showing unusual increase in malaria cases
c. Health care providers are informed about unusual fever activity or clustering of cases during their visit to village or sub center.

These activities shall be carried out in collaboration with RRT under IDSP and the state's NVBDCP team will assist them.

5.1.3 Sub-Component 1.c: Effective Vector Control

The project will carry out micro-stratification of districts based on epidemiological and ecological data for more effective targeting of IRS or ITN or other vector control options. The high risk areas and populations identified will be targeted for either IRS or ITN.

In the project districts the national policy of insecticide rotation for IRS will be introduced to lessen the risk of insecticide resistance and good pesticide management practices consistent with WHOPES recommendations will be supported.

Gradually, the use of IRS will be restricted to high risk areas where ITNs are unacceptable to the population due to ecological conditions or there is other

evidence for superior effectiveness of IRS and for the control of epidemics with a focus on quality and completeness of IRS coverage.

The project will promote the use of Long Lasting Insecticidal Nets (LLINs). Areas consistently reporting high Annual Parasite Incidence (API) in all age-groups - indicating intra-domiciliary transmission - will be given priority for this, with a target of achieving 80 percentage coverage.

The success of this thrust will require efficient distribution systems and effective BCC strategies for demand generation and proper use. The LLINs, expected to be available from the second year of the project, will be distributed by the public sector free of charge, possibly through performance contracts with NGOs. However, the project will support efforts to enhance net distribution through public-private initiatives such as social marketing, with the government providing a partial subsidy, depending on household economy in a given area. This activity shall be expanded only after 18-21 months following the early implementation review by the World Bank. Under GFATM, PPP services of presence of CBOs, FBOs, VHSC will also be utilized in selected blocks in project districts.

1.c. a) Indoor Residual Spraying (IRS)

IDR review by NVBDCP 2006 has shown that uniform and complete spray has been carried out only in approximately 10% of house hold.

The programme is developing a strategy of limiting the areas to be sprayed but ensuring spraying with good quality insecticide and spraying the households completely and uniformly. The selection of villages and households will be based on national recommendations about the focused areas of spraying.

Geographical information system (GIS) and remote sensing (RS) has been used by NVBDCP for stratification of areas for focused IRS operation in high endemic districts. This strategy will help economize insecticide consumption and also help reduce environmental degradation through in discriminate spraying.

Selective IRS would be done when surveillance has been geared up and geographic mapping with validation is made available. Until then IRS would be undertaken on case reporting in the village on the basis of API. The main strategy of vector control in malaria programme is IRS with DDT. In districts where malaria is reported and DDT resistance is a concern, Synthetic pyrethroids or other alternatives for DDT will be considered. Rotating the insecticide every 3 years would reduce the development of resistance development.
IRS would be done at the most appropriate time twice a year. IRS is expected to achieve maximum coverage uniformly to have a lasting impact. Spray staff would be trained for quality spray as well as environment safety and personal protection. Community support will be taken for maximum

coverage and its quality. Other than high endemic districts, IRS would also be undertaken in areas during out break.

IRS will be supported by entomological studies and vector monitoring to assess the efficacy of IRS. This activity shall be outsourced to NIMR. Around 40-50 sites covering all eco type zones will be covered with state entomologist team of states and field stations of NIMR and VCRC. This study will help to evolve a comprehensive insecticide resistance map for country and will help better informed insecticide policies system.

WHO has developed guidelines on IVM strategy which shall be adopted/adapted as per national programme need in project districts. This would comprise of selection of the mix of interventions from amongst IRS, personal protection including the use of ITNs. The IVM strategic plan would be developed. Vector studies including vector behaviour and bionomics and vector surveillance would be an integral part of IVM strategy.

The procurement of synthetic pyrethorids shall be met from project fund. DDT supply will be from domestic source for areas falling under DDT coverage. The spray wages for seasonal workers shall be drawn from Domestic Budget Support (DBS) under NVBDCP after approval from MOHFW. The activity schedule for the first year is presented in Table-3.

Table–3 Activity schedule for the first year

Result	Indicator	Activity	Time Schedule	Responsibility
25 % high risk area receive uniform and complete spray	% of houses that have received full & quality spray	High risk area identified	Nov 08	DMO,SPO
		Insecticide Procured	Dec 08	NVBDCP
		supplied up to PHC level	Jan 09	State NVDBCP
		Safe stocking of insecticides	Jan 09	DMO, MO
		Staff trained in spraying and protection	May 09	DMO, SPO
		IEC/BCC	May 09	MO, DMO
		Spraying activities Post spray quality assessment	June 09-Oct. 09 July- Aug. 09 Nov- Dec. 09	MO, DMO Agency ,NIMR

Result	Indicator	Activity	Time Schedule	Responsibility
Spraying activities during an out break	% of houses that have received full & quality spray	As above	As per need	MO, DMO, State

1.c. b) Long lasting Insecticide treated nets

The strategy is to identify population in the district to be protected with insecticide treated nets. The in depth review (2006) showed that the possession and use of ITNs was low and varied from district with high possession and coverage in some districts (Assam) to lack of ITNs in other districts (Rajasthan). Even though the nets were available a large proportion of these had not been treated during the preceding 6 months. Therefore the programme proposes to use LLINs for which frequent re-impregantion (every six months) are not required and the longevity o LLINs is also high say 3-5 years. In view of the current possession of nets by the population, arrangements will have to be made for their re-treatment until these nets are phased out. Since the target for ITN coverage (treated nets/LLINs) is 80% for effective transmission reduction the system for procurement and distribution will be required. Partnerships with Private and NGO sectors would also be required to achieve the target.

The Village will be unit for distribution of LLINs. Each household will be provided 2 bed nets so as to reach coverage of 80% in identified villages. LLINs distribution is a key component of the project. The distribution of nets is proposed through all available channels and outreach efforts. For example, LLINs will be distributed during the antenatal clinics, contacts during immunization sessions and through community volunteer groups.

Besides free distribution of nets to families in endemic areas, an attempt will be made to create awareness and distribute LLINs to others in the identified villages through Social marketing or alternative strategies with the help of NGOS/ self help groups. The NGOS and SHGs will be allowed to charge distribution, storage and service fees from the community. The NGOS and SHGs will also create awareness for regular use of the nets and also monitor its usage. Partnerships are proposed with the private sector with the use of innovations to ensure wide adoption and usage. LLINs shall be piloted in 1-2 districts in 5 states during the 2nd year of project. The first year of project will ensure logistic management, BCC/IEC to community, dialogues with stakeholder.After piloting LLINs in project districts, up scaling shall be expanded only after Impact evaluation results.

5.2 Other Issues

5.2.1 Therapeutic Efficacy

A standard protocol for therapeutic efficacy will be used based on WHO recommendation and at least **15 studies** will be undertaken every year. The National Institute of Malaria Research Centre (NIMR) will have overall responsibility for implementing this activity which involves finalization of protocols, recruitment and training of staff, assuring the quality, complete the data and organizing annual consultation and feedback. NIMR will also be responsible for recruitment of Research Officers on contract for the units located with the Regional Directors of ROHFW where no post of Research Officer is in position. The 13 therapeutic team under NVBDCP located at Regional Offices will work in close co-ordination with the NIMR. An MOU shall be signed with NIMR for effective utilization of manpower that exists in Regional Offices.

5.2.2 Pharmaco -Vigilance

This activity will be introduced first time in the programme. NIMR will also undertake this activity along with therapeutic study. At national level, NIMR will have a advisory group supported by a full time Consultant (Pharmacologist) who will help in developing protocol, site selection training etc. At the operational side pharmaco- vigilance programme shall be linked with sentinel surveillance and facilities that treat severe malaria cases. By September 2008, NIMR will submit detailed protocol to NVBDCP which will include reporting formats. The protocol shall be shared with experts and the World Bank.

5.2.3 Quality Assurance of RDTs and Other Commodities

The quality assurance of microscopy, diagnostics and drugs are critical for the programme to ensure that end users are getting benefit of tested products. NVBDCP will request WHO to provide Consultant for further work on this issue with NIMR and submit a detailed protocol for development of SOPs for implementation at field level. The Consultant with the help of NIMR and NVBDCP will develop protocol by December 2008. Quality assurance of RDK supplied under the programme in the field will start from January 2009 by NIMR and the batch testing will start from April 2009 by when the new laboratories of NIMR are expected to be ready. NVBDCP has already requested NIMR to undertake external quality assurance of microscopy and quality panels are being prepared by the NIMR. To sustain the activity, NVBDCP will also hire the services of accredited laboratories for testing the samples drawn from field.

5.2.4 Insecticide Resistance Monitoring

The project will undertake insecticide resistance monitoring in the country to know the susceptibility status of vectors to insecticide in use under Indoor residual spray. This will help the programme to switch over to next effective insecticide for killing of vector population and *inter- alia* reduction in human vector contact. Some of the states like Gujarat, Maharastra, Tamilnadu, Karnataka, and Andhra Pradesh has well established entomological set up. However, in project states, entomologist and

supportive staff posts are either not filled, if filled with few skeleton staff. Due to this, vector behavior towards insecticide is not known and programme is facing challenges to overcome this problem. NIMR has established this facility. Therefore, NVBDCP will collaborate with NIMR who will undertake this study in 8 eco-type zones in the country. Approx. 200 sites are identified by NIMR and each year around **40-50 such** sites covering all eco-epidemiological zones will be covered with the help of Entomologist and Consultant (Entomologist) positioned in the project and field stations of NIMR and other ICMR Institutions. This will help NVBDCP to evolve a comprehensive insecticide resistance map for country which will help better informed insecticide policies.

Chapter 6

Elimination of Kala-azar

6.1 Project Component 2: Improving access and use of services for elimination of Kala-azar [Rs. 1676 million]

GoI proposes to achieve Kala-azar elimination by 2010. The target is to reduce Kala-azar cases to 1 per 10,000 population at sub-district level. This component will include activities to eliminate Kala-azar through introduction of rapid diagnostic kits, effective new medicines, training, equipment, insecticides, IEC/BCC materials, equipment, furniture, transport, computer hard and software, incremental staff, honorarium for community mobilizers, and operating costs and consultants in 46 Kala-azar endemic districts.

- Sub-Component 2.a: Improving Kala-azar Case Management [Rs. 1600 million]
- Sub-Component 2.b: Strengthening Kala-azar Surveillance [Rs. 60 million]
- Sub-Component 2.c: Effective Vector Control [RS. 16 million]

Activities in the project would include:

(a) effective and early diagnosis and complete treatment by supplying ‘rapid diagnostic kits, oral miltifosine capsules , providing treatment completion cards, maintenance of individual patient treatment boxes, training of health care providers and their supervisors, and establishing partnerships with NGOs and other private sector providers

(b) strengthening of disease and vector surveillance

(c) rationalization of selection of villages based on GIS and vector studies and targeting complete and uniform coverage of targeted households with quality insecticides (DDT)

(d) improved housing for the poorest of the poor in the villages where the problem of kala-azar is maximal with support from rural health development ministry

(e) behavior change communication at the local and national levels

(f) strengthening of management at state and district levels, and provision of additional staff at district and sub-district level to enhance supportive supervision and monitor treatment outcomes

(g) innovations like use of bed nets, operational studies with hand compressor pumps with DDT 75% wdp insecticide

These interventions will be introduced in 16 districts in the state of Bihar during the first year. The national programme in addition will continue its efforts towards elimination of Kala-azar in the other endemic districts. Based on the implementation experience during the first year, the elimination efforts will be extended to other 32 districts in second year and 46 in third year. All 46 districts will be covered in the last three years of project. The GOI target is to eliminate Kala-azar from the 52 endemic districts by 2010. The impact objective of the project is to achieve the

elimination target in at least half of these districts at the sub district level. This will contribute to the achievement of the national goal since the project focus will be on the districts that contribute maximally to the cases of Kala-azar in India.

6.1.1 Sub Component 2.a: Improving Kala-azar Case Management

6.1.1 2.a. a) Early diagnosis, complete treatment and referral

Early diagnosis and complete treatment strategy would help elimination of the parasite, reduce case fatality rates and increase the credibility of the health system, which in turn will help to increase the utilization of health services by people affected by Kala-azar

The case definition of kala –azar will be uniformly applied. A case of kala-azar is a person from an endemic area who has fever of more than 2 weeks with splenomegaly and positive dipstick test. All Patients suspected to be suffering from kala-azar should be tested by dipstick test. Confirmation of Kala-azar cases can be done by examination of bone marrow aspiration in hospital settings since these are envisage. However, this would be required in a few patients only since dipstick test is quite reliable. Once diagnosed, Miltefosine a safe oral drug will be administered under direct observation. In order to retain its efficacy and delay the appearance of drug resistance, treatment cards and patient wise box would be made available at the treatment point. Drug can not be used during early pregnancy and married women in reproductive age who do not use contraception regularly and in infants. The programme will undertake pharmaco vigilance as a part of efforts to maintain the usefulness of this drug in the programme for a long time. Miltefosine will be introduced in 16 districts. In other districts, SSG will continue to be used provided that the resistance level to SSG is less than 10%. Monitoring of side effects and management of side effects will be intensified to minimize the complications from this drug. Efforts will be made to intensify completion of medicine and the use of rescue drugs if there is unresponsiveness and toxicity from SSG. In the districts where resistance levels are higher than 10%, amphotericin B will be used as recommended by the national programme.

The activity schedule for the first year is presented in Table 1. A detailed log-frame for subsequent years will be developed later, based on lessons learnt in the six months of implementation.

Table – 1 Activity schedule for the first year

Result	Indicator	Activity	Time Schedule	Respon sibility
30% of Kala-azar cases are diagnosed and given complete treatment with first line drug	No of PHC offering Dx Rx according to national guidelines and SOPs	Develop district action plan	Nov 08	District, state
		Identify areas for use of RDK & Mf Map the high risk areas, Calculate need	Nov 08	District, state
	No of PP/ NGO sector facilities offering Dx Rx	Supply RDK, Miltefosine	Jan 09	NVBDCP , state
		Train staff	Jan 09	State, NVBDC
		Use diagnostic kits and Miltefosine	Feb 09	State, District
		Compliance follow up	ongoing	District
Severe cases treated at referral centers Case fatality is less than 10%	Case fatality rate	District Action Plans are made	Sept 08	MO PHC District
		Referral centers identified and mapped	Jan 09	MO PHC District
		Health workers are trained to identify severe cases	Feb 09	MO PHC District
		Staff at referral centers are trained to treat severe cases Including reserved beds for for treatment of Kala-azar	Feb 09	MO PHC District
		PHC/ CHC MO are trained to treat severe cases of Kala-azar	Feb 09	State NVBDCP
		Centers are equipped with medicines needed	Feb 09	State NVBDCP

Result	Indicator	Activity	Time Schedule	Respon sibility
Introducti on of RDK & Miltefosine	Number of health facilities using RDT for diagnosis Percentage of health facilities using 'RDK' for diagnosis of kala-azar	RDK – Miltefosine procured RDK, Mf are tested for quality RDK, Mf stored and distributed with safety RDK, Mf supplied to all health workers in PHCs RDK, Mf use reported with adverse reaction, if any	Dec 08 Dec 08 Jan 09 Feb 09 Continu ed	NVBDCP NVBDCP State, district District District

6.1.2 Sub Component 2.b: Strengthening of Kala-azar surveillance

Surveillance of Kala-azar will include Kala-azar, PKDL and vector surveillance. Currently the programme depends on reports from passive case detection, and cases detected through active case detection done in the form of case search during the Kala-azar fortnight. Passive case detection includes only cases reported to the government authorities. This does not take into account the cases diagnosed and treated in the private sector. The in depth review (2006) has shown that more than half the cases of Kala-azar are treated in the private sector. The yield from Kala-azar fortnight is low. There is a clear need to revamp surveillance and strengthen the reporting system.

Passive case detection of kala –azar will include regular reporting of the following information:

- Kala-azar cases diagnosed by RDK
- Kala-azar cases diagnosed by bone marrow/splenic aspiration
- Number of cases who complete treatment according to national guidelines
- Number of cases currently on treatment of kala-azar
- Side effects of medicine for each medicine used in the programme
- Number of patients where the treatment of kala- azar was discontinued
- Number of deaths due to kala-azar

It is proposed to use standard case definition of Kala-azar *(a case of kala-azar is a person from an endemic area who has fever of more than 2 weeks with splenomegaly and positive dipstick test)* and document cases that conform to the case definition. Cases confirmed through parasitological diagnosis will also be included as case of Kala-azar. Passive case detection will also include information on completion of treatment. It is proposed to

partner with the private and NGO sectors for reporting of Kala-azar and PKDL.

Active case search will be undertaken around **hot spots** and by organizing camps in the villages which report one or more cases. This is proposed as a strategy since Kala-azar occurs in the form of clusters of cases. Efforts will be made to strengthen BCC and active case search.

Reporting and information systems will be developed and the focus will be on the use of reports for feedback and supportive supervision at the sub district and district level. Computerization is proposed at the district, state and central levels.
Detailed information will be obtained through sentinel surveillance where information on the cases diagnosed and treated in the OPD and admitted patients inn selected sites will be provided through line listing of cases. This will help to provide detailed information and Kala-azar outcomes as proportional mortality and case fatality rates. The sentinel sites will also participate in pharmaco vigilance and drug resistance/non responsiveness. With success in implementation of the project, the active case search will be intensified. The activity schedule is presented is Table-2.

Table –2 Passive case detection and active case search

Result	Indicator	Activity	Time schedule	Responsibility
Passive case detection in govt and private sector	% of health institutions in Govt sector reporting on Kala-azar	Reporting formats and guidelines developed	June 08	VBD, BMO, Concerned PHC / KA Block Supervisor
		Mapping of govt facilities and private facilities for reporting	Oct 08	
	% of identified providers reporting on Kala-azar	Training of health Workers, pvt providers & KTS	Dec 08	
		System for data entry established	Jan 09	
		Supportive supervision for validation of reports	Ongoing	
		Reporting of cases monitored & supervised	April 09	
		Guidelines & formats prepared for ACD	Aug 08	
		Training on options to be used for ACD	Dec 08	VBD ,BMO, Concerned PHC / KA Block Supervisor
Active case	Number of active case	Review of cases recognized through ACD	Mar 09	

Result	Indicator	Activity	Time schedule	Responsibility
search	searches done in a month	Selection of sentinel sites		
		Development of guidelines and formats	Oct 08	
		Appointment & training of staff	Dec 08	VBD ,BMO, Concerned PHC
		Establish system for line listing and use of software for reporting	Dec 08	
Sentinel surveillance	No of sentinel sites reporting	Reporting of cases and mortality	Jan 09	
			Feb 09	

The data obtained through passive case detection, active case detection and sentinel surveillance will be maintained separately for each district to facilitate analysis.

6.1.3 Sub Component 2.c: Effective Vector Control

WHO has developed guidelines on Integrated Vector Management (IVM). This will be used in areas as per NVBDCP programme policies and would comprise of selection of the mix of interventions from amongst IRS, personal protection including the use of ITNs, improved housing of the poorest and the most affected. Based on this, the IVM strategic plan would be developed. Vector studies including vector behaviour and bionomics and vector surveillance would be an integral part of IVM strategy.

The main thrust will be on IRS with DDT since the vector continues to respond to DDT. In districts where malaria is reported and DDT resistance is a concern, pyrethroids or other alternatives for DDT can be considered. However, this strategy shall be applied only after careful studies and strong evidence of vector resistance.

The programme is developing a strategy of limiting the areas to be sprayed but ensuring spraying with good quality insecticide and spraying the households completely and uniformly. The selection of villages and households will be based on national recommendations about the focused areas of spraying.

NVBDCP has mapped Kala-azar areas through GIS mapping for focused IRS interventions. This system shall be updated and applied in other Kala-azar areas also by using Geographical information system (GIS) and remote sensing (RS) after ensuring capacity for the use of these systems. This

strategy will help economize insecticide consumption and also help reduce environmental degradation through in discriminate spraying.

Selective IRS would be done when surveillance has been geared up and geographic mapping with validation is made available. Until then IRS would be undertaken on case reporting in the villages. Spraying will be done in accordance with the national strategy.

IRS would be done at the most appropriate time twice a year. IRS is expected to achieve maximum coverage and uniformly to have a lasting impact. Community support will be taken for maximum coverage and its quality.

With the help of expertise available in the state IRS will be supported by entomological studies and vector monitoring to assess the efficacy of IRS.

Surveillance of *P argentipes* i.e. vector is important to determine the distribution, population density, major habitats and spatial and temporal risk factors related to Kala-azar transmission. Insecticide resistance monitoring would be done on a regular basis.

6.1.3 2.c a) Insecticidal Residual Spray

Indoor DDT spraying in all cattle sheds and human dwellings up to 6 ft. height from ground at the rate of 1 gm per sq. mt.) is proposed. Efforts will be made to plan IRS, supervise IRS, organize BCC and ensure safe disposal of the insecticide to minimize the risk from IRS. The activity schedule is presented is Table– 3

Table –3 Activity schedule for first year

Result	Indicator	Activity	Time Schedule	Respon-sibility
High risk area receive complete and uniform spray with insecticide of good quality	% of houses that have received complete and uniform spray	High risk area identified and mapped, villages selected for IRS , Plans developed for IRS 3 months before IRS	Oct 08	SPO, DMO,DC, BMO/KA Supr.
		Insecticide Procured	Dec 08	NVBDCP
		Insecticide supplied up to PHC level	Jan 09	States
		Safe stocking of insecticides	Jan 09	States
		Staff trained in spraying and personal protection of spray team members & equipment for personal protection of spraying staff available	Jan 09	States/District

Result	Indicator	Activity	Time Schedule	Respon-sibility
		BCC activities organized for community participation during IRS	Feb 09	District
		Spraying activities with supportive supervision of spray staff and BCC	Feb 09 onwards	District
		Post spray quality assessment	Apr & Jun 09	NVBDCP/ NIMR
		Assessment of safe disposal of insecticides	Apr –July 09	NIMR

The procurement of DDT & spray worker's wages shall be met from domestic budget centrally.

6.2 Others issues – Kala-azar

The priority would be on effectively and ensuring complete treatment of the cases reported at health facilities. This will require directly observed treatment and follow-up of cases with treatment cards for each patient and maintaining individual treatment boxes. Weekly analysis of the reported cases will identify the disease "hot spots" in each district where active cases search will be undertaken by the kala-azar technical supervisors who working in tandem with the ASHA community volunteers will undertake community mobilization activities to identify new cases as well as help in eliminating the breeding places for sand fly and improve community compliance for indoor residual spray operations and ensure quality of the spray operations. This will be done under the guidance and supervision of the district Kala-azar co-ordinator.

Catholic Relief Agency is working in few districts in Jharkhand for effective kala-azar case management. This was through state health Society under NRHM. NVBDCP will utilize the services of Catholic Agency during the project period on single source basis to improve kala-azar case management services covering 3-4 districts in the state of Jharkhand. This contract will be awarded by the NVBDCP. However, the release of funds will be based on the performance reports from the state. The detailed modalities will be finalized with the state and the Catholic agency. Rajendra Memorial Research Institute (RMRI), Patna will complete two days standardized competency based training for the lab technicians in the 16 districts selected for the first year of the project by July 31, 2008 and the NVBDCP will ensure availability of treatment cards and laboratory register. The NVBDCP will identify 4 sentinel sites in the state of Bihar covering all endemic regions of the state in consultation with RMRI which will position a Research Officer in each of these locations to monitor the severe cases, case fatality rates and undertake pharmaco-vigilance. The operations

research proposed for kala-azar will include therapeutic efficacy and insecticide resistance monitoring, QA of rapid diagnostic kits and IVM pilots covering 5 blocks in 2 districts and role of LLINs in kala-azar prevention. The detailed modalities will be finalized with RMRI, Patna.

External review of introduction of new case management practices in 16 districts shall be undertaken during first year before scaling up the project implementation to all 46 Kala-azar endemic districts. External review shall be undertaken with the help of WHO, experts and World Bank. The dates of external review shall be finalized after six months of implementation in the field.

RMRI, Patna has conducted House hold surveys on Kala-azar in the year 2006. On the basis of experience gained and the indicators identified in the PIP, RMRI will revise the household survey protocol with technical inputs from WHO and the World Bank for project areas by July 2008. The survey will provide a reliable baseline data for the project indicators on health seeking behavior, IRS coverage and Kala-azar prevalence desegregated by gender, age and social group. It would provide information on the coverages achieved in diagnosis and complete treatment of Kala-azar. The base-line survey covering a representative sample of districts included in FY 2008-09 will be undertaken during September-October 2008. A repeat survey will be carried out during the same period in 2009 covering the 50% earlier and 50% new districts. For kala-azar, the survey will provide statistically valid data to show 50% or more reduction in the number of kala-azar cases in a community block.

Chapter 7

Policy and Strategy Development, Capacity Building and Monitoring and Evaluation

7.1 Project Component 3: Policy and Strategy Development, Capacity Building and Monitoring and Evaluation [Rs. 2084 million]

Component 3 is a cross cutting area. It would be covering both malaria control and Kala-azar elimination and will include three sub-components:

- Sub-Component 3.a: Policy and Strategy Development [Rs. 924 million]
- Sub-Component 3.b: Program Management and Capacity Building [Rs. 968 million]
- Sub-Component 3.c: Monitoring and Evaluation [Rs. 192 million]

7.1.1 Sub-Component 3.a: Policy and Strategy Development

The Directorate of the NVBDCP is primarily responsible for policy development and strategic planning. To facilitate these tasks, the project would complement the ongoing technical assistance from GFATM with appropriate consultant support in the areas of procurement, financial management, M&E, Information technology, vulnerable community plan and environmental safety. Activities organized by the unit would include the updating of evidence-based policies for prevention, diagnosis and treatment of malaria and elimination of Kala-azar and translation of these policies to operational guidelines training materials and courses; quality assurance, operational research & evaluation of different delivery models in the private and public sectors, Impact evaluation for malaria control, periodic external reviews of the program; monitoring of drug resistance and insecticide effectiveness; assessment of quality of medicines and the promotion and establishment of public-private partnerships for the distribution of long-lasting insecticidal nets.

NVBDC will update and strengthen monitoring of therapeutic efficacy of antimalarial and anti Kala-azar medicines, insecticide resistance and quality of medicines to contain the problems of drug and insecticide resistance and ensure their efficacy. This will be done through monitoring of therapeutic efficacy of SP and ACTs so that effective drugs are used in the treatment of malaria. Similiarly, therapeutic efficacy of new first line anti Kala-azar medicines will be monitored. For this purpose, at least five units will monitor the quality of medicines and insecticides at different sites in the country. One unit in each State will be responsible for quality assurance of diagnosis. In addition, there will be an independent inspection agency monitoring the quality of pharmaceuticals by testing random samples. This sub-component will also include strengthening of laboratory work through quality assurance for RDKs (for malaria and Kala-azar)and microscopy (for malaria) and

implementation of good pesticide management practices in accordance with WHOPES at all levels.
It is proposed to develop strategic national and state plans in the form of Project Implementation Plans. These plans will be complemented by district plans and sub district supportive supervision plans. The district operational plans will be developed on a yearly basis and will be monitored regularly for implementation by district programme officer. Elaboration of operational plans will be the responsibility of district malaria officer, VBD Consultant. The operational plans will be consistent with state and national strategic plans. Policy and strategy development will include the following key elements:

- Quality assurance (e.g., RDKs [malaria & KA] and microscopy);
- Operations research including technology assessment (e.g. different pumps for IRS, spray with DDT 75% ,RDKs for vivax malaria);
- Evaluation of different delivery models and partnerships between the private and public sectors;
- Impact evaluation for malaria control and Kala-azar elimination;
- Periodic external reviews of the malaria control and Kala-azar elimination programs;
- Monitoring of drug resistance ACT (artimisinin and SP) and first line drugs for Kala-azar;
- Pharmaco vigilance;
- Assessment of insecticide resistance and effectiveness;
- Assessment of quality of medicines

For policy and strategy development NVBDCP will work closely with the Regional Directors, ICMR institutions, medical colleges, private and NGO partners. There will be a feedback provided to the Technical Advisory Committees for continued guidance. Policy and strategy development will be evidence based.

7.1.1.1 Quality Assurance

All manufacturers/ distributor will be required to obtain clearance of the diagnostic kits before distribution from the NVBDCP or its authorized agency institution.
The Directorate will undertake trainings in quality assurance in Diagnostics (RDK, Microscopy), treatment protocols, recording and reporting. NVBDCP will also undertake testing of Diagnostic kits for malaria and kala-azar, etc from the open market to determine the quality of product available through the private sector and to undertake measures that reduce the availability of substandard diagnostic kits. All batches of Diagnostic kits, drugs, insecticides will be tested in Government approved laboratories before they are released into the supply chain. Appropriate action will be taken against defaulting companies who do not adhere to quality assurance.

New drug are proposed to be used for the treatment of cases of *Pf* and Kala-azar. The portfolio of medicines for the treatment of malaria and Kala-azar is limited. It would be necessary to use the medicines available for best results. It is proposed to maintain constant vigil on the side effects through

pharmaco- vigialnce. This is proposed to be initiated in selected sides with the help of NIMR and RMRI in collaboration with experts.

7.1.1.2 QA matrix for malaria

Activity	Sub-activity	Tools	Internal	External
Case Manage-ment	Diagnosis	RDK	a) Visual Inspection (To be included in MTS Checklist) • Storage • Procedure b) Field sample collection for External Quality (Quarterly 4 samples by each MTS)	Pre-dispatch Batch testing for Quality by inspection agency Field sample testing by accredited laboratory Samples collected during HH surveys, during mid term and at the project end
		Microsco py	(a) Visual inspection (To be included in MTS check list) • SOPs • Slides • Microscopes • Reagents • Records/Reports (b) 10% Positive Slides (c) 5% of Negative Slides	EQAS during training and then ongoing twice a year per each lab technician All lab technicians will participate in EQAS twice every year
	Treatment	ACT for Pf	Visual Inspection (To be included in MTS Checklist) • Storage • Procedure Post-dispatch physical inspection – Quantity and Package by district VBD officer Field sample Collection by MTS (District, PHC, Village)	Pre-dispatch inspection by inspection agency Field sample testing by external agency
		Radical treatmen t for Pv	Monitoring of compliance checking the treatment card (To be included in MTS Checklist)	Pre-dispatch inspection by inspection agency.
Vector Control	IRS		(a) Visual inspection by MTS/VBD	Pre and Post dispatch inspection

Activity	Sub-activity	Tools	Internal	External
(includes malaria and kala-azar)			officer/Zonal/state entomologist • Stock verification • Storage • Spray equipment functionality • Use (discharge rate, full coverage, quality) • Community awareness (prior intimation, mud plastering) Bio-assay and susceptibility tests using WHO kits by zonal entomologist/ NIMR at least 2 samples/district in an year)	of insecticides by inspection agency Testing of wall scraping samples by accredited labs
		LLINs	Use by identified high risk groups	Pre and post dispatch inspection by external agency

7.1.1.3 Quality assurance in Kala-azar

This includes the following:

- quality assurance of diagnostic kits
- Monitoring therapeutic efficacy of drugs
- Pharmaco vigilance
- Monitoring of insecticide resistance

Activity	Sub Activity	Tools	Internal	External
Case Management of Kala-azar	Diagnosis	RDK	Visual Inspection (To be included in KATS Checklist) • Storage • Procedure Field sample collection for External Quality (Quarterly 4 samples by each KATS), includes samples collected from the market	Pre-dispatch Batch testing for Quality by inspection agency Field sample testing (public and private sector) by accredited laboratory Samples collected during HH surveys during mid term and at the project end

Activity	Sub Activity	Tools	Internal	External
		Bone marrow or splenic aspirate examination	5% of 'RDK test positive. All non responders to first line drugs. Cases admitted to the wards in the hospital where these examinations can be safely done	Cross check through a sample testing by PCR which detects the parasite accurately
	Treatment	Miltefo-sine	Visual Inspection (to be included in KATS Checklist) • Storage • Procedure Post-dispatch Physical inspection – Quantity and Package by district Kala-azar VBD Officer Field sample collection by KATS (District, PHC, Village) from public and private sector	Pre-dispatch inspection by inspection agency. Field sample testing by external agency in institutions approved by NVBDCP
		Complete treatment of Kala-azar	Monitoring of compliance through client interview, checking the treatment card (To be included in KATS Checklist)	Pre-dispatch inspection by inspection agency.
Pharmaco vigilance	First and second line drugs	Determine the minor and major side effects of each medicine used in the programme	Sentinel and selected specialized sites to use proforma and consolidate the findings for submission to the district VBD Officer once in a month.	Identified specialized centers to monitor laboratory parameters to detect sub clinical abnormalities relating to drugs

Activity	Sub Activity	Tools	Internal	External
		Develop a system for pregnancy detection and registration	Checking of antenatal registers and monitoring of Kala-azar treatment in pregnant women If miltefosine given during early pregnancy, monitor the outcome for the mother and the foetus	
Therapeutic efficacy of drugs	First and second line drugs	Determine the non responsiveness in Kala-azar cases in selected sites	Use agreed protocols to determine the success with each drug in at least 30 patients.	Selected specialized sites. Use PCR as a marker for parasite detection
Vector Control	IRS		Visual inspection by KATS/District Coordinator /Zonal Entomologist/NIMR • Stock verification • Storage • Spray equipment functionality • Use (discharge rate, full coverage, quality) • Community awareness (prior intimation, mud plastering) Bio-assay and susceptibility tests using WHO kits by zonal entomologist (at least 2 samples/ district in an year)	Pre and Post dispatch inspection of insecticides by inspection agency Testing of wall scraping samples by accredited labs

The activity schedule for quality assurance for malaria and Kala-azar will be the same. This is summarized below:

Result	Indicator	Activity	Time Schedule	Respon-sibility
Good quality of drugs and commode-ties ensured	% of districts from where samples were tested % of samples passed	Requirements for all items consolidated	**To be discussed**	NVBDCP/NIMR /RMRI
		Quality specification set for kits , drugs and commodities	April 08	NVBDCP/ SPO
		Procurement plan made and submitted to UNOPS	May 08	-do-
		Distribution plan made and submitted to states and districts	June 08	-do-
		Inspection agency hired through UNOPS/ICMR Institution	Aug 08	NVBDCP/NIMR /RMRI
		Samples collected for testing from field as well as at point of procurement at central level	Sept 08	-do-
		Results communicated to the districts and supplying agencies.	Quarterly Continuous	-do-

7.1.1.4 Operational research and technology assessment

The program will identify priorities for research. Some of the areas identified are:

- Validation of rapid diagnostic test for *Pv and Pf;*
- Operational experience with 'rk 39';[presently used in the programme]
- Trials of alternative ACT; and fixed dose combination
- Monitoring of drug resistance – ACT, Miltefosine;
- Monitoring of vector susceptibility test;
- Evaluation of different delivery models in public private partnerships including private providers for curative services in malaria control and Kala-azar elimination;
- Cost effective active case detection for malaria and kala-azar;
- Treatment of PKDL;
- Research on shorter duration treatment of kala-azar with combination drugs;
- Increasing the access to diagnostic and treatment services to the poor and people living in inaccessible areas;
- The trial of compression sprayers in improving IRS with DDT 70%wdp;

- Environmental studies and impact of climate change in relation to disease
- Assessment of different strategies for communication to promote the use of Insecticide treated nets , especially LLINs in tribal population including assessment of the influence of housing types and mobility;
- Studies on disease burden for both malaria and Kala-azar
- Studies on transmission dynamics in relation with vector, parasite and environmental conditions in different eco epidemiological stratum;

NVBDCP with the help of ICMR Institutions, researchers and academicians will produce protocols for operational research and support the development of capacity in research. Active collaboration with ICMR, Medical Colleges, NGOS and other agencies would be encouraged to carry out Operational research. The oversight in operational research will be provided with the help of trained research monitors. It is also proposed to organize meetings and consultations to bring researchers and programme staff together for exchange of information and to discuss the programme implications of important research findings. In turn the researchers will be guided by the needs of the programme.

Result	**Indicator**	**Activity**	**Time Schedule**	**Responsibility**
Operational research relevant to program undertaken	Number of OR studies commissioned	OR committee constituted	Sept 08	NVBDCP/ MOH
		Development of research protocols and methodology	Nov 08	NVBDCP/ SPO
		NVBDCP Publicizes the proposed OR activities	Nov 08	-do-
		RFP for funding invited	Nov 08	-do-
		Proposals evaluated	Dec 08	-do-
		Grants sanctioned & released	Jan 09	-do-
		Capacity development of researchers	Feb 09	-do-
	Number of OR studies completed and published	Progress reports monitored	Quarterly August 09 onwards	-do-
		Assistance provided for dissemination of findings of research and publication in peer reviewed journals	*(need based)*	-do-

The approach for technology assessment for policy and evidence is common for malaria control and Kala-azar elimination. This is proposed to be done

by NIMR for malaria and RMRI for Kala-azar in collaboration with Regional Directorates in the different states. Assistance will be requested from medical colleges and other relevant institutions that have interest and expertise in collaboration with NIMR and RMRI. The proposed activity schedule and time lines for malaria control and Kala-azar will be the same. The description that follows therefore applies to both malaria control and Kala-azar elimination.

7.1.1.4.1 Therapeutic efficacy monitoring

Therapeutic efficacy monitoring is integral to the program, and will be carried out by NIMR and other ICMR institutions in collaboration with NVBDCP. A standard protocol for therapeutic efficacy will be used based on WHO recommendations and at least 15 studies will be undertaken every year. The National Institute of Malaria Research Centre (NIMR) will have overall responsibility for implementing this activity which involves finalization of protocols, recruitment and training of staff, assuring the quality, consolidation of the data and organizing annual consultation and feedback. Since the monitoring will be jointly done with the Regional Directors, NIMR will also be responsible for recruitment of Research Officers on contract for the units located with the Regional Directors of ROHFW where no post of Research Officer is in position. The 13 therapeutic teams under NVBDCP located at Regional Offices will work in close co-ordination with the NIMR. An MOU shall be signed with NIMR for effective utilization of manpower that exists in the Regional Offices.

Activity schedules

Result	Indicator	Activity	Time schedule	Respon-sibility
Knowledge of the status of resistance level	No. of studies conducted and completed	Signing of agreement	July 08	NVBDCP/ NIMR/RMRI
		Finalize the study tools and protocol	Aug 08	NVBDCP/ Agency
		Selection of sites for monitoring	Sep 08	Agency
		Allocation of study to Regional Directors and NIMR field sites	Oct 08	NVBDCP
		Training of researchers	Nov 08	
		Studies commenced	Dec 08	
		Report submission	Quarterly starting Mar09	
		Review of findings jointly with NVBDCP and action taken for program	Quarterly starting Mar 09	NVBDCP/ World Bank

7.1.1.4.2 Assess drug quality

This section will comprise of systematic drug quality assurance system which will be an inbuilt component of NVBDCP.

Activity schedules

Result	Indicator	Activity	Time schedule	Respon-sibility
Drug quality assessed	No of studies conducted	Finalize the study tool and protocol	Sept 08	NVBDCP/ NIMR/RM RI
		Signing of agreement	Oct 08	NVBDCP
		Selection of staff and training	Nov 08	NVBDCP/ AGENCY
		Studies commenced	Dec 08	AGENCY
		Report submission	Quarterly start Mar 09	NVBDCP/ state
		Joint review of progress	Quarterly starting Mar 09	NVBDCP/ World Bank
		Action taken by program	Jun 09	NVBDCP

NVBDCP will request Consultant support from WHO. He/she will work closely with NIMR for development of protocol. The protocol shall be discussed by experts, WHO and World Bank.

7.1.1.4.3 Vector Susceptibility Studies

The efforts will comprise of studies on vector resistance for the insecticides use in the programme for changing of insecticides on the basis of susceptibility test results. This study will be coordinated and conducted by Zonal Entomological teams in the states, NIMR, RMRI and Universities (Zoology department). Every year at least 40-50 studies in designated sites will be completed by NIMR entomological team in collaboration with state and Regional offices. This study will help to evolve a comprehensive insecticide map for India and this will help better informed insecticide policy.

Activity schedule

Result	Indicator	Activity	Time schedule	Respon-sibility
Status of vector resistance and effectiveness is known	No. of studies conducted	Finalize the Study tool and protocol	June 08	NVBDCP/NIMR/RMRI
		Approval of study	Sept 08	Agencies
		Signing of agreement	Oct 08	NVBDCP
		Studies commenced	Jan 09	NVBDCP/ AGENCY
		Report submission	Mar 09 and then quarterly progress	NVBDCP
		Joint review of progress	Jul 09	NVBDCP/ State/WB
		Action taken for program	Sep 09	NVBDCP

7.1.1.4.4 Pharmaco- vigilance

NVBDCP will undertake this activity alongwith therapeutic efficacy. This activity shall be outsourced to agency like NIMR and RMRI who will have an advisory group supported by full time Consultant (Pharmacologist). At the operational level, this activity shall be linked with the sentinel surveillance and facilities that treat severe and complicated malaria or patients with Kala-azar admitted to referral hospitals. This activity is proposed to be started early in the project phase by September 2008. NIMR and RMRI will develop detailed protocols including reporting formats for undertaking pharmaco-vigilance with the help of experts.

7.2 Sub-Component 3.b: Program Management and Capacity Building

This sub-component would include additional human resources, activities for capacity building and management strengthening for effective malaria control and kala-azar elimination. For programme management functions, the staff in position and additional staff hired will be expected to provide managerial and operational support to malaria control and Kala-azar elimination. They will also contribute to the control of other vector borne diseases where appropriate. Capacity building is needed at the central regional, state, zonal, district and sub-district levels. Training includes staff dedicated fully to the control of malaria and elimination of Kala-azar as well

as staff responsible for providing general health services at district and sub district level.

At the state/district levels, specific activities would include: provision of additional staff e.g., for procurement, financial management, BCC, M&E,; deployment of additional entomologists at state level; management training for state and district program teams; training on supportive supervision to MTS and KTS and integrated vector management training for inspectors and state entomologists. It would also include training, study tours, and exchange programs for national and state program managers. Training in insecticide management, usage and disposal will be provided to malaria officers, inspectors and spray workers respectively.

7.2 3.b a) Human Resource

The project envisages additional human resources such as Malaria Technical Supervisors (MTS), Kala-azar technical supervisors (KTS) and VBD Consultants respectively at sub-district & district level to enhance the programme implementation. The table below shows the staff at present in sub-centre/district/state, regional level & national level. It is proposed to hire additional Consultants/supervisors for strengthening programme implementation at national, state, district & sub-district level.

Level	Existing Staff	Additional Staff	Remarks
Village	ASHA/AWW	None	
Sub Centre	MPHW (F); MPHW(M)	None	States to fill vacant MPHW (M) positions under NRHM
Addl. PHC	MPHS (F); MPHS(M); MO	None	Fill vacancies
Block PHC	Lab Technician, MPHS (F); MPHS(M); MO	MTS/KTS	Fill vaca ncies
CHC/FRU/Sub Dist. Hosp.	Lab Technician, MPHS (F); MPHS(M); MO	Malaria Technical Supervisor/KA Technical supervisors	To be supported by NVBDCP
District Hospital	Lab Technician, Staff Nurses, MO, Specialists	At sentinel sites – 4/ per dist Sr lab tech	1 dist hosp, 1 Pvt 2 CHCs
District	District Malaria officer	VBD consultant, Fin & Proc. Assistant & supporting staff	To be supported by NVBDCP
Zone	Entomologist and other support staff	Entomologist	To be supported by State
State	SPO officer	Social development /scientist, M&E, Consultant (training), Entomologist, Procurement. Fin. consultants; Accountant , GIS data entry & supporting staff	

Level	Existing Staff	Additional Staff	Remarks
Regional	RD, CMO, Lab Technicians,	Medical Officer	Through IDSP
National	Program officers	Consultants, supporting staff at NVBDCP & consultant, microbiologist, Research Officer, Sr lab tech(2), supporting staff by NIMR/ RMRI/ VCRC as per agreed protocol	To be supported by NVBDCP

MALARIA CONTROL

National level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	Consultant (Procurement)	2	40-50000
2.	Consultant (Public Health)	1	40-50000
3.	Consultant (Training)	1	40-50000
4.	Consultant (M&E)	1	40-50000
5.	Consultant (Financial Management/ Accounts, Budget)	2	40-50000
6.	Consultant (NGO/PPP)	1	40-50000
7.	Consultant (Social Development/ BCC)	1	40-50000
8.	Consultant (IT/GIS)	2	40-50000
9.	Consultant (Environment Safety)	1	40-50000
Supportive Staff			
10.	Section Coordinator	3	16000
11.	Computer Programmer	3	12000
12.	Accountant	2	12000
13.	Secretarial Assistant	15	8500
14.	Data Entry Operator	3	8500

State level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	Consultant (M&E)	8	35000
2.	Consultant (Training)	8	35000
3.	Consultant (Procurement & supply chain)	8	25000
4.	Consultant (Financial Management)	8	25000
5.	Consultant (Social Development / PPP)	8	25000
6.	Consultant (Vector Control)	8	25000
7.	Entomologist	8	35000

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
Supportive Staff			
8.	GIS data entry	8	6500
9.	Accountant	8	10000
10.	Secretarial Assistant (one per state)	8	6500
11.	Insect Collector (two per state)	16	8000

District level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	District VBD consultant	93	30000
2.	Financial & Logistic Assistant (one per district)	93	8000
3.	Data Entry Operator (one per district)	93	6500
4.	Lab Technicians (3 per district in endemic areas)	300	6000
5.	Malaria Technical Supervisor (MTS - 6 per district) @1 per 2.5 lakh pop.	558	10000*

***:** *The fee of Rs.10000/- includes POL for field visit + DA. The details of numbers of field visits per month and DA are reflected in MTS TOR.*

KALA-AZAR ELIMINATION

National Level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	Consultant (Public Health)	1	40-50000
2.	Consultant (Vector Control)	1	40-50000
Supportive Staff			
3.	Section Coordinator	1	16000
4.	Secretarial Assistant	2	8500
5.	Data Entry Operator	1	8500

State Level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	Consultant (Kala-azar)	3	40000
2.	Consultant (Vector Control)	3	25000
3.	Consultant (Procurement/	1	25000

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
	Supply Chain) – Bihar		
4.	Consultant (Financial Management) – Bihar	1	25000
5.	Consultant (Social Development)	3	25000
6.	Consultant (Training)	3	25000
Supportive Staff			
7.	Accountant	3	10000
8.	Insect Collector (two per state)	6	8000
9.	Secretarial Assistant	3	6500

District Level

S. No.	Designation	No. required	Consolidated monthly fee – Rs.
1.	District VBD consultant	46	30000
2.	Financial & Logistic Assistant (one per district)	46	8000
3.	Data Entry Operator (one per district)	46	6500
4.	Kala-azar Technical Supervisor (KTS - 6 per district) @1 per 2.5 lakh pop.	276	10000*

***:** *The fee of Rs.10000/- includes POL for field visit + DA. The details of numbers of field visits per month and DA are reflected in KTS TOR.*

Note:

1. Consultant at National level consolidated salary in the range of Rs. 40-50000/- per month depending on qualifications and experience
2. State consultant in the range of Rs. 25-35000/- per month consolidated depending on qualifications and experience
3. District level consultant in the range of Rs.30000/-, consolidated depending on qualifications and experience
4. District supporting staff 1st & 2nd years in 50 malaria districts from 3rd year onwards in remaining 43 districts. Similarly, all the Supporting staff at district level shall be filled up in all 46 Kala-azar districts in Year-1.
5. Malaria Technical Supervisor/ Kala-azar Technical Supervisor @ 6 per district [1 per 2.5 lakh population] with provision of motor bike.
6. 5 % increase in consultant's and support staff salary at district, state and national levels for both Malaria control & Kala-azar elimination on performance based every year proposed to meet the price rise. Provision for increase upto 10%, if price index rises further on the basis of VIth Pay Commission's salary structure report.
7. Staff in the states are provisioned in case the states have the staff under NRHM, the same staff will look after the work instead of new hired staff.

The key malaria control and kala-azar elimination interventions under the project will be implemented in the following states and districts, with a few capacity building inputs (malaria technical supervisors and integrated vector control) being supported in all endemic districts:

7.2.4 List of States & Districts under the Project

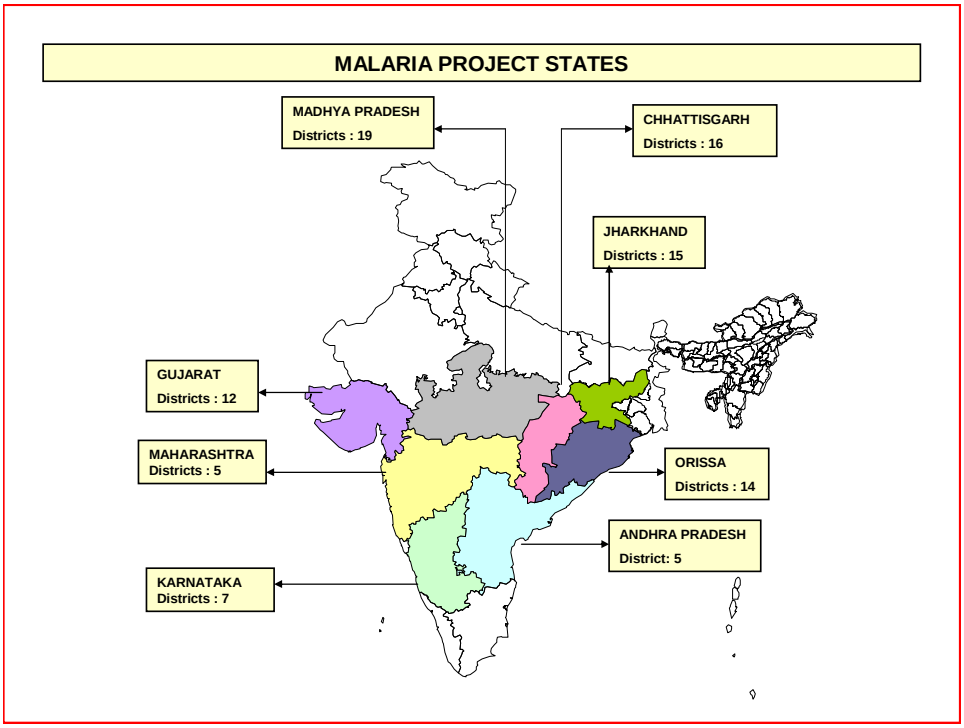
Malaria

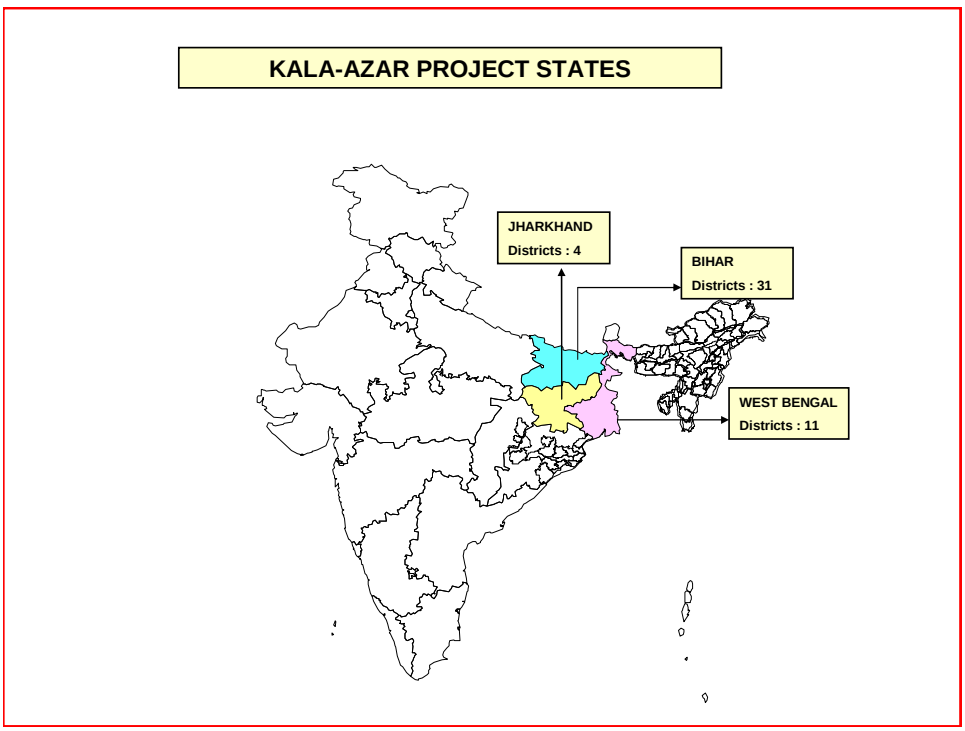
States	Year I & II Districts PHASE -I (FY2008/09 to 2010/11)	Year III -V Districts PHASE -II (FY2010/11 to 2013/14)
Andhra Pradesh (5)	Srikakulam, Vizianagaram, Viskhapatnam, East Godavari and Khammem (5 districts)	continued
Chhattisgarh (16)	Korba, Ambikapur, Korea, Rajgarh, Jashpur Nagar, Raipur, Dhamtari, Bastar (Jagadalpur), Denteveda, Kanker and Bilaspur (11 districts)	Janjgir (Champa), Mahasamund, Durg, Rajnandgaon, and Kawardha (5 districts)
Jharkhand (15)	Ranchi, Gumla, Simdega, East Singhbhum, West Singhbhum, Saraikela, Sahibganj, Godda, Dumka, Latehar, Pakaur, and Lohardaga (12 districts)	Jamtara, Garhwa and Dhanbad (3 districts)
Madhya Pradesh (19)	Sidhi, Shahdol, Dindori, Chhindwara, Mandla, Betul, Jhabua, Balaghat and Guna (9 districts)	Dhar, Ratlam, Rajgarh, Shivpuri, Sheopur, Satna, Sagar, Panna, Jabalpur and Seoni (10 districts)
Orissa (14)	Gajapati, Jharsuguda, Kalahandi, Phulbani (Kandhamal), Keonjhar, Koraput, Malkangiri, Mayurbhanj, Nawarangpur, Nuapada, Rayagada, Sambalpur and Sundergarh (13 districts)	Puri (1 district)
Gujarat (12)		Nadiad, Anand, Surendranagar, Patan, Vadodara, Godhra, Dahod, Surat, Rajkot, Kutchh (Bhuj), Junagarh and Ahmedabad Corp. (12 districts)
Karnataka (7)		Kolar, Tumkur, Chitradurga, Belgaum, Raichur, Koppal, and Dakahina Kannada (7 districts)
Maharashtra (5)		Raigarh, Gr. Mumbai, Chandrapur, Gadchiroll and Thane (5 districts)

Kala-azar

States	Year I & II Districts PHASE -I (FY2008/09 to 2010/11)	Year III -V Districts PHASE-II (FY2010/11 to 2013/14)
Bihar (31)	Patna, Nalanda, Jahanabad, Bhojpur, Saran, Siwan, Gopalganj, E. Champaran, W. Champaran, Sitamarhi, Vaishali, Darbhanga, Madhubani, Samastipur,Muzaffarpur, Bhagalpur, Munger, Khagaria, Bagusarai, Purnea, Kathihar, Saharsa, Madhepura, Suppaul, Kishanganj, Ararea, Buxar, Sheohar, Sekhpura, Lakhisarai, and Arwal (31 districts)	
Jharkhand (4)		Sahebganj, Dumka, Pakur and Godda (4 districts)
West Bengal (11)	Malda	Darjeeling, 24-Parganas (N), Nadia, Hooghly, Burdwan, Dinajpur (N), Dinajpur (S), Birbhum, 24-Parganas (South), and Murshidabad (10 districts)

Project Districts for malaria control & kala-azar elimination





7.3. Sub Component 3.c Monitoring and Evaluation

This sub-component would include activities for making computerized management information system (MIS) functional and for monitoring and evaluation-related surveys and studies. A Geographic Information System (GIS) would be expanded and strengthen systematically as a tool for micro-stratification, planning, monitoring and advocacy. Activities in the sub-component would mainly be the responsibility of the NVBDCP, working in close cooperation with the state-level program managers. Development of monitoring and evaluation framework and capacity development will be undertaken by NVBDCP. THE M&E framework development will be same for GFATM project and the World Bank project.

District level implementation of malaria control and Kala-azar elimination activities under the NVBDCP

In consonance with the National Rural Health Mission strategy, the NVBDCP supports a decentralized district centered program which is responsive to local needs operating within the national policy framework. The World Bank will provide support for this approach with special focus on malaria prevention and control, and Kala-azar elimination. Collaboration with IDSP will be undertaken at all levels preventing overlap between the two projects. Experiences of earlier malaria project funded by the World Bank and other disease control programs, especially the Revised National Tuberculosis Control Program and RCH will be used for the implementation strategy.

Typically there will be four stages in district oriented program evolution:

Preparatory Stage
Appraisal and approval Stage
Initial Implementation
Expanded Implementation

Preparatory Stage: This begins with a detailed review of available epidemiological data which helps in identifying and prioritizing the high burden districts. NVBDCP has identified 93 districts for malaria control and 46 districts for Kala-azar elimination for intensive inputs under the World Bank supported project. A sensitization workshop for the district and state program managers and policy makers from malaria high burden districts and respective states was held in June 2007 to share the new national policies and strategies, and specific actions to be completed by these districts for effective implementation of the new district focused paradigm. Similar consultations involving a wider range of stakeholders including the non government sector are planned at state and district levels. A similar sensitization workshop will be conducted for Kala-azar endemic districts and states

Appraisal and approval stage: NVBDCP will constitute expert teams to review the district VBD action plans using the readiness filters. The readiness filters were discussed with World Bank also during negotiation

and appraisal. Additional technical support will be provided to those districts which fail to pass the readiness filters. During the first year focus will be given to ensure that at least 35% districts under malaria will pass readiness filters for malaria control and all 16 districts for Kala-azar elimination. Guidelines for district readiness filters have been prepared. NVBDCP will organize 4 regional workshops to sensitize VBD for Phase I districts. These guidelines shall be prepared by October 2008 with the help of experts. Following the development of guidelines, a panel consisting of experts from NIMR, RMRI, states and NVBDCP will assess the readiness criteria by visiting these phase I districts. District Collectors shall be involved at all stages for development of and application of readiness filters in the district.

The project has envisaged additional human resources such as malaria technical supervisor, Kala-azar technical supervisors and VBD consultant respectively at sub district and district levels to enhance the program implementation. This will be followed by local recruitment of consultants, and management of training of district VBD and assist the VBD Officers and consultants to enhance their capacity to evolve district VBD action plans which will include: (a) a resource mapping exercise (both government and non government sector providers); (b) micro-stratification of district clearly identifying focus areas for RDK use and microscopy, and intensive IRS and LLINs operations, special strategies for reaching VBD services to vulnerable populations; and (c) phasing of project inputs relevant to district needs and capacities.

For improving malaria and Kala-azar case management in private sector, each project district will undertake a mapping of private providers who are popular among the communities and known to influence overall prescription behaviors of other providers, especially the informal sector. The district VBD officer supported by consultant will organize a sensitization workshop to these providers about the new policy and process proposed to be followed. They will subsequently visit the identified providers to assess their ability (infrastructure, staff etc.) and interest to function as accredited facilities providing quality malaria and Kala-azar case management services. A simple check list for undertaking accreditation and a contract form will be included in the operations manual for the district program managers.

The project will provide hands on training to all accredited providers and the lab technicians working with them in malaria and Kala-azar case management. Wide local publicity will be given on availability of quality services at these locations. The project will ensure supply of registers, lab reagents, diagnostic kits and medicines as per the national policy. Each accredited facility will have at least one designated staff to maintain the records like any other public health facility of the government (stock register, lab register and treatment card/register). The designated staff will provide monthly update on private sector to the District VBD officer after validation by the MTS. The District VBD consultant will visit each accredited provider at least once every month to assess compliance and quality of services as per the contract. This opportunity would be particularly used to reinforce good treatment practices (detailing). Performance of the VBD

Consultants would be assessed in part based on the output from private sector both in terms of coverage and quality. The project MIS will include the accredited private facilities and data on cases treated will be disclosed at the district health office.

Criteria for assessing readiness of districts**:** To evolve district action plans relevant to district needs, a common protocol of action has been developed by the NVBDCP and placed under Implementation Arrangements chapter 10.

Initial Implementation: This will be undertaken during the first 24 months in the high burden districts selected for the first phase of the project. The new MIS will be used to evolve a district score card to comprehensively assess and rank district performance. The quality assurance systems for case management (diagnosis and treatment) as well as vector control will also be piloted during this phase. A Joint Monitoring Mission consisting of external and national reviewers is planned during the first 18 to 21 months of implementation. Findings of this review will help in identifying the deficiencies in program design and suggest appropriate changes required for an effective decentralized district based VBD control program.

Expanded Implementation: Once there is a shared understanding of the appropriate design and inputs required among all key stakeholders, the NVBDCP will pass on the responsibility of appraisal and approval of district plans to the states. This process is expected from the third year of the project. With shifting of the responsibilities, the Directorate of NVBDCP will play a facilitator role. There will be quarterly monitoring visits to randomly selected districts by joint teams consisting of NVBD officers and staff of NIMR/RMRI with independent experts and annual program reviews.

Training Plan

Sl. No.	Activity	Level	Unit cost	No of Units					Cost (INR Million)					
			INR	Yr I	Yr II	Yr III	Yr IV	Yr V	Yr I	Yr II	Yr III	Yr IV	Yr V	Total
1	International fellowships and study tours for national and state officers	**Centre**	150,000	5	3	2			0.75	0.45	0.30	-	-	1.50
2	National study tours for state officers	**Centre**	35,000	11	11	11	11		0.39	0.39	0.39	0.39	-	1.54
3	Specialised training for NVBDCP staff	**Centre**	50,000	5	5	5	5	-	0.25	0.25	0.25	0.25	-	1.00
4	Specialised training for state staff	**Centre**	25,000	50	100	100			1.25	2.50	2.50	-	-	6.25
5	Program Management Training for State VBD teams covering district plans, social mobilization, PPP, Sentinel Surveillance and QA	**Centre**	100,000	12		10			1.20	-	1.00	-	-	2.20
6	Induction Training of District VBD officers (for 3 months)	**Centre**	200,000	82	57				16.40	11.40	-	-	-	27.80
7	Reorientation training for District VBD officers (Once in two years)	**Centre**	35,000			82	57		-	-	2.87	2.00	-	4.87
8	Induction training to State Entomologists in monitoring vector bionomics and IVM	**Centre**	50,000	11					0.55	-	-	-	-	0.55
9	Reorientation training for State Entomologists (Once in two years)	**Centre**	25,000			11			-	-	0.28	-	-	0.28
10	Trainers training in Malaria and KA case management to IMA trainers (2 per state + 4 from centre)	**Centre**	25,000	26		26			0.65	-	0.65	-	-	1.30
11	Trainers training for MTS (4 per state)	**Centre**	25,000	20	12				0.50	0.30	-	-	-	0.80

Sl. No.	Activity	Level	Unit cost	No of Units					Cost (INR Million)					
			INR	Yr I	Yr II	Yr III	Yr IV	Yr V	Yr I	Yr II	Yr III	Yr IV	Yr V	Total
12	Trainers training for KTS (4 per state)	**Centre**	25,000	12					0.30	-	-	-	-	0.30
13	Trainers training in Severe Malaria Case Management (2 per state)	**Centre**	25,000	16					0.40	-	-	-	-	0.40
14	Training for MTS (for 10 days)	**Centre**	10,000	300		258			3.00	-	2.58	-	-	5.58
15	Training for KTS (for 10 days)	**Centre**	10,000	96	96	84			0.96	0.96	0.84	-	-	2.76
16	Training for Lab Technicians in Malaria Microscopy (2-week training)	**Centre**	5,000	150		129	20		0.75	-	0.65	0.10	-	1.50
Sub-total									**27.35**	**16.25**	**12.30**	**2.73**	**-**	**58.62**
17	State level trainers training in Malaria Control (Orissa 8 per state rest 4 per state)	**State**	10,000	24		24			0.24	-	0.24	-	-	0.48
18	State level trainers training in KA elimination (Bihar 8 and remaining 2 states 4)	**State**	10,000	16		16			0.16	-	0.16	-	-	0.32
Sub-total									**0.40**	**-**	**0.40**	**-**	**-**	**0.80**
20	Training in Severe case Management and Sentinel surveillance for selected hospital staff	**District**	10,000	66	16	60			0.66	0.16	0.60	-	-	1.42
21	Decentralized training in Malaria case management and social mobilization for PHC MO (2 batches per district)	**District**	50,000	75	25	86			0.75	0.25	0.86	-	-	1.86
22	Training for Lab Technicians in use of KA rapid diagnostic kits	**District**	2,000	96	96	84	15		0.19	0.19	0.17	0.03	-	0.58

Sl. No.	Activity	Level	Unit cost	No of Units					Cost (INR Million)					
			INR	Yr I	Yr II	Yr III	Yr IV	Yr V	Yr I	Yr II	Yr III	Yr IV	Yr V	Total
23	Orientation training in Malaria and KA case management to private sector through IMA (2 sessions per project district) per session	**District**	50,000	82	82	57	57		4.10	4.10	2.85	2.85	-	13.90
24	Decentralized training in Malaria case management and social mobilization for MPHW (15 batches per district)	**District**	20,000	500	250	645			25.00	12.50	32.25	-	-	69.75
25	Decentralized training in Malaria case management and social mobilization for village based volunteers (ASHA, AWW etc) (50 batches per district)	**District**	15,000	1,500	1,000	2,150			75.00	50.00	107.50	-	-	232.50
26	Decentralized training in KA case management and social mobilization for PHC MO (2 batches per district)	**District**	50,000	32	32	28			1.60	1.60	1.40	-	-	4.60
27	Decentralized training in KA case detection and social mobilization for MPHW (15 batches per district)	**District**	20,000	240	240	210			12.00	12.00	10.50	-	-	34.50
28	Decentralized training in KA case detection and social mobilization for village based volunteers (ASHA, AWW etc) (50 batches per district)	**District**	15,000	800	800	700			40.00	40.00	35.00	-	-	115.00
29	Sensitization training for Village Health & Sanitation Committees/village panchayats/self help groups covering new services provided under the project and community oversight (around 600 villages per district)	**District**	1,000	24,600	24,600	17,100	16,800		24.60	24.60	17.10	16.80	-	83.10

Sl. No.	Activity	Level	Unit cost	No of Units					Cost (INR Million)					
			INR	Yr I	Yr II	Yr III	Yr IV	Yr V	Yr I	Yr II	Yr III	Yr IV	Yr V	Total
Sub-total									**183.90**	**145.40**	**208.23**	**19.68**	**-**	**557.21**
Total in INR Million									**211.6**	**161.6**	**220.9**	**22.4**	**-**	**616.6**
Total in USD Million									**5.29**	**4.04**	**5.52**	**0.56**	**-**	**15.42**
Development of Training modules		**Central**	2000000	1	1				**2**	**2**	**0**	**0**	**0**	**4.00**
Translation & Publication of Training modules		**Central**	1000000	1	1	1			**1**	**1**	**1**	**0**	**0**	**3.00**

Cost Summary of Training

Training Cost	Yr I	Yr II	Yr III	Yr IV	Yr V	Total
Central	30.35	19.25	13.30	2.73	-	65.62
State	0.40	-	0.40	-	-	0.80
District	183.90	145.40	208.23	19.68	-	557.21
Total in INR Million	**214.65**	**164.65**	**221.92**	**22.41**	**-**	**623.63**
Central	0.76	0.48	0.33	0.07	-	1.64
State	0.01	-	0.01	-	-	0.02
District	4.60	3.64	5.21	0.49	-	13.93
Total in USD Million	**5.37**	**4.12**	**5.55**	**0.56**	**-**	**15.59**

Chapter 8

Impact Evaluation

The impact evaluation studies conducted under the NVBDCP will generate evidence to assist in the realization of two important goals in disease control efforts: (1) to provide timely diagnosis and treatment services for malaria control, most notably through the introduction of ACT in endemic areas. (2) to increase the number of people benefiting from effective prevention, including the promotion of LLINs. Impact evaluation will be used to investigate the effectiveness and cost-effectiveness of alternative strategies in disease control efforts to be evaluated for ongoing NVBDCP activities and this will be conducted in the first two years of the project to inform policy going forward. The summary of the interventions, for case management and for involving the distribution of LLINs are described below:

8.1 Case management

Technical Advisory Committee (TAC) in 2008 has approved the use of Artesunate Combination therapy (ACT) for all confirmed diagnosed *P.falciparum* cases in 50 districts under the World Bank project. NVBDCP has introduced the revised policy for malaria diagnosis and treatment to all the states including states under GFATM and the World Bank. With the help of the existing structures of the NRHM, ASHA or other Voluntary Health workers already available at the village level will serve as the local frontline representative for fever/malaria control and will dispense ACT to *P. falciparum* confirmed fever cases. To assist the ASHA in her efforts, the NVBDCP has positioned Malaria Technical Supervisor (MTS), who will be fully devoted to the control of malaria in high-burden areas. As per implementation arrangement, NVPDCP will hire around 6 MTS at the district level who will together support the work of roughly 450-500 ASHA workers.

ASHAs responsibilities are numerous, including family planning, nutrition, and vaccination. These multiple jobs raise the distinct possibility of under-performance concerning malaria treatment and control. The case management component of the impact evaluation will evaluate the effectiveness and cost-effectiveness of enhanced saturation by MTS to supervise the ASHA worker on a more regular basis in order to explore whether and to what extent ASHA performance will benefit from more intensive training and supervision. Under this design, two Malaria Technical Supervisors (MTS) will be posted at the block level and each individually will be responsible for 75 ASHA workers. This ratio of MTS to ASHA workers ensures that the travel burden of each MTS will be greatly reduced and that each ASHA worker will be directly supervised at least once monthly. Supervision will also include BCC for villagers in her catchment

area, and a strengthened supply chain of key malaria control commodities such as RDTs and ACTs with the aim of minimizing stock outages and commodity leakages from health center stores. This arrangement will however, be further strengthened after judging the capacity of ASHA and MTS during the project period.

8.2 Distribution of LLINs

National policy for the use of LLINs is currently crystallizing on a position to scale up as rapidly as possible for universal coverage of LLIN target populations. Presently, the target population is a village or sub-center area with intense transmission (indicated by API above 5/1000), and poor accessibility for IRS operations (for example, roads inaccessible during the rainy season).

The erstwhile World Bank assisted project provides the opportunity to evaluate alternative models of distribution and social mobilization activities. In this group of evaluations, the control will be constituted by the NVBDCP policy of public sector distribution of two LLINs to each household at no cost. Against this control activity, two potential modes of distribution aimed at increasing the total coverage and proper usage of LLINs will be compared. These two activities are:

1. Priming households with the free distribution of one LLIN to households the first year, followed up by another LLIN distributed in the following year (i.e. a 1+1 vs 2 approach)
2. Free LLINs distributed to all households through cooperation with local community based organizations, notably self-help-groups (SHGs).

The first treatment intervention will test the effect that experience of one net by the household has on their take up of the second net in the following year. Given that LLINs are scarce in comparison with the size of the eligible population; effective coverage may possibly be higher if only one net per household were distributed initially since twice as many households will be covered. Furthermore, if a "priming" effect on net adoption, through direct experience, is important then higher usage rate may be achieved if nets are delivered in an incremental scheme rather than all at once. This approach would also have the additional benefit of reducing the household incentive to sell freely provided valuable goods to local markets.

In the second intervention, local SHGs will work with the government distribution mechanisms and take responsibility for social mobilization efforts as well as the monitoring of LLIN distribution and initial use. SHGs have traditionally been a small group of persons (primarily women) who come together with the intention of accessing micro-credit programs. SHGs may

afford easy and credible access to the community, and thus have the potential of playing a significant role in strengthening prevention activities at the village level.

8.3 Size of study

Power analysis indicates that a sample of 4,350 households will be sufficient to detect moderate improvements in net usage and fever treatment at standard levels of statistical significance. 1,050 of these study households (in 35 villages) will be located in blocks that receive the case management treatment of additional MTS and 1,050 will be in comparable and randomly selected control blocks. Villages in additional blocks will be randomly assigned to one or two prevention treatment arm or the prevention control arm. Each arm of the prevention treatment will involve a sample of 750 households distributed across 30 villages.

8.4 Data Collection and Analysis

The survey data will be collected in two phases. Baseline data collection will occur during September – November 2008, the peak transmission season following the rainy period. Intervention activities will then commence in the January – March period of 2009. Follow-up surveys with the same households will be fielded exactly 12 months after the baseline in September – November 2009, and then again in 2010. The follow-up survey will be partly based on the baseline survey instrument but will also record detailed information on the household responses to the experimental intervention in terms of adoption and behavior change.

The data will be collected using a professional survey team and will be entered in India with sufficient safeguards being taken to ensure accuracy and respondent privacy. Supplementary information will be provided by the HMIS. As soon as preliminary results are validated they will be shared with the NVBDCP directorate.

** This activity is being financed as a separate non-lending task and is not part of the financing provided through NVBDCP although its planning and implementation are coordinated with the project.*

Chapter 9

MONITORING AND EVALUATION

Malaria control and KA elimination programs have been using an independent MIS to monitor and evaluate the program at different levels of the health system. This task is done by health care providers at different levels supported by staff provided by the state and NVBDCP. Data generated is analyzed and reported to the states and NVBDCP to guide the program. To strengthen the system, CMIS was developed and introduced as a part of EMCP. It has not worked well due to poor accessibility and other factors. IDSP has already developed CMIS program and NVBDCP malaria MF 4 and MF 11 were revised and integrated with IDSP. NVBDCP has already reduced the MF formats to around eight, and the new MIS is to be implemented. Malaria control and KA elimination programs will stress on passive case detection and improved reporting. KA elimination program will use key indicators to monitor case reporting and develop treatment cards to monitor completion of treatment. NVBDCP has mapped high burden districts for focused IRS spray with the help of GIS. Some of the states like Gujarat & Maharastra have already developed GIS, which is being used by these states in the program. The GIS based information would be expanded systematically by NVBDCP to other priority districts as a tool for micro stratification, planning, monitoring and advocacy.

9.1 Project management and monitoring system

A well-defined project management and monitoring system will be implemented to monitor progress towards targets and objectives and provide continuous feedback to strengthen and improve delivery mechanisms at the district level to achieve this. The project's M&E activities include:

For malaria control

(a) Strengthening of HMIS for tracking malaria incidence and operational indicators;
(b) Sentinel surveillance to collect data on severe malaria, hospitalized malaria cases and malaria deaths from selected hospitals in each district;
(c) Decentralized measurement of outcomes at district and PHC levels through Lot Quality Assurance Sampling (LQAS) and cross-sectional surveys (later every second year) to support local decision-making and provide monitoring results to the central level;
(d) Logistic Management Information System for supply chain management;
(e) System to monitor the quality of rapid diagnostic tests and medicines to ensure their quality upon delivery and at point of use.

For Kala-azar elimination

(a) Strengthening of HMIS for tracking the progress of kala-azar elimination and key operational indicators;
(b) Case detection and line listing of patients;
(c) Decentralized assessment to validate the outcomes at district, CHC and PHC levels through LQAS and surveys (2010 and 2013);
(d) Logistic management information system for supply chain management;
(e) System to monitor the quality of 'rk39', and first line medicines.

Additional activities closely related to M&E, though not strictly a part of the M&E system are:

- Monitoring of parasite resistance to antimalarial medicines, in particular the first-line ACT (artesunate plus sulfadoxine-pyrimethamine), anti kala-azar medicines (especially new medicines), and vector resistance to insecticides;
- Pharmaco-vigilance focusing on the first-line ACT and first line medicines for treatment of kala-azar ;
- Operational research and impact evaluation;
- Periodic Technical Program Reviews for malaria control and kala-azar elimination by NVBDCP, and the World Bank with the help from WHO, the and other international organization.

In the above list, activities (a)-(c) will be the main responsibility of malaria technical supervisors (MTS) and kala-azar technical supervisors (KTS), who will be science graduates recruited and trained for this work and employed on a contractual basis. Depending on the population size, there will be 5-6 MTS/KTS per district. These supervisors will also be trained to support activities (d) and (e). Additional activities will be done with the help of institutions under the Department of Health Research, especially National Institute for Malaria Research (NIMR), Delhi for malaria and Rajendra Memorial Research Institute (RMRI), Patna for kala-azar.

As most of the malaria high-burden districts in the country are financially supported through grant–in–aid either GFATM or the World Bank (retroactive financing), it has been envisaged that both GFATM and World Bank will work in coherence for development of new M&E systems.T he mechanisms will be fully harmonized in the districts concerned and will gradually, based on lessons learnt, and with due consideration of different needs in districts with lower endemicity, be adopted nationwide in malaria control. For example, MTSs will have the same training and responsibilities across Global Fund and World Bank supported districts. The kala-azar elimination initiatives however will be limited to GoI and World Bank support in the endemic districts for kala-azar.

(a) Strengthening of HMIS

Malaria surveillance has been one of the strongest parts under the NVBDC Pprogramme. Based on the examination of about 100 million blood slides per

year, covering all endemic districts, it provides information on trends in malaria incidence and the geographic distribution of the disease in the country, but not absolute size of the burden. Strengthening of the disease surveillance and operational data management will take place as described below:

- The introduction of RDTs and ACTs will by itself improve data quality by attracting more patients to public services (and temporarily increasing the recorded annual case-load). A protocol has been devised to dove-tail the RDT data with microscopy at all levels. In the case of kala-azar similar results are likely to accrue following the introduction of 'rapid diagnostic kits' for diagnosis and new first line drugs are very effective and safe.
- New streamlined formats, including computerized data management from the block level and upwards have been prepared and will be piloted in three districts (Sundergarh, Mayurbhanj(Orissa) and Kanker (Chhattisgarh) from June to September 2008. These formats allow for example monitoring of proportion of villages with a provider of RDTs and ACTs and the comparison of operational data on coverage in populations at risk with data obtained through surveys and LQAS. Similar activities will be undertaken in the kala-azar elimination project to monitor the coverage and quality of case management services.
- A protocol under preparation by NVBDCP will be used by MTS/KTS to check data completeness of both surveillance and operational data on a sample basis at all levels in the district. During supportive supervision, kala-azar treatment supervisor will validate the data of the general health workers.
- Revamp of the web-based management information system, NAMIS through World Bank funding, which was introduced a few years ago, but has poor functionality due to poor connectivity in districts and lack of follow up.

GIS is already being used in kala-azar elimination program and malaria high burden districts on a limited scale and this would be further strengthened and will be used for more effective planning of the spraying activities in the district. GIS would be utilized to track the progress of elimination of kala-azar.

(b) Sentinel surveillance

The weaknesses of the existing malaria surveillance are the lack of articulation with hospitals, which means that severe malaria cases are not reported separately (if at all) and that only a small fraction of malaria deaths is recorded.[9] Therefore, sentinel surveillance will be established, by selecting, in each district, 2-3 hospitals/health centres with high malaria case-loads (these can be private or mission hospitals) for recording of all in-patients with malaria and malaria-related deaths introducing classification according to defined criteria.

[9] Kumar A, et al. Burden of malaria in India: retrospective and prospective view. *Am J Trop Med Hyg.* 2007 Dec;77(6 Suppl):69-78

For kala-azar in each district 3 hospitals/health centers will be selected for undertaking sentinel surveillance where detailed information will be collected. Besides detailed information on patients who are treated at home the sentinel surveillance would also provide information on patients of kala-azar who are hospitalized and include case fatality rates.

(a) A rapid population-based survey system including the LQAS method

This will be established in each project district to track coverage and use of LLINs, RDTs and ACTs at the PHC level on an annual basis. Similar tracking in kala-azar would be done for Rapid diagnostic kits/rk39 (presently used), first line medicines and treatment completion. It will also be used to assess IRS coverage. LQAS is a rapid survey used by VBD Officer to determine whether Primary Health Centres (PHC) are reaching pre-established targets for key project indicators. The same data can be used to calculate point estimates for outcome indicators at district levels. The project will explore the possibility for use of hand held computers, tablets etc.for rapid data entry and to avoid information bottlenecks. A data for decision-making component will be established to determine underlying program problems identified with LQAS. All data will be used during annual work planning sessions to restructure and improve the project, as well as to set targets for the subsequent year. To ensure the accuracy of the information collected a small sample of questionnaires will be sampled and the corresponding interviewee, interviewed again. By counting the concordant pairs, the reliability of the data can be established. The data collection and preliminary analysis will be carried out by MTS. The LQAS is being used because it requires the least amount of information to judge whether outcomes are on track at the PHC level. This is due to its small sample size requirements. The following describes the process in more detail.

Each District (N=1.2 to 1.5 million population) will have approximately 6 MTSs or 6 KATS whose primary job is program monitoring and supervision. As per NRHM norms each District consists of approximately 45 sectors (PHC areas, "new PHC" areas) with a population of 20-30,000, so there are about 15 sectors per MTS. Each PHC area is comprised of approximately 30 villages (N=1000 each). All LQAS analyses will be at the PHC level and measure key project indicators using focused mini-questionnaires. Three mini-questionnaires are currently envisioned: (a) an ITN/LLIN coverage and use module, (b) a fever management and treatment seeking behavior module, and (c) an ASHA questionnaire. The fever management module may take place in the household where the previous mini-questionnaire is used or in subsequent households. It applies only to people who have had a fever in the last 2-weeks. The third mini-questionnaire requires the MTS to contact the frontline service provider to inspect the condition of ACTs and RDTs, whether stock-outs have occurred in the last 3-months, and whether this provider can use RDTs and

treat malaria correctly. Modules for use by KATS for LQAS are being developed to include client interviews, provider interviews and observation of the facilities.

In order to minimize data collection the project will apply a new approach to LQAS analysis called Large Country LQAS (LC-LQAS).[10] Using this approach a statistically determined sample of sectors will be made at a point in time (e.g., 15 sectors or 5 blocks per MTS).This approach will permit assessment of the 15 sectors after 5 weeks and also calculate a point estimate for the district. LC-LQAS permits the program to carry out an innovative approach to program monitoring for it can carry out 3 waves of data collection at key times of the year (e.g., at the beginning of the high transmission season, at the end of the high transmission season, and at the low transmission season. The resulting data will permit program managers to determine the stability of net use and case management throughout the year, and therefore inform program managers about priority support that is needed in PHCs. Most key program outcome indicators will be measured using the LC-LQAS data.

In addition, two cross-sectional household surveys to collect the same data plus selected other variables, especially malaria prevalence will be carried out in 2010, and 2013 across the high-burden districts after approval from MOH.

Cross sectional household and health facility surveys have been carried out for kala-azar in 2006 and the findings were used in the JMM. These surveys were very useful in planning the kala-azar programme. Similar surveys are proposed in 2008, 2010 and 2013 to monitor progress in kala-azar elimination.

(b) A Logistic Management Information System (LMIS)

This will be created to track LLINs, insecticides, RDTs and ACTs from their purchase or point of entry to the project districts to the decentralized distribution points in the PHC areas. For kala-azar it is proposed to include RDK and first line medicines. The LMIS will use a standardized form that records the quantity of LLINs, RDTs (or 'rk39') and ACTs (or first line medicines for the treatment of kala-azar) at each point where an organization takes delivery or delivers these commodities. The LMIS tracks the distribution of the products down to the lower sub-district level service delivery points. Each district will be responsible for tracking its own allotments but will be required to use one reporting system and forward this information centrally to the NVBDCP. The LMIS will show the spatial distribution of LLINs, RDTs, ('rk39') ACTs and first line medicines for kala-azar in the project area, and provide the project management with information to determine whether any area is deprived of needed commodities. The MTS/KTS or a different person (e.g., a designee or

[10] Bethany Hedt, Casey Olives, Marcello Pagano, Joseph J. Valadez, "Large Country-Lot Quality Assurance Sampling: A New Method for Rapid Monitoring and Evaluation of Health, Nutrition and Population Programs at Sub-National Levels." The World Bank. (In Review 2008). LC-LQAS has already been used in Eritrea, Kenya, Nigeria and Uzbekistan.

agent of the DMO) will annually sample the LMIS data and verify the chain of transactions from the time of delivery in the district down to service delivery points in PHCs to authenticate the information. This same agent will assess the quality of ACT/RDT, 'rk39' or first line medicines for kala-azar and vector control supplies storage facilities. The LMIS will not track the distribution of LLINs and ACTs to patients as that is the role of the HMIS. The MOHFW is in the process of establishing a comprehensive LMIS for the health sector with support from DFID in three states. Two of these states where such piloting is taking place are also malaria endemic states proposed to be included under the project (Orissa and Madhya Pradesh) and efforts would be made to ensure integration of the project LMIS with this initiative. RNTCP has hired the services of Consultant agency for supply chain management for keeping track of inventory down from block level to state level. The same agency shall be hired by NVBDCP for similar work.

(c) System to monitor the quality of rapid diagnostic tests and medicines to ensure their quality upon delivery and at point of use

NVBDCP has prepared a protocol for monitoring the quality RDTs in accordance with WHO recommendations and technical documents. This will now translate to an action plan, which includes the training of a limited number of laboratory technicians in each state, who will sample and control RDTs. Similarly, a protocol will be established for quality assurance of antimalarial medicines (especially ACTs), which will be sampled according to established and approved protocols in the context of the work described under (d). NVBDCP will seek Consultant from WHO for this purpose. Quality assurance of 'RDK and first line drugs used in the treatment of kala-azar will be undertaken with the help of RMRI, Patna. Help will also be taken from the Regional Directors, ROHFW for implementation.

(d) Monitoring of parasite resistance to antimalarial medicines, in particular the first-line ACT (artesunate plus sulfadoxine-pyrimethamine), Miltefosine and vector resistance to insecticides

With the adoption of an ACT including the long-acting sulfadoxine-pyrimethamine (SP) as a component, close resistance monitoring including molecular markers becomes essential. This work will be led by NIMR, which has established a protocol in collaboration with NVBDCP. ACT therapeutic efficacy and molecular markers for SP resistance will be collected from 30 sites, where patients will be sampled and examined every second year in each site. In addition, susceptibility of *P.vivax* to chloroquine will be monitored in 3-4 of these sites. Monitoring of resistance to miltefosine will be undertaken in three (3) sites by rotation and RMRI will be involved in oversight of this activity.

Monitoring of insecticide resistance across the country has been weak for many years despite the availability of trained entomologists in research centres. A protocol has been established by NIMR in collaboration with NVBDCP to assess over a 5-year period, the susceptibility of anopheline vectors to the main

insecticides in use in 200 sites, which will be selected to be representative of the malaria-ecological patterns in the country. Each year around 40-50 such sites covering all eco-type zones will be covered with states Entomologist unit and field stations of NIMR and VCRC. This study will help NVBDCP to evolve a comprehensive insecticide resistance map for the country and will help better-informed insecticide policies. DDT continues to be used for kala-azar elimination. To date widespread resistance has not been reported but continued vigilance to determine development of resistance is necessary. Protocols will be developed by RMRI and in collaboration with the Regional Director. Insecticide resistance for KA vector will be undertaken in at least 3 sites every year and these sites would be selected in consultation with the affected states.

(e) Pharmaco-vigilance focusing on the first-line ACT and Miltefosine.

As ACT and Miltefosine are newly adopted in country on a large scale, it is important to monitor safety in the program conditions. In due course, new partner drugs may be considered for ACT and new promising drugs on Kala-azar may be added in the list of first line drugs for kala-azar treatment. A protocol for prospective monitoring, coordinated with drug susceptibility testing, in 5 sites has therefore been prepared by NIMR and similarly pharmaco vigilance would be undertaken in 3 districts included under the kala-azar elimination program by RMRI.

(f) Operational research and impact evaluation

A list of priorities for operational research (malaria & kala-azar) under this project has been established. The operational research projects will be carried out by research institutes based in country, where appropriate, in collaboration with overseas partners. NVBDCP /Regional offices will be co–investigator/ facilitator for all operational research projects. The list includes:

- Validation of rapid diagnostic test for *Pv and Pf;*
- Operational experience with 'rk 39';[presently used in the programme]
- Trials of alternative ACT; and fixed dose combination
- Monitoring of drug resistance – ACT, Miltefosine;
- Monitoring of vector susceptibility test;
- Evaluation of different delivery models in public private partnerships including private providers for curative services in malaria control and kala-azar elimination;
- Cost effective active case detection for malaria and kala-azar;
- Treatment of PKDL;
- Research on shorter duration treatment of kala-azar with combination drugs;
- Increasing the access to diagnostic and treatment services to the poor and people living in inaccessible areas;
- Environmental studies and impact of climate change in relation to disease

- Studies on transmission dynamics in relation with vector, parasite and environmental conditions in different eco epidemiological stratum;
- Trial of compression sprayers in improving IRS with DDT 70%wdp;
- Assessment of different strategies for communication to promote the use of Insecticide treated nets , especially LLINs in tribal population including assessment of the influence of housing types and mobility;
- Studies on disease burden for both malaria and kala-azar

In addition, protocols for two important randomized controlled studies have been developed for impact evaluation:

(a) Assessment of the effect of delivering one net per household as a start and one net a year later, compared to delivering two nets from the outset. The hypothesis is that staggered delivery might be associated with higher usage rate and lower risk of being sold.
(b) Assessment of the effect of strengthening supervision of ASHAs and other village volunteers providing curative services by increasing the number of supervisors to the point, where each volunteer is supervised monthly.

(i) Technical Program Reviews

The programme implementations are being reviewed periodically by experts, WHO and World Bank to guide the programme for optimum utilization of available tools, and suggestion to improve further. The last review that took place in late 2006/early 2007 was of crucial importance for introducing the new policies, which will be piloted and taken to scale through this Project. NVBDCP will undertake such exercises again in 2009, 2011 and 2013 and will seek permission, approval from MOHFW to set up a team to provide the external expertise. The emphasis in 2009 review will be on effectiveness, efficiency and quality of implementation rather than policy issues.

Framework for Malaria MIS

Purpose	Level	Person	Frequency	Comments
Fever surveillance	Village	ASHA/AWW	Weekly	MF 11 Form has already been modified
Malaria Case Management	Village Sub centre	Trained ASHA/AWW MPHW	Monthly	Requires a simple register to be maintained at village level and a form for preparation of monthly abstract by the MPHW (Draft already prepared by NVBDCP)
Laboratory	Designated	Lab	Monthly	Requires a lab

Purpose	Level	Person	Frequency	Comments
confirmation	microscopy centre (Block PHC)	technician		register and updating of MF 8 for monthly reporting
Consolidated report covering case management, IRS, ITN/LLINs and stock situation	Block PHC	Medical Officer IC, MTS	Monthly	MF 4 Form revised
Reporting of trends in malaria (including severe malaria cases) and malaria mortality	Sentinel Centre (District hospital/ health centre; Private/NGO hospital)	Lab Technician; Medical Doctor I/c	Monthly	Requires a new reporting form; being developed
Supervision Checklist	Sub division/ Malaria Unit	MTS	Weekly	Requires updating of current checklist MF 12 & MF 13; being updated
Consolidated district report	District	DMO/ VBD Consultant	Monthly	Requires a new form; being updated

Framework for Kala-Azar MIS

Purpose	Level	Person	Frequency	Comments/ Additional needs
Active Case Search	Village/sub-centre	ASHA/AWW Kala-azar activist/health worker	Monthly	Surveillance form
Self-referred	PHC	PHC staff	Daily	
KA Case Management	PHC	PHC staff	Supervised treatment	Treatment card (patient and facility retained)
	Follow up in SC/village	ASHA/AWW Kala-azar activist/health worker		Individual treatment box Reporting format for program, Line listing of patients compatible

Purpose	Level	Person	Frequency	Comments/ Additional needs
				with coding on treatment cards (pilot in selected sites first).
Laboratory confirmation	Referral centers	Doctors with the help of Laboratory staff	Selected cases (a proportion of RDK positive for QA, non responders and complicated cases)	District medical officer to collaborate with referral centers/hospitals where bone marrow and splenic puncture tests can be done.
Consolidated report covering case management, IRS, and stock situation of drugs and supplies	Block PHC	Medical Officer IC; KTS	Monthly	Requires format for monthly reports
Reporting trends in KA (including severe cases) and KA mortality	Minimum two sentinel sites per district to report details of OPD & indoor patients	Data entry operator; Medical Officer IC	Monthly	Requires a new reporting form that includes line listing and complete information on patients seen in the OPD and those who are admitted with kala-azar
Supervisor Checklist	Selected blocks in the district where the kala-azar incidence is high	KTS	Weekly	Requires developing a supervisory checklist and a format for reporting of feedback
Consolidated district report	District	Kala-azar VBD consultant	Monthly	Requires a new form Computer facilities and data operator

Monitoring and Evaluation will include process, outcome and impact indicators, which are as follows:

	Process	Outcome (result)	Impact
Case management	Procurement, logistics, training, supervision, IEC, service delivery, quality assurance	Coverage Quality	Reduction in morbidity and mortality, Reduction of epidemics
Integrated Vector Management	Procurement, logistics, training, supervision, IEC, service delivery, quality assurance	Coverage Quality	
Policy and Strategy Development, Capacity Building, Monitoring and Evaluation	Depending on planned activities		

Evaluation is an episodic activity, which usually involves several external entities. The indicators needed for evaluation are the ones generated through monitoring.

Process monitoring is usually based on the use of managerial information generated during implementation. It will be strengthened by the use of new formats and supplemented by LQAS. Process indicators are sometimes categorized as input, process (proper) and output indicators. Of these, the most important ones are the output indicators. Like outcome and impact indicators, they need to be standardized across a programme and reported on in a standardized manne.

Outcome monitoring is usually based on population and health facility indicator surveys. It includes assessment of coverage and its quality.

Monitoring of impact is usually based on surveillance data. Existing routine surveillance will be modified and supplemented by sentinel surveillance. In addition, the project will introduce impact evaluation, which aims to compare the impact of different implementation modes.

9.2 Process Indicators

Indicators

a. At least five sites monitor the post purchase quality of drugs and insecticides recommended for use by the national policy;

b. Percentage of planned additional trained staff for management strengthening who are in position at each level (central, state and district);
c. All endemic districts have quality-controlled data on incidence of malaria & Kala-azar segregated by age and gender, obtained through sentinel surveillance.

Collection of data
Monitoring of implementation by State NVBDCs

Reporting
Inclusion of information in standardized annual report from state to NVBDCP. Consolidation in NVBDCP annual report.

9.2.1 Case management output indicators
Indicators
a. Annual and Monthly Blood Examination Rate by microscopy (ABER), separated for active and passive case detection;
b. Annual and Monthly RDT examination rate;
c. Percentage of suspected malaria cases observed by accredited health volunteers or health facilities in project districts, who have a test result, and if it shows *P.falciparum*, receive ACT no later than the day after the reported start of fever.

Collection of data
a) and b): Routine malaria surveillance system
c) : Malaria Technical Supervisor according to Lot Quality Assurance Scheme

Reporting and use of data
Used by all levels from PHC to national to monitor coverage of surveillance and case management

9.2.2 Case management outcome indicator
Indicator
Percentage of fever cases in project districts, who have a test result, and if it shows *P.falciparum*, receive ACT no later than the day after the reported fever.

This indicator is calculated as the product of the following two indicators A and B, which are obtained at annual household surveys:

A = proportion of persons with fever, who obtained a test result no later than the day after the reported fever

Numerator
Number of persons interviewed (including caretaker for young children) who report having had a fever episode during the last 14 days and who had a

finger-prick blood sample taken by a health care provider and were informed about the result no later than the day after the reporting of the fever.

Denominator
Number of persons interviewed (including caretaker for young children) who report having had a fever episode during the last 14 days

B = proportion of persons with RDT showing *P.falciparum*, who started 3 day ACT treatment on same day as testing was done.

Numerator
Number of persons interviewed (including caretaker for young children) who reported having had a fever episode during the last 14 days, who had a rapid diagnostic test done, were shown that it was positive for falciparum malaria (2 stripes) and were then – except if they were pregnant - given a 3 day ACT treatment starting on the same day as the positive test result was obtained (RDT positive and negative, as well as ACT must be shown to the client by interviewer).

Denominator
Number of persons interviewed (including caretaker for young children) who report having had a fever episode during the last 14 days and who had a rapid diagnostic test done and were shown that it was positive for falciparum malaria (2 stripes)
Note: Indicator B asks only about RDT test results, because, while it is uncertain, whether patients will be able to recall a microscopy test result, it should be possible for patients to recall an RDT test result, if providers are instructed to tell and show all patients the result (positive or negative) and visual aids are used in the interviews. Patient records can be used to assess, whether microscopy confirmed PF cases are more or less likely than RDT confirmed cases to receive ACT.

9.2.3 Integrated Vector Management Output indicator
Output indicator
Percentage of population in high-risk areas, who are protected by ITNs or IRS in a year according to operations data.

Numerator
Number of persons living in houses that have been completely sprayed at least once during the year) + (number of nets treated at least once during year + number of *effective LLINs* (see below) that have been delivered to the high risk population) x 2.5.

Denominator
High risk population = the population at risk of malaria, which is considered eligible for either IRS or ITNs in the planning for the year. This is the

population that should have such protection. It may be larger than the population actually targeted in an annual operational plan, which could be constrained by limited supplies or funds.
An effective LLIN is one that has been delivered to a household less than e years before, where e = longevity of the net, nowadays assumed to be either 3 or 5 years depending on brand. Thus, there needs to be record-keeping on LLIN delivery for the past year to calculate the cumulative number of effective LLINs.

The data should be supplemented by corresponding village-based data (proportion of villages in high risk areas with at least 80% coverage of IRS or ITNs), which should be broken down by "tribal and non-tribal"

Data collection
Monthly performance records prepared on standard formats by MPHS with support from MTS.

Reporting
Monthly and annual report from block to district and district to state

9.2.4 Integrated Vector Management Outcome indicators
Percentage of individuals in project districts belonging to ITN target population (defined by district planning according to national guidelines) who report having slept under an ITN during the previous night.

Percentage of individuals in project districts belonging to IRS target population (defined by district planning according to national guidelines) who report having slept in a house, where all rooms had been sprayed once or twice (according to norm for the area) over the last 12 months and, where no room had been replastered/repainted since last spray.

Data collection
Annual household surveys

Reporting
Annual report from state and national level

Denominator populations
Delimitation of target populations for vector control is done according to the operational guidelines. Target population is the population that should be protected by a given intervention (eligible population), not the one that was planned to be protected in an annual plan affected by resource constraints. Nonetheless, the learning process may over time lead to modifications in the delimitations of these target populations. Different target populations are allocated village-wise to be targeted by either IRS or ITNs. Thus, each sub-centre area, block and district has the following denominator populations:

A	Total mid-year population
B	Total population at risk of malaria (of A)
C	Target population for ITNs (of B)
D	Target population for LLINs (of C)
E	Target population for IRS (of B)

9.3 Indicators of impact

Indicators

a) Annual Parasite Incidence (API)
b) Slide Positivity Rate (SPR)
c) Annual falciparum incidence (AFI)
d) Slide falciparum rate(SFR)
e) RDK(PF) positivity rate
f) Gametocyte rate (proportion of PF infections showing gametocytes)
g) Malaria mortality rate
h) Proportional malaria mortality rate (malaria deaths as a proportion of all deaths)
i) Severe malaria incidence rate
j) Malaria in-patient (severe and non-severe) incidence rate

Data collection

The indicators a) to f) are obtained by the routine surveillance system, but must now be broken down by under five and five years and above.

The indicators g) to j) are obtained from sentinel surveillance.

Results Framework and Monitoring Matrix

PDO	Outcome Indicators	Use of Outcome Information

(a) To enhance the effectiveness of government response to control malaria and eliminate kala-azar. *(This will be achieved by increase in the number of people benefiting from effective prevention, diagnosis and treatment services for malaria control and kala-azar elimination)*.	For malaria: (i) Percentage of fever cases in project districts receiving a malaria test result no later than the day after the first contact[11]. (ii) Percentage of individuals in project areas belonging to eligible ITN target population who slept under an ITN during the previous night. For kala-azar: (iii) At least 50% of sampled blocks which at baseline have not achieved the elimination goal of less than one kala-azar case per 10,000 persons, will achieve the elimination goal by endline.	Review current strategies and make tactical changes to the program plan to improve effectiveness Develop clear lessons about effective strategies that can be brought to scale and support the design of the next phase of the program
Component One: Improving Access to and Use of Malaria Prevention and Control Services		
1.a. Control of Malaria	a. i. Percentage of population in high-risk project areas protected by LLINs or IRS. a. ii. Percentage of RDT positive cases in project districts receiving ACT no later than the day after the first contact[12]. a. iii Percentage of designated providers of malaria diagnosis and treatment[13] who have not had an ACT or RDT stock out during the last 3 months a. iv Percentage of villages with a trained designated provider of malaria diagnosis and treatment services.	District-level: to make tactical changes to the program plan to improve effectiveness and correct problems. State and central level: to adjust training and supervision activities; to identify problems requiring comprehensive change to the program plan. Establish results based management system to guide financial investments.
Component Two: Improving Access to and Use of Services for Elimination of Kala-azar		

[11] Indicator a.ii is likely to be highly correlated with PDO (i), because in rural areas with limited range of service providers, individuals who have access to an RDT should also have access to ACT. Population survey data will also indicate where care was sought. The ideal indicator to assess ACT use would be the % of Pf positive cases in the population who were given ACT no later that the day after the fever started. But it is not possible to measure directly because: (a) not all fever cases will seek and receive a test result from designated providers, and (b) not all fever cases who receive a test result will be Pf positive as most do not have malaria or have only Pv. The ACT treatment indicator for Pf+ cases can be estimated indirectly, from health service data. The PAD is not proposing this as a PDO indicator as it cannot be estimated from surveys with adequate precision. It will however be calculated routinely from service data.

[12] "Adults" here would mean individuals 15 years or older. Cases in this age group having a positive test for Pf will be expected to receive an ACT blister pack, which will be easy to measure in surveys. Younger age-groups are expected to receive loose artesunate and sulfadoxine-pyrimethamine tablets, which will be difficult to identify in surveys. Current blood examination rates suggest that a majority of blood tests are currently conducted in the 15+ years age group. Also see footnote #1.

[13] These individuals are ASHAs and other providers and Multi-Purpose Health Workers.

2a. Elimination of kala-azar	a.i. Percentage of diagnosed kala-azar cases completing the standard treatment as per the national guidelines. a.ii. Percentage of houses in targeted kala-azar endemic areas covered with effective insecticide spray. a.iii Percentage of Block PHCs that do not have a 'Rapid Diagnostic Test for Kala-azar' or, first line medicines stockout during the last 3 months.	District-level: to make tactical changes to the program plan to improve effectiveness and correct problems. State and central level: to adjust training and supervision activities; to identify problems requiring comprehensive change to the program plan. Establish results based management system to guide financial investments.

Component Three: Policy and Strategy Development, Capacity Building and Monitoring and Evaluation		
3.a. Policy and strategy development	a. i. Monitoring system established in 5+ sites to monitor the quality of RDTs, drugs and insecticides delivered by the procurement system a.ii *Monitoring of therapeutic efficacy of ACTs with at least 15 studies per year and* pharmaco-vigilance system including at least 3 sites monitoring the first line medicines introduced under the kala-azar	Ensure drugs and insecticides used in the project conform to national policy and are of the highest quality. Monitor implementation of the management strengthening plan.
3.b. Capacity building and program management	elimination program established . b. i. Percentage of planned additional staff who are in position at central, state and district levels and received induction training. b.ii Proportion of districts meeting the readiness criteria (chapter 10) for each period of implementation.	Establish priorities for program planning
3.c**.** Monitoring and evaluation	c.i. Percentage of endemic districts with quality controlled incidence data of vector-borne diseases stratified by age and gender	

This framework will include assessment of equity as determined by the access of scheduled tribes and scheduled castes (SC/ST) to the quality services, which

will be established. Thus, most of the indicators described above, and derived either from HMIS or from large surveys, will be disaggregated by general population/SC/ST as described in the Vulnerable Communities' Plan (Chapter 15).

Arrangements for Outcome and Results Monitoring

	PDO: Project Outcome Indicators										
(a) Increase the number of people benefiting from effective prevention, diagnosis and treatment services for malaria and kala-azar,			Current Status	Target Values					Data Collection and Reporting		
				Yr. 1 08/09 (Base-line)[14]	Yr. 2 09/10	Yr. 3 10/11	Yr. 4 11/12	Yr.5 12/13	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
(i) Percentage of fever cases in project districts receiving a malaria test result no later than the day after first contact.	E	23%[15]	30%	50%	70%	80%	>80%	Annual	Population-based Study/LQAS	MTS / National Institute of Malaria Research
	L	TBD[16]	NA	NA	25%	50%	70%			
(ii) Percentage of individuals in project areas belonging to eligible LLIN target population who slept under an LLIN during the previous night.	E	TBD	NA	20%	40%	60%	80%			
	L		NA	NA	10%	30%	50%			
(iii) Percentage of blocks that achieve the elimination goal of less than one kala-azar case per 10, 000 persons at the sub district level		0%		16%		33%	50%	Bi-annual	Sample population based survey/HMIS	Rajendra Memorial Research Institute

(Malaria) Early phase: 50 districts starting implementation in 2008; Late phase:43 remaining districts starting implementation in 2010; NA: Not Applicable; TBD : To be Done

[14] A survey using LQAS will be carried out during the first year by trained MTSs and will constitute the district baseline.
[15] This figure is valid for Orissa State only and was produced by the In-depth review in 2006 (NIMR, 2007).
[16] A small sample will be taken in the first LQAS to establish the baseline.

Intermediate Result: ***Component One: Improving Access to and Use of Malaria Prevention and control Services***										
1. a. i. Percentage of population in high-risk project areas protected by ITNs or IRS	E	No Reliable Data	25%	40%	60%	80%	>80%	Annual	HMIS and LQAS/Popula-tion surveys	MTS (LQAS) / National Institute of Malaria Research (large-scale surveys)
	L		NA	NA	25%	40%	70%			
1. a. ii Percentage of RDT positive cases among adults receiving ACT no later than the day after the fever started	E	NA (new Program)	50%	60%	70%	80%	>80%	Annual	HMIS	
	L		NA	NA	50%	60%	70%			
1. a. iii Percent of designated providers of malaria diagnosis and treatment who have not had an ACT or RDT stock out during the last 3 months	E	NA (new program)	80%	80%	90%	90%	90%	Annual	Health facility survey-LQAS	
	L		NA	NA	80%	90%	90%			
1. a. iv Percentage of villages with a trained designated provider of malaria diagnoses and treatment services.	E	20%	60%	70%	80%	>80 %	>80%	Annual	LQAS	
	L		NA	NA	20%	30%	70%			
Component Two: Improving Access to and Use of Services for Elimination of Kala-azar										
2. a.i. Percentage of diagnosed kala-azar cases completing the standard treatment.		TBD		60%		80%	>80%	Bi-annual	Population-based Study	KTS/ Rajendra Memorial Research Institute
2. a.ii. Percentage of houses in identified in kala-azar endemic areas covered with effective insecticide spray.		TBD		60%		80%	>80%	Bi-annual	Population-based Study	KTS / Rajendra Memorial Research Institute
2 a.iii Percentage of facilities reporting no stock-outs of 'Rapid Diagnostic Test for Kala-azar' and first line medicines.		NA	50%	80%	90%	90%	90%	Annual	Health facility survey-LQAS	KTS/ Rajendra Memorial Research Institute

Component Three: Policy and Strategy Development, Capacity Building and Monitoring and Evaluation									
3. a. i. Monitoring system established in 5+ sites to monitor the quality of RDTs, drugs and insecticides delivered by the procurement system	0 (new program)	2	4	5	5	5	Annual	HMIS	National Institute of Malaria Research
3. a.ii Pharmaco-vigilance system established in at least 3 sites to monitor the first line medicines for kala-azar elimination	0	2	3	3	3	3	Annual	HMIS	National Institute of Malaria Research
3. b.i Percentage of planned additional staff who are in position at central, state and district levels and received induction training.	0% (new program)	50%	100%	100%	100%	100%	Annual	HMIS	National Institute of Malaria Research
3. b.ii Proportion of eligible districts meeting the readiness criteria (Chapter 10) for each period of implementation.	0	100%	100%	100%	100%	100%	Annual	Readiness filters	NVBDCP
3. c.i. Percentage of endemic districts with quality controlled incidence data of vector-borne diseases stratified by age and gender	0% (new program)	20%	30%	40%	50%	60%	Annual	HMIS	National Institute of Malaria Research

Chapter 10

Implementation Arrangements

Implementation arrangements for the NVBDCP have been designed taking into account the above systemic weaknesses and findings of the institutional assessment carried out by the World Bank during the project preparation. The project will adopt learning by doing approach by providing inputs to a limited number of high malaria and kala-azar burden districts during the first two years. A comprehensive review will be undertaken before further scale-up. Minimal inputs will be provided to other high endemic districts to sustain the current level of services. The project will require implementation actions at the central, state, district and sub-district levels. Existing institutional arrangements at all these levels, with appropriate strengthening as required, will be used. The proposed implementation arrangements are briefly described below:

Central-level: The overall implementation responsibility of the project will rest with the Ministry of Health & Family Welfare (MOHFW), Government of India (GOI) under the framework of the National Rural Health Mission (NRHM). The Directorate of National Vector Borne Disease Control Program (NVBDCP), under the Directorate General of Health Services, MOHFW, Government of India (GOI), is the national level government unit dedicated to the program. NVBDCP consists of seven program divisions each addressing control of a disease. There are similarly four support service divisions, i.e., IEC/BCC, procurement, training and administration. Joint Director Malaria, heading the Malaria Division has two Deputy Directors, an Assistant Director, a Senior Research Officer and several office staff supporting her/him. The NVBDC Director, a Deputy Director-General level officer, will coordinate and supervise the implementation in the NVBDCP.

NVBDCP is responsible for formulating policies and guidelines, monitoring, and carrying out evaluations from time to time. NVBDCP would provide the technical leadership and support for day to day operational decisions for the project. It will constitute a "*Project Management Group*" responsible for the project and headed by the Director. The project management group will have a focal point for each of the high burden states who will undertake state visits at least once every quarter and share their observations in the quarterly project review meetings. The project will provide consultant support to the management group.

The National Institute of Malaria Research (NIMR) is an institution under the Indian Council of Medical Research (ICMR), part of the Department of Health Research in the Ministry of Health and Family Welfare. NIMR will be responsible for operational research and will also support project initiatives to improve therapeutic efficacy monitoring, promote quality assurance and improve monitoring of service delivery through periodic household surveys. NIMR has a number field stations located in different parts of India.

Project Steering Committee: A steering committee is being proposed to ensure that there is regular review, discussion and action on project implementation involving both the central and the state levels. In several projects, often actions required at the central level get delayed, e.g., important procurement, and the states watch helplessly while implementation suffers. Similarly often the states do not have clarity on some project activities and neglect their implementation. The Project Steering Committee will be chaired by the Joint Secretary, MOHFW, representative from NRHM and have the following members: Director; Joint Director, Deputy Director malaria and Deputy Director, kala-azar from the NVBDCP; Regional Directors for the concerned states; and Programme Officers, NVBDCP from the five states of Andhra Pradesh, Chhattisgarh, Jharkhand, Madhya Pradesh and Orissa. WHO, GFATM, the World Bank and IDA will participate in the meetings as observers. The Steering Committee will meet quarterly to discuss specific agenda to be circulated two weeks in advance; similarly minutes of the meetings will be prepared and circulated within two weeks after the meeting. The Steering Committee will help keeping project implementation on track by reviewing and ensuring that all key actions, at central and state levels, get taken and any constraints that impede progress are addressed. It will also provide policy support and administrative approvals for state plans and for key program decisions. The Joint Secretary will have overall coordination responsibility in the MOHFW, to be supported by Director level Officer, MOH; Joint Director, NVBDCP will be the Member Secretary of the Project Steering Committee.

NVBDCP is being strengthened for implementation of this project by (i) GFTAM providing consultants and support staff for malaria control; WHO providing six consultants to address kala-azar; and the project itself supporting ten consultants at the central level and over 100 staff/consultants in procurement, financial management, environment, training, supervision, etc. at the state, district and sub-district levels. These consultants will be in position in time for startup in the initial project districts and for other districts at the time of review of the districts readiness criteria. NVBDCP will also contract with national NGO's and other technical agencies to strengthen capacities for supporting decentralized programming, community monitoring, and other implementation needs.

Regional-level: The MOHFW's 17 Regional Offices for Health and Family Welfare, located in 17 States, will also play a role in project implementation. These regional offices support the NVBDCP. They conduct entomological studies in collaboration with the States, drug resistance studies, cross-checking of blood slides for quality control, capacity building at the state level, and monitoring and supervision. The National Institute for Malaria Research under the Indian Council for Medical Research has field stations in 9 States and supports the malaria control program through operational and applied field studies.

State-level: The States are responsible for implementing the program's preventive and curative services, and monitoring in accordance with central guidelines. Every State has a Vector Borne Disease Control Unit under its Department of Health and Family Welfare. The state unit is headed by the State Program Officer, mostly a Joint Director, who is responsible for day-to-day management as well as technical aspects of the program. She/he will be accountable for the preparation and implementation of state project implementation plan. The state PIP will be based on district implementation plans developed following the guidelines provided by the NVBDCP. The focus will be on improving outcomes in high burden districts for malaria and kala-azar ensuring effective coordination with the NRHM.

The States have established State Vector Borne Disease Control Societies, which are now in the process of being integrated with similar entities established for other Centrally Sponsored Schemes into a single state-level Health and Family Welfare Society under the NRHM. The State Integrated Health Society will have the overall coordination responsibility for the implementation of the project plans approved by the central Project Steering Committee. Its main role will remain to channel funds from the GOI to the States (and onwards to districts) for the financing of the programs (VBDCP and other CSSs). These societies will also play a role in district planning and in monitoring of program activities within districts.

State Project Coordination Committee: To ensure effective project coordination and review, a State Project Coordination Committee for the five high disease burden states of Bihar, Chhattisgarh, Jharkhand, Orissa, and Madhya Pradesh is proposed to meet once a quarter. This committee will be chaired by the Chief Secretary/ or a senior officer designated by him and will have the following membership: Health Secretary; Finance Secretary; Director of Health Services; Mission Director of the State Health Society; Regional Director,ROHFW; State Joint Director/State Program Officer acting as the Member Secretary. This high-level Committee will review implementation progress and address constraints through summary orders. Agenda will be circulated two weeks in advance and minutes of the meeting within two weeks after the meeting.

District-level: At the district level, the District Integrated Health and Family Welfare Society chaired by the District Collector will be responsible for the overall coordination. It will approve and monitor the implementation of the district action plans prepared by district Vector Borne Disease (VBD) officer. At the district level, District Malaria Offices have been established in most places headed by the District Malaria Officer who will be designated as nodal officer for vector borne disease control. This is the key unit for the planning and monitoring of the program. For high malaria and kala-azar burden districts, the project will provide additional consultant support to the district VBD Officer. Both of them will be provided management training covering the core program principles, resource mapping, implementation arrangements for improved

service delivery in public and private sectors, quality assurance, supply chain management, monitoring and evaluation, contracting non-government sector for project activities, social mobilization, financial reporting and procurement.

Service delivery and passive and active case detection will be carried out by staff at the district hospitals, block and sector Primary Health Centers (PHC) and sub centers of the States' Health and Family Welfare Department. In addition, peripheral health workers and community volunteers like malaria link workers, fever treatment depots and drug distribution centers will provide outreach services.

10.2 Criteria for assessing readiness of districts

To evolve district action plans relevant to district needs, a common protocol of action has been developed by the NVBDCP. This includes the following activities, which focus on three core strategies of the programme.

Effective case management

- Mapping of health providers in the districts including popular private providers
- Listing of service delivery points proposed at village and facility levels for diagnosis and management of uncomplicated cases
- Listing of hospitals for management of severe cases/individuals requiring hospitalization
- Training plan for service providers to implement new treatment policies
- Ensuring regular supply chain including identification of stores for drugs and diagnostic kits
- Preparing plan for internal quality assurance

Integrated Vector Control

- Listing of sub centers/villages reporting high disease burden
- Prioritizing sub centers/villages for IRS and LLIN/other personal protection activities
- Ensuring regular supply chain of insecticides and identification of stores

Surveillance

- Identifying sentinel sites (blocks) for monitoring incidence of VBDs
- Identifying sentinel sites (hospitals) for monitoring incidence of severe VBDs and deaths
- Organizing training for the core staff at selected sentinel sites

A standard protocol for processes and certification to assure district level readiness for project implementation has been developed. This protocol will be applied in all the Phase 1 districts and will be reviewed at the time of the early implementation review for possible revision. Information will be available from

project supervision activities including the regular HMIS, the World Bank's supervision missions, and the sample district reviews to provide regular feedback on district activities.

In each project district, the following will be put in place to assure readiness criteria for implementation:

1. A full-time VBD officer or consultant posted by the state and actions to recruit contractual staff at district level and below following project norms.
2. The district VBD officer/consultant received orientation training in district planning for VBD control.
3. A draft District Implementation Plan prepared including the following:

    a) Case management: identification of villages for providing case management (RDTs, ACT) by ASHA.
    b) Integrated vector management: listing of villages for vector control activities (IRS or LLIN).
    c) Logistics: storage and distribution arrangements for medicines, RDKs, insecticides, and LLINs detailed.
    d) Training: prepare plan for training in case management and social mobilization to health staff and community volunteers, and sensitization of CBOs.

Once districts have completed these steps, each district will be visited by a review team including NVBDCP Officer/consultants and State level Officer/consultants to review the draft plan and readiness with the VBD project team and the District Programme Officer. The plan will also be presented to the District Magistrate/ Collector. Upon satisfactory completion of the readiness processes, the team can certify the district ready for implementation.

At the time of the early implementation review, approximately 18 months after effectiveness, Phase 1 districts will be reviewed for implementation status. A scorecard will be used for this purpose. Attachment 1 shows a draft scorecard developed by NVBDCP for this purpose. This will be revised and agreed with the World Bank before the early implementation review.

Attachment-I. Districts achieving 50% score (26 points or more) will be deemed ready for implementation.

Attachment - I

Criteria For Assessment of Districts			
Input		**Status**	**Yes: 1 No:0**
1	Regular Program Staff in position	District VBD officer	1
		All identified microscopy centres have lab technicians	1

2	Additional Staff in position	District VBD consultant	1
		Malaria Technical Supervisor	1
3	Supplies	No stockout of ACT at identified facilities	1
4	Surveillance	Sentinel sites identified	1
5	Training in Program management provided	Program managers	1
		Malaria Technical Supervisor	1
Input		**Status**	**Yes: 1 No:0**
6	Training in management of Severe Malaria completed	District and Sub District Hospital staff	1
7	Cascadal training in malaria Case Management, passive surveillanc, vector control and social mobilization completed	General Duty Medical officers	1
		Lab Technicians	1
		Supervisors	1
		Multipurpose workers	1
		ASHAs	1
Maximum Score			**14**
Output		**Status**	**Yes: 2/3 No:0**
1	District Plans prepared	Lists phasing of case management services	2
		Stratifies areas for IRS/ITN	2
		Maps Vulnerable communities	2
		Indicates specific actions to improve services for VC	2
		Lists popular private providers for accreditation	2
2	Case Management	Identified public faculties providing 24 hrs. services as per protocol	2
		At least 50% of identified popular providers accredited	3
3	Surveillance	Sentinel Site Type I functional	2
		Sentinel Site Type II functional	3
Maximum Score			**20**
Impact		**Status**	**Yes:4 No:0**
1	Surveillance	At least one suspected outbreak is investigated	4
2	Case Management	At least 50% of fever cases reporting at identified public/accredited private facilities are tested for malaria within 24 hours	4

		At least 75% of persons found positive for *Pf* (except pregnant women in their first trimester) by identified facilities receive adequate treatment	4
3	Vector Control	At least 25% of households targeted for IRS are completely sprayed in each planned spray round	4
Maximum Score			**16**
TOTAL SCORE			**50**

During the project implementation, it will be ensured that at least 40% districts will pass the benchmark criteria.
Procurement: The detailed procurement arrangements are described in Chapter 12.

10.2 Institutional Set-up for Quality Assurance

Drug Controller of a state is responsible for ensuring quality of drugs manufactured or sold in the state, whether in the government sector or private sector. She/he is authorized to grant licenses for manufacture, storage by medical stores including government stores, and for sale of drugs. She/he also issues GMP certificate following the procedures laid out in the Revised Schedule M of Drugs and Cosmetics Act. However, the WHO GMP certificate is issued only after undertaking a joint inspection with the representative of the Drug Controller General of India. The DRA in most states is generally small and inadequately staffed, the exceptions being Maharashtra and Madhya Pradesh which have comparatively larger organizations. The drug inspectors are field officers of the Drug Controller's organization and generally one or more are posted in a district, depending on the workload. The lack of capacity of DRA is a major concern particularly with MOH making of GMP certification using revised Schedule M mandatory since July 2006.

In some states, powers of the Drug Controller have been delegated to district authorities. For example, in some states, the Drug Inspectors report to the district authorities and work under their control and the power of granting drug license has been delegated to the districts and usually the Chief Medical Officer of Health exercises the powers. There are testing labs under the Drug Controller's Organization but they do not have adequate capacity. Efforts will be made to strengthen capacities of the drugs testing laboratories under the Bank supported Food and Drugs Capacity Building Project (Credit No. 37770-IN).

The quality of Diagnostic Kits on the other hand is governed by ISO standards (which is a process standard for the manufacturing facilities) and quality assurance test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit etc. These are decided on case to case basis.

The Central Insecticide Board (CIB) under the Ministry of Agriculture is responsible for ensuring the safety of various insecticides and allied products such as LLIN. CIB also issues license for use of such products, which are imported in the country.

In context of quality, there are two major challenges. Firstly, the difference between the regulatory standards between those set out by the Government of India and international best practices like WHO GMP. Secondly and more serious concern is the weak capacity for monitoring the compliance of the quality standards. A World Bank commissioned study compared the WHO GMP with that of Indian GMP standards under the revised schedule M and listed the key differences. The MOHFW has prepared a technical note to guide the drug inspectors in addressing these deficiencies during the implementation of revised Schedule M. Familiarization of the drug inspectors identified by states in the use of these additional technical notes has started by MOHFW through organizing a series of workshops. For the supplies from other countries with weaker regulatory regimes, the quality of products also poses considerable risk.

MOHFW is working on strengthening the revised Schedule M through introduction of technical notes and training of drug inspectors. Until such time this process is completed to the satisfaction of the Bank, WHO GMP shall only be used for all procurement of pharmaceuticals and medical supplies. Pre-dispatch and post-dispatch inspections shall be conducted to ensure the adherence to agreed specifications and quality standards. An independent inspection agency (selected by MOHFW or by procurement agent through competitive selection procedure) will monitor the quality of pharmaceuticals by picking up the random samples during the project period and getting these tested at accredited labs. In addition, five government-owned units (such as ICMR) will also monitor the quality of drugs and insecticides procured under the project. World Bank has also hired an expert on pharmaceutical quality to deal with quality related issues.

Quality assurance of RDTs is of critical importance for maintaining quality of diagnostics. NVBDCP has prepared draft guidelines based on WHO recommendations. These will now be reviewed by a WHO consultant, who will

also work with NVBDCP and NIMR to set up a plan for implementation including standard operating procedures for collection of samples from stores and end-users and laboratory evaluation at NIMR's facilities.

10.3 Supply Management and Logistics

Inspection of goods supplied by NVBDCP will be carried out at a designated place in the warehouse on arrival, and the incoming goods will be quarantined and not distributed until appropriate quality control has taken place. Random and periodic stock checks will be carried out and a stock auditing system will be put in place. When issuing supplies, it will be made sure that batch samples are kept at the warehouse until expiry for control purposes

The NVBDCP will ensure that physical inventory check of all products is carried out at least semi-annually and will make sure that, as a minimum, the following information is kept in the stock records: product name, beginning stock balance, receipts, issues, losses and adjustments, ending stock balance, and transaction reference. It will also be ensured that adequate and appropriate storage capacity with adequate storage equipment is available for the commodities.

Sufficient and adequately trained staff will be made available by the state to operate the warehouse and adequate security measures will be put in place to prevent theft. It will be ensured through states that storage conditions (e.g., temperature, humidity, cleanliness) are appropriate for the commodities and the systems to deal with expired products are in place. Proper transportation arrangements will be made for distribution of the commodities to facility level. At facility level, it would be ensured that stock and distribution registers are maintained and proper storage is available.

Financial Management: Of the total project cost of USD 250 million, approx 85% is expected to be incurred at the Central level by the Directorate primarily on procurement of drugs, long lasting bed nets and M&E. The decentralized expenditures to be financed under the project are limited to contractual staff salaries and their mobility costs and training cost.

The detailed financial management arrangements are described in Chapter 11

Monitoring and Evaluation: The NVBDCP Directorate would have the overall responsibility for monitoring and evaluation. The following indicators will be used to measure the project success:

- Percentage of fever cases in project districts receiving a malaria test result no later than the day after the first contact.

- Percentage of individuals in project areas belonging to eligible LLIN target population who slept under an LLIN during the previous night.

- Atleast 50% of sampled blocks which at baseline have not achieved the elimination goal of less than one kala-azar case per 10,000 persons, will achieve the elimination goal by endline Percentage of kala-azar endemic districts that achieve the elimination goal of less than one kala-azar case per 10, 000 persons at sub-district level.

For effectively implementing the M&E framework, specific inputs like human resources and training will be provided to build capabilities of districts to undertake M&E in accordance with the framework. The M&E tools, including a set of standardized forms and records to track the stocks, storage, distribution, and use of commodities, would be developed by NVBDCP in partnership with the States, and field-tested and standardized with consultant support.

There will be monthly reviews at district, quarterly reviews at state, and semi-annual reviews at national level; these reviews would be more frequent during the first year, say, monthly at the state and quarterly at the national level. These reviews would be supplemented by systematic visits undertaken by NVBDCP and Regional Directors of Health Services to the States and districts; a mid-term and an end-line expert review; and two household and health facility surveys, one at mid-point and the other at project end. Monitoring by the community would be an important activity which is consistent with the objectives of NRHM and more realistic to provide for than in the past due to the availability of new technologies such as rapid diagnostic kits and GIS.

Chapter 11

Financial Management and Disbursement Arrangements

The National Vector Borne Disease Control Project (NVBDCP) is a follow on project to the Enhanced Malaria Control Project closed in December 2005. NVBDCP will focus on malaria control activities in 93 Districts from 8 States and on kala-azar elimination in 46 districts in 3 States. In phase I of the project 50 districts from 5 States (Orissa, Chhattisgarh, Jharkhand, Madhya Pradesh and Andhra Pradesh) under Malaria and 16 Districts under Kala-azar in the state of Bihar will be covered. The project will be extended to Phase II after a period of 18 months based on early implementation progress review by the World Bank team.

The project will be financed 100% by Bank on certain categories(the details of categories is described in this chapter. NVBDCP will finance other activities under the program. About 85 % of the project cost will be incurred at the Central level by the NVBDCP Directorate primarily on procurement of drugs, long lasting bed nets, BCC, M&E, contractual staff and operating costs activities. The expenditure to be financed under the project at the decentralized level i.e. states and districts will be limited to contractual staff, their mobility cost and training which is estimated to be Rs 1480 million. Expenditures on other activities at the state/district level such as consumables and lab articles, IEC, spray wages and office costs will be financed by GoI out of domestic budget for which NVBDCP shall obtained a separate approval for this project from MOH.

11.1 Implementing Entities

The Malaria and Kala-azar component of the project will be implemented by the Directorate, NVBDCP at the centre, by the State and District Health societies at the states and districts respectively. In addition limited activities relation of surveillance, studies and training will be executed by research institutions under ICMR. Directorate, NVBDCP is responsible for overall management of the project and will have a financial management cell (2 Financial consultants) at the centre to monitor the financial management and with FMG group of NRHM at national level, the finance staff of National Rural Health Mission (NRHM) supplemented with project specific finance staff at the states and districts will be responsible for the financial management of NVBDCP at their respective levels.

11.2 Financial Management at the Central level

Budgets and funds flows: At GOI level, NVBDCP funding requirements are projected within the budget of the MOHFW. NVBDCP has a separate budget head (minor head). At the national level, the budget is operated by the Directorate, NVBDCP and adequate provision form the proposed project on malaria control and Kala-azar elimination has been made in the budget for the year 2008-09. Funds for procurement by the procurement agent will be made available by the Directorate by drawing on the non-plan budget and based on actual utilization/submission of settlement documents, the expenditure is charged to the plan budget. Need based funds will be provided to the Research Institutions for specific activities for which utilization certificate and SOEs duly signed by appropriate authority will be submitted to Directorate of NVBDCP.

11.2.1 Accounting, Internal control and Financial Reporting

The accounting for expenditures at the central level is done by the Pay and Accounts Office (PAO) headed by the Chief Controller of Accounts within the MOHFW. The NVBDC Directorate maintain cash book and other subsidiary records (including advances to and settlements by the procurement agent etc), the balances in which are periodically reconciled with the PAO. Grants provided to States against approved actions plans are recorded as expenditure in the books of account of MOHFW. All sanctions for expenditures/ release of funds are required to be approved by the Financial Advisor in MOHFW. These financial records will form the basis of preparation of the Interim and Annual Financial reports for submission to IDA, the formats of which have been agreed to. Until such time as the procurement and supply management capacities of the NVBDCP are developed to the satisfaction of IDA, all ICB/LIB and NCB procurement above US$ 100,000 will be carried out by a qualified procurement agent or through a UN agency hired to do so on turn-key basis (viz. from receipt of the indent till the delivery of the goods to consignees). The procurement of services at the central level will also be handled by the procurement agent till the Directorate of NVBDCP develop in-house capacity. However, in procurement of services, the role of the procurement agent will be limited up to the contract award recommendation stage, while the contract shall be signed and managed by MOHFW. Under this project a specific delegation of power to Project Director i.e Director, NVBDCP upto Rs. 50 lakhs shall be obtained from MOH for effective implementation of certain activities like training, operational research, workshop, seminar publication of guidelines and day to day project office expenditure.

11.2.2 Finance Staffing

The existing accounts cell in the directorate of NVBDCP will strengthen by contracting in two finance consultants, of which one is already in position and the second will contracted by *September 2008*. The finance consultants will have responsibility for liaison with procurement agent (fund transfer, collection

of expenditure reports and settlement of advances etc) and oversight on the financial management arrangements at the state and districts together and with the financial management group established under National Rural Health Mission (NRHM) at national level.

11.2.3 Audit Arrangements

The annual financial statement of the expenditures incurred at the central level will be audited by the Comptroller & Auditor General of India (C&AG) who is constitutionally independent. The World Bank and the Ministry of Finance are in discussion with the C&AG to agree on a Standard Terms of Reference which will provide a framework for audit. A project specific TOR will be agreed within the framework after the negotiations as the C&AG requires the finalized legal documents to provide its concurrence. (Project Specific TOR to be consented to by C&AG).

Implementing Agency	Audit	Auditors	Timeline
The Directorate, NVBDCP	Project Audit for central level activities including expenditures incurred by procurement agent.	Comptroller and Auditor General of India	30 September

11.3 Financial Management Arrangements at the State/District level

The key issues that emerged from the earlier World Bank EMCP project are: the financial management arrangements in some states and districts were not adequate, with the weaknesses mainly being (i) lack of familiarity with double entry accounting and maintenance of ledgers by govt staff resulting in delays in SOE and preparation of financial statements; (ii) inadequate internal & operational controls; (iii) consequent delays in submission of audit reports. The issues indicated above shall be strengthened during this project. The activities at the decentralized level, to be financed under the project are limited to contractual staff, their mobility costs and training.

11.4 Integration of financial management arrangements under National Rural Health Mission

A detailed financial management assessment carried out covering a sample of 5 states in January 2007 suggested several measures for improving financial management in the NVBDCP. Subsequently in August 2007, the MOHFW has decided 'in principle' to integrate various disease control programs including the financial management arrangements with the NRHM. Thus, the financial management capacity of NRHM will have a major bearing on the successful implementation of financial procedures for NVBDCP. While there will be a

separate financial management cell in the NVBDCP Directorate at the centre, the financial management arrangements for NVBDCP at the state, districts and sub district levels are proposed to be integrated with NRHM. This will include funds flow, administrative and financial delegations/ rules, accounting & internal control, finance staffing, financial reporting and audit assurance mechanisms.

The MOHFW has constituted a committee under the Chief Controller of Accounts (CCA) of MOHFW to guide the development of a common financial management manual by Financial Management Group (FMG) applicable for all programs funded by MOHFW, while retaining the needs, especially financial reporting requirements, of individual programs. As a first step the MOHFW has already issued (a) Guidelines on budgets, annual plans and funds flow and banking arrangements; and (b) Financial guidelines and framework for delegation of administrative and financial powers. From the NVBDCP perspective, this will essentially mean incorporating the budget formats, chart of accounts and financial reporting formats of NVBDCP in the NRHM finance manual. In addition, the FMG is developing procedures to enhance the audit assurance by strengthening the process of selection of auditors. These are expected to be completed by September 30, 2008. As a part of the integration of the disease control program with NRHM, finance staff under NRHM at the state as well as district levels will be responsible for funds flow, accounting and reporting the expenditure for all disease control programs including NVBDCP. The Books of Accounts at the Directorate, NVBDCP, states and districts will be maintained as per the NRHM financial guidelines. Standard Books of Accounts will be maintained on a double entry basis in the state and district societies which would include cash and designated Bankbook, journal, fixed assets register and advances ledger. Expenses would be recorded on a cash basis and would follow broadly the project activities.

11.5 Internal Procedures applicable to the decentralized activities (about 10% of the project cost) to be followed by NVBDC Directorate and arrangement between MOHFW and the States/ Districts

The Directorate of NVBDCP will follow the normal process of releasing funds as cash grants to states against approved Annual Action Plans (AAPs). The AAP for each state is approved based on the actual pace of implementation and incorporates the district plans. The States in turn will transfer funds to districts for implementation of project specific activities. The annual budget allocated to each state will be released in two installments during the first and third quarters of each fiscal year through the electronic transfer of funds. The state unit will transfer funds for activities to be implemented by the districts. The funds will be transferred to the designated Bank account in the state as well as districts, which will be maintained as a sub account for NRHM Bank account, as per the NRHM guidelines. The districts and states will maintain program specific books of account including activity wise ledger accounts as specified in the

NRHM financial management manual and submit quarterly financial reports to the FMG in MOHFW and NVBDCP. The annual audit report of all programs under NRHM (consolidated for the State and Districts) will be carried out as per the TOR specified in NRHM manual/ guidelines and will be submitted to MOHFW/NVBDCP within six months of the close of the financial year.

11.6 Financing of Selected Decentralized Activities and Fiduciary Assurance to World Bank for Related Expenditures

The World Bank will finance the selected decentralized activities for states and districts (contractual staff, mobility costs of various staff and training cost) based on standard costs for such activities agreed between MOH/NVBDCP and World Bank . The standard costs will be derived from a detailed list of the planned expenditures by district and state, which will be reviewed by World Bank for reasonableness. Considering that the activities proposed to be financed by World Bank under the project are (a) a small subset of relatively simple and non technical activities to be carried out at the State and District level which are covered by MOU between the central and state governments (b) associated with fewer financial transactions and can easily be costed with reasonable assurance (c) carry inherently lower risk activities and transactions (d) limited to selected states/ districts within the larger program of MOHFW; and (e) necessary for effective implementation of overall district program activities (i.e., there is a low risk that the financed activities will not take place and the expenditures is not incurred); the following approach of integrated implementation and fiduciary review of such activities including focusing on intermediate outputs will be used to obtain necessary fiduciary assurance that the funds are used for intended purposes.

- NVBDCP being responsible for oversight of the project, will provide the World Bank with quarterly performance reports for project activities in the states and districts as per agreed timeframe.
- The NVBDCP within 120 days of the end of the year will provide the World Bank with annual state and district-wise physical and financial reports which will enable comparison of the transfers (from the national government to the states and districts) with the actual expenditures reported by the districts.
- An independent monitoring consultant will be appointed by NVBDCP after approval from MOHFW to conduct implementation and fiduciary review of the selected activities in a sample of states/ districts providing feedback on whether planned staff were appointed through the appropriate process, are in position, have requisite contracts, are paid regularly in accordance with the contracts, and whether they are effectively performing their duties, and whether the training activities were being implemented as per program norms. The TOR for such integrated review has been agreed by MOHFW and the World Bank during negotiations.

- World Bank will review of the annual audited project financial statements (which will include the funds transferred by NVBDCP to the States, along with other central level project expenditures), field visits and desk reviews of MIS information on staffing and training, review of standard costs and units as well as training programs; and a review of the sample of audit reports which will be received by the NVBDCP.
- Financial management capacity building activities at state /district and central level.
- Annual Lot Quality Assurance Sample Surveys confirming the availability of trained village level providers and thereby confirming that the training took place and is benefiting the implementation of the programme). These surveys will include the same sample districts as being reviewed by the independent consultants.
- Bi-annual Technical Program reviews to the satisfaction of the World Bank.

During early implementation review, based on the results of the integrated implementation and fiduciary review and a comparison of the actual costs with the standard cost, this method of financing, the standards costs and assurance mechanism will be assessed by World Bank and redesigned, if necessary.

This approach is considered more appropriate as it integrates implementation and fiduciary review and given the relatively lower risk associated with the activities to be financed at the decentralized level and limited financial exposure per district. In addition the financial exposure on decentralized expenditure in Phase I of the project is only estimated to be USD 12 million (Rs 480 million). There will however, be a residual risk given (a) the decentralized nature of operations; (b) delayed implementation in certain districts leading to standard costs being higher than actual expenditure, and (c) internal control weakness in some of the districts. The sample of coverage in the integrated review will be reviewed based on the findings of the review in the first one year. The details of standard costs- units, unit cost and basis of determination are given in Chapter 4. These will be reviewed at project effectiveness for this component and may be revised for phase I, if considered necessary.

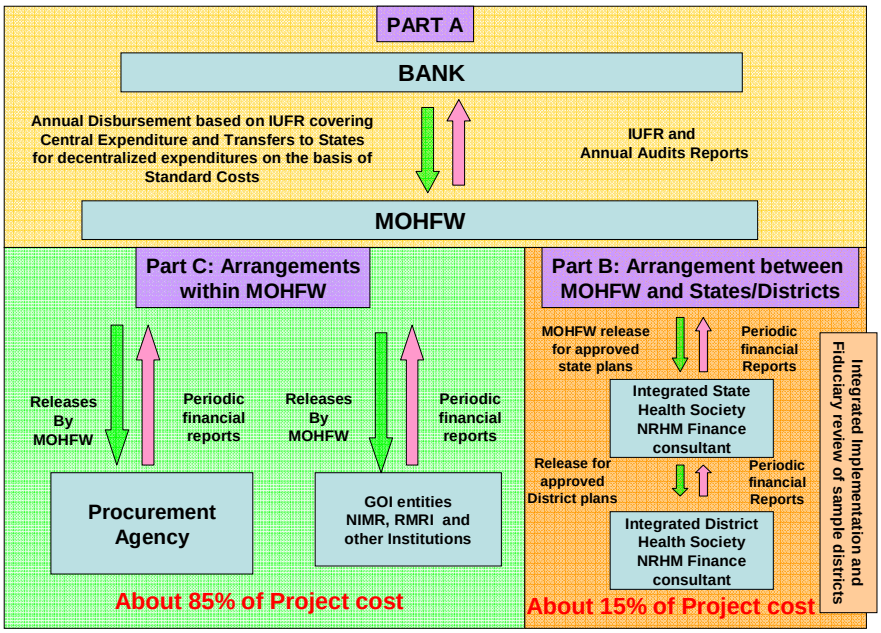
Financial Reporting and Disbursement Arrangements: The project will submit quarterly interim unaudited financial reports (IUFR) in the agreed formats, which will reflect the central level expenditures (including those incurred by the procurement agent and research institutions); the grants transferred to states for decentralized project activities and the standard cost of the selected decentralized activities to be financed by IDA27. The IUFR will be submitted within 45 days of the end of each quarter. Reimbursement by IDA will be made annually using report-based disbursement, as for the project as a whole. The IUFR at the end of the financial year will be the basis for reimbursing MOHFW;

[27] The standard cost of the selected decentralized activities to be financed by the World Bank will be calculated on annual basis and presented in the agreed format of IUFR for the last quarter of the financial year.

reimbursement will be limited to the central level expenditure and the agreed standard costs for decentralized activities at the state and district levels to be financed by IDA. A district will be eligible for reimbursement of such standard costs in 3 months28 after being certified as ready by NVBDCP for implementation of the selected activities financed by IDA. The central level expenditures and transfers to states reported in the IUFRs at the end of the financial year will be validated by annual audited financial statements to be received within 6 months of the closure of the financial year. Any variance between the amount reported in the IUFR (central level) and the audited expenditure (central level) will be adjusted (recovered or reimbursed) from the next disbursement to the GOI.

The chart below illustrates the disbursement and reporting arrangement between World Bank and GOI/ MOHFW (Part A) and reporting arrangement between MOHFW and States/ Districts and normal funds flow (Part B) and the arrangements within MOHFW/NVBDCP (Part C for central expenditures).

India – VBDCP - Funds flow and Reporting



11.7 Financial Management Capacity Building and Support

[28] It is estimated that it takes about 3 months to recruit staff and initiate necessary project related activities.

In parallel and in support of enhancing the overall program control environment, World Bank is working with the MOHFW to further build capacity of the states/ districts to improve financial management. These activities include developing an integrated financial management manual under the National Rural Health Mission (NRHM) (which includes the NVBDCP activities), training and capacity building and enhanced audit assurance mechanism. The enhanced audit assurance includes agreeing on specific selection criteria and the contracting process for auditors of the state and district program implementing entities. All of these activities are directed at improving the country systems used by MOHFW for receiving assurance over the use of its own funds. These, and other, actions by the government to promote and receive enhanced assurance are additional mitigating actions that support World Bank and other IDA integrated and holistic approach to receiving assurance over the limited decentralized project expenditures.

11.8 Oversight by MOHFW

MOHFW/NVBDCP will provide an oversight to the project and will appoint independent consultants, based on TOR approved by World Bank to carry out review of the selected decentralized activities covering a sample of districts. MOHFW will obtain the actual expenditure reports and audit reports from the state (which will include reports from the districts) as per their internal requirements; these will cover the totality of program activities, not just the project financed activities.

11.9 World Bank Supervision

World Bank supervision will include a desk reviews of the results of the oversight arrangements by MOHFW/NVBDCP, annual audited project financial statements (which will include the funds transferred by NVBDCP to the States, along with other central level project expenditures) and MIS information on staffing and training, review of standard costs and units as well as training programs; and a review of the sample of state audit reports which will be received by the NVBDCP. In addition, World Bank supervision will cover field visits to 4 states and 4 districts on annual basis including site visits to review a sample of inputs, (ii) activities, (iii) outputs, (iv) program audited financial statements for that location; and (v) overall project operations. World Bank will also track the financial management capacity building and enhancement activities by working in close coordination with the financial management group in MOHFW to assess progress on effective integration of all disease including malaria control programme control programs within NRHM. Based on the results of the integrated implementation and fiduciary review and a comparison of the actual costs on the basis of the information collected with the standard

cost, this method of financing, the standards costs and assurance mechanism will be assessed and redesigned, if necessary.

Based on the above arrangements the risk for malaria and kala-azar component of the project is assessed as substantial; break up of which is as under: (This as per WB PAD document).

Risk	Residual Risk Rating	Risk Mitigation Measures	Condition of Negotiations, Board or Effectiveness (Y/N)
Inherent Risk			
Country Level	Modest		N
Entity Level (MOHFW)	Substantial	The MOHFW has limited control over the States. It is however moving in a positive direction by bringing in financial management of all disease control programs under the supervision of NRHM at central, state and district levels.	N
Project Level	Modest	About 85% of the project expenditure will be at the central level (as the procurement is centralized and to be carried out by procurement agent; and expenditure at State level will mainly relate to contractual staff and training.	N
Control Risk			
Budgeting	Low		N
Accounting	Moderate	An integrated FM manual under NRHM is being developed to guide the state and district societies	N
Internal Control	Substantial	The integrated society at the state and district level and strengthened audit assurance mechanisms will help improve the control framework	N
Funds Flow	Low		N
Financial Reporting	Substantial	Reporting formats are being standardized under NRHM. Finance staff have been recruited under NRHM who will also be responsible for NVBDCP at the district level. MOHFW is also taking stock of the vacancies in states/ district as a result of attrition based on which another round of recruitment will be planned.	N
Auditing	Moderate		N

Risk	Residual Risk Rating	Risk Mitigation Measures	Condition of Negotiations, Board or Effectiveness (Y/N)
Overall Risk	Substantial		

11.10 Project Covenants

Apart from the covenants regarding audit and submission of IFRs, the following covenants has been included in the financing agreement:

NVBDCP will establish and retain during project implementation a financial management cell at the central level with two finance professionals with qualifications acceptable to the World Bank.

Appoint a consultant agency as per TOR acceptable to the World Bank to carry out periodic implementation and fiduciary reviews of decentralized activities financed by World Bank in the project states and districts.

11.11 Advance

The disbursement from the World Bank will be on an annual basis, an advance of USD 20 million (Rs 800 million) will be provided to NVBDCP to finance the activities of this component in the interim period. This will be adjusted in the last six months of the project.

11.12 Project Preparation Facility

A Project Preparation Facility (PPF) for the project was established for US$ 1 million (reference: IDA-Q5040-IN) for the project. The refinancing date for the PPF has been extended until June 30, 2008. No further extension beyond June 30, 2008 has been seeked by NVBDCP.

11.13 Retroactive Financing:

World Bank has provided retroactive financing for certain level of activities. The NVBDCP has initiated agreed preparatory activities at the central level and procurement of drugs and insecticides through UNOPS for the proposed project. World Bank has, agreed retroactive financing of central level expenditures on procurement subject to a limit of USD 10 million (Rs 400

million). These will be claimed by the NVBDCP as part of the financial report for the year 2008-09.

11.14 Polio Component ($270 M)

The Polio component has been included under the overall financing of the proposed project by World Bank. About USD 270 million will be used for vaccine procurement, which will be financed 100% by World Bank. MOHFW will be the implementing entity. No role of NVBDCP has been envisaged for this component.

11.15 Eligible Expenditure Categories wise

The following table specifies the categories of eligible expenditures and percentage of expenditure to be financed and reimbursed for eligible expenditures in each category that may be financed.

Category	Percentage of Expenditures to be financed
(1) Expenditures incurred on Pharmaceuticals and Medical supplies;	100%
(2) Expenditures incurred on: a) Long lasting bed nets; and b) Other Goods, Services and Operating costs	100%
(3) Grants to Eligible Project States and Eligible Project Districts to finance Project contractual staff, associated mobility costs and training	100%
(4) Refund of Project Preparation Advance	Amount payable pursuant to Section 2.07 of the General Conditions of World Bank

a) "Eligible Project State" means a Project State that has executed and furnished a Letter of Undertaking, satisfactory to NVBDCP and World Bank.
b) "Eligible Project District" means a district certified by NVBDCP as ready to undertake Project activities, according to District readiness criteria acceptable to World Bank.
c) "Other Goods" includes vehicles, furniture, computers hardware and software, insecticides and insecticide treated bed nets.
d) "Operating Cost" means reasonable and necessary expenditure fro purpose of implementing the project which includes costs of operation and maintenance of office, automation, vehicle, payment to contractual staff salaries of incremental non civil servant staff, travel allowances, vehicle hiring for project staff for implementation, coordination and monitoring.

Chapter 12

Procurement Arrangements

The NVBDCP envisages large scale procurement of pharmaceuticals, insecticides, long lasting insecticide treated nets, diagnostic kits, vehicles and services etc. while no civil works are planned under the project. About 85% of total project cost is estimated to be incurred on procurement of goods and services. The project will cover selected high burden districts among the diseases prone states. Initially the procurement under the project will only be handled at National level[29]. The proposed assessment of the procurement capacities of the states (which MOHFW is taking up in association with the World Bank and DFID) will determine the decision on decentralizing procurement to states or state agencies found to have satisfactory capacity. The details of items to be procured at NVBDCP level are indicated in the Table.

12.1 Items to be procured at Central Level

Pharmaceuticals and Medical Supplies	Other Goods	Consultancy Services	Non-Consultancy Services
Procurement of RDK, ACT, Drugs for severe Malaria, Rapid diagnostic kits, Miltefosine or other second line drugs etc.	Procurement of LLIN, Insecticides for IRS and treatment of bednets, Vehicles, Furniture, Computer hardware and software, laboratory equipment etc.	Hiring consultant agencies for: Service delivery, Procurement, BCC, development and translation of training manuals/modules, operational research, impact evaluation, Quality Assurance and improvement, Monitoring and Evaluation, MIS software updating and maintenance, Development and implementation of Geographic Information System, EMP implementation, supply chain management etc.	Printing and publication of modules, etc.
Total (US$58 M)	**Total (US$ 76 M)**	**Total (US$ 36 M)**	**Total (US$ 1M)**
Rs 2320 Mn	**Rs 3040 million**	**Rs1440 million**	**Rs 40 million**

[29] The recruitment of contractual staff at regional, state and district levels will be as per GoI procedure. Apart from expenditure on contractual staff, there will be some expenditure on training and mobility of staff at decentralized levels, which may involve a few very low value purchases of routine items. These expenditures (totaling to US$ 25.28 Million) will be monitored as per the procedure described in Chapter 10 and no procurement post review will be conducted for these transactions.

12.2 Assessment of the Procurement Capacity of the Implementing Agencies

12.2.1 Institutional Set-up for Procurement for NVBDCP

MOHFW has established an Empowered Procurement Wing (EPW) to professionalize the procurement of health sector goods and services under centrally sponsored health programs. Prior to formation of EPW, MOHFW did not have a Central Procurement Organization and both health and family welfare departments had separate purchase committees. Director (Procurement) under DGHS and Director (SSM) & Director (UIP) under the supply division handled procurement related activities in the Ministry. In addition, program divisions procured their respective requirements either directly or through Procurement Support Agencies (PSAs) which did not handle procurement on a turn key basis. As per its mandate, EPW is responsible for handling the strategic procurement and providing oversight for the procurement handled under different centrally sponsored health schemes.

However, in practice EPW plays relatively limited role in supervising the procurement in MOHFW. The services of PSA are being used for handling most of the NVBDCP procurement funded by the domestic budget. An internationally selected consultancy with appropriate technical expertise in pharmaceuticals, biomedical engineering, quality assurance, IT and supply logistics, is helping EPW in developing its capacity. EPW is also utilizing the services of in other matters such as reviewing specifications of items being procured by MOHFW etc. Under the current procurement arrangement for the project, where most of the procurement is to be handled by the procurement agent, the role of EPW is not significant, and its current lack of capacity will not adversely affect the project implementation.

MOHFW has hired the services of the United Nations Office for Project Services (UNOPS) on May 30, 2007 to act as procurement agent for handling the procurement of health sector goods under donor funded projects. As per the agreed matrix of responsibilities, UNOPS is handling the procurement on turnkey basis and seeking only the financial concurrence of MOHFW before entering into the contract with suppliers. NVBDCP is responsible for providing technical specifications, quantity to be procured, delivery schedule and the list of consignees to UNOP after getting approval from MOHFW.

UNOPS is following the World Bank procurement guidelines for all the procurement where it is acting as procurement agent. UNOPS is having a well laid down internal control system in place, which involves review of all the contracts exceeding US$ 100,000 in value. UNOPS has contracted independent

agencies for taking up inspections and has been involving independent experts in bid evaluation process.

The Directorate of NVBDCP, under the Directorate General of Health Services of MOHFW, is the nodal organization to decide policies, develop evidence based intervention strategies with the support of the research and development organizations, prepare operational tools and guidelines, as well as provide technical guWorld Bank nce and resource support to States which are responsible for the implementation of the program. The Directorate is also responsible for budgeting of centrally financed component and monitoring the program implementation. For effective coordination with the states, the Directorate has various divisions, one of them is the procurement division for procurement under domestic budget support (DBS) and also procurement of insecticides, drugs and equipment under the externally assisted component (EAC). Even if most of the procurement at central level shall be handled by UNOPS, the Directorate will still is responsible for drafting the technical specifications, demand forecasting and procurement planning, coordination with UNOPS and EPW, monitoring the state/district level procurement, inventory management, capacity building of the states, collecting the data regarding the contracts issued under the project and monitoring the end use of supplies made etc.

Under NVBDCP, the Regional Offices for health and family welfare, located at various state capitals, are responsible for coordination and supervision of all activities at the state and below level. They are also responsible for monitoring the therapeutic efficacy of anti malaria drugs, insecticide resistance to vectors as well as internal quality assurance of microscopy including training of laboratory technicians. As there is no procurement to be handled at decentralized level initially, the role of the Regional Directorates, state integrated NRHM health societies and District health societies will be only limited to implementation of the project. Services of NIMR, RMRI and other ICMR Institutions will be utilized for carrying out technical studies.

MOHFW in association with the World Bank and DFID is in the process of assessing the procurement capacities of selected state level agencies including having adequate systems and procedures, internal controls etc. Based on this assessment, a plan shall be developed by NVBDCP with collaboration with World Bank for strengthening the capacity in identified areas of weakness. Following this process, these state level agencies could be entrusted with responsibility to handle the procurement under the project at decentralized level as and when mutually agreed by World Bank, MOH and NVBDCP.

12.2.2 Broader procurement related policies

The Constitution of India (Seventh Schedule) lists specific subjects in which the Union Government or the State Government alone can make laws and concurrent subjects in which both the Union and State governments can make laws. Procurement falls in the concurrent list. Procurement of goods/works and services by MOHFW and the State Governments (except for Tamil Nadu and Karnataka, who have passed their own procurement legislations) is regulated mainly by the General Financial Rules (GFR), 2005; State Finance Rules, Indian Contract Act 1872 as amended to date and the Sales of Goods Act.

12.2.3 Policies related to Health Sector Procurement

Since procurement of drugs is a specialized subject, further guidelines have been issued by MOHFW to regulate drug procurement. Salient feature of the guidelines issued by MOHFW are:

- *The bidder should be in possession of drug license for manufacturing and sale of the drug on the date of tender opening.*
- *The bidder should be in possession of Good Manufacturing Practice (GMP) certificate for at least two years, which should be valid on the date of tender opening.*
- *The bidder should not have been convicted. A certificate from the State Drug authority should support this.*
- *The bidder should have proper arrangements for maintaining cold chain during storage/transit, whenever needed.*
- *Apart from the sample to be tested by the inspectors, supplier should also test the drugs and produce test results to the inspector at the time of inspection.*
- *At the time of offering for inspection the drugs should not have crossed 1/6th of the life, and should have a shelf life of not less than that specified in the tender from the date of manufacture.*

Each State Government has also issued further instructions which are applicable for health sector procurement in the state. These are mainly based on policy of MOHFW.

12.2.4 Country/State Procurement Assessments

A Country Procurement Assessment Report (CPAR) was prepared in 2001, which provides an understanding/overview of GoI's National Procurement System. State Procurement Assessment Reports (SPAR) were also prepared for the States of Karnataka, Tamil Nadu, Maharashtra and Uttar Pradesh in 2002 and 2003. Based on these assessments, the existing basic framework of public procurement rules and procedures in the country requires open tenders to all qualified firms without discrimination, use of non-discriminatory tender documents, public bid opening, and selection of the most advantageous

contractor/supplier. However, the various assessments (CPAR/SPAR) revealed significant weaknesses and lack of compliance with the basic framework of rules and procedures. These included the absence of: a dedicated policy making department, a legal framework, credible complaint/ challenge/ grievance procedures, and the standard bidding documents. The assessments also highlighted cases of preferential treatment in procurement, delays in tender processing and award decisions, use of two envelope system and incidents of inappropriate negotiations.

12.2.5 Procurement Capacity Assessment for the Project

Other procurement capacity assessment studies conducted by the Bank for the health sector projects have pointed out issues such as weak procurement organization, problems due to use of PSAs, delays in finalization of annual procurement plans and poor quality of procurement plans, ambiguous and incomplete specifications for equipment and drugs, delays in procurement decisions including delay in technical evaluation, piece-meal procurement by implementing entities, non availability of appropriate Standard Bidding Document (SBD) for carrying out procurement on rate contract basis, absence of procurement manual, quality assurance and inspection of goods, weak supply chain management, poor logistics and storage facilities, low capacity of procurement personnel, absence of post-award reviews, and weak complaint handling mechanisms etc.

The procurement capacity assessment of NVBDCP was carried out by the World Bank as part of mandatory assessment which pointed out to specific weaknesses such as lack of trained procurement staff, intentional splitting of Contracts to avoid use of more competitive procurement procedures, delays in contract awards due to time taken in evaluation, getting IFD clearance etc. and the stocks/drugs are allocated based on the past use rather than the forecasted disease burden.

12.3. Procurement Arrangements

12.3.1 Procurement Plan

For each major contract to be financed by World Bank, the different procurement methods or consultant selection methods, the need for prequalification, estimated costs, prior review requirements, and time frame are agreed between the NVBDCP and the World Bank project team in the Procurement Plan. The Procurement Plan will be updated at least annually or as required to reflect the actual project implementation needs and improvements in institutional capacity. It will also be available in the Project's database and in the World Bank's external website. MOHFW has prepared the procurement plan

for ICB/NCB procurement and major consultancies to be taken up during the first 18 months of the project, which is attached at **Appendix 1**. This plan will be published also on NVBDCP and MOHFW website.

Rapid Diagnostic Kits(rk39) for Kala Azar and Miltefosine Capsules (50mg and 10mg) are proprietary items (as on date) procured on Direct Contracting basis. Procurement of IEC services from Prasar Bharti (for Doordarshan, the state television channel and the All India Radio, the state radio channel), which is a Government owned agency and release in private print and electronic media through DAVP (a Government Department acting as implementing agency) may be considered on single source basis (with prior review of the Bank) as per the details provided in Procurement Plan, provided these agencies agree to use the contract format acceptable to the Bank. At state level also, state information department (similar to DAVP at central level) will be assigned the responsibility to implement IEC campaigns (once the state level procurement is agreed). Some NGOs may also be contracted for delivery of services, monitoring etc. on single source basis due to their unique qualifications/ experience and presence in project states.

12.3.2 Advance Contracting

NVBDCP has initiated the procurement process for Synthetic Pyrethroids (WDP), Synthetic Pyrethroids (Liquid), Rapid Diagnostic Test Kits for Malaria, Rapid Diagnostic Test Kits for Kala Azar, Capsule MILTEFOSINE (50mg) and Capsule MILTEFOSINE (10 mg), Combi Blister Packs (Artesunate + Sulphadoxine Pyrmethamine Tablets, Tablet Artesunate (50mg) and Tablet Sulphadoxine Pyrmethamine (500 mg); and Arteether Injections. GFATM procurement is also being conducted along with the World Bank funded procurement under the same bid documents. The advance contracting would be made only after obtaining NOC from World Bank by NVBDCP.

12.3.3 Procurement Manual

In case the procurement is to be decentralized to the state level in future based on the outcomes of ongoing capacity assessment of the state level agencies, NVBDCP will utilize the procurement manual available under NRHM to guide the implementing agencies at all the levels in handling the procurement. This manual will be shared with the Bank and finalized before delegating any procurement. All the contracts issued under the project will follow the World Bank's Guidelines: Procurement under IBRD Loans and WORLD BANK Credits" dated May 2004; and "Guidelines: Selection and Employment of Consultants by World Bank Borrowers" dated May 2004 respectively.

12.3.4 Procurement Methods

The table given below gives highlight of the various procurement procedures[30] to be used by NVBDCP. These along with agreed thresholds would be reproduced in the procurement plan. The thresholds indicated in the following table is for the current implementing agencies and in case the decentralized procurement is used in the future, the thresholds may be revised for the state level procurement agencies.

Table: Procurement Methods to be used for NVBDCP

Category	Method of Procurement	Threshold (US$ Equivalent)
Goods and Non-consultant services	**ICB**	**>1,000,000**
	LIB	**wherever agreed by World Bank**
	NCB	**Up to 1,000,000**
	Shopping	**Up to 50,000**
	DC	**As per para 3.6 of WB Guidelines**
	Procurement from UN Agencies	**As per para 3.9 of WB Guidelines**
Consultants' Services	**CQS/LCS**	**Up to 100,000**
		Up to 50,000
	Service Delivery contractor procedure	**As per para 3.21 of WB Guidelines (selection procedure to be agreed)**
	Individuals	**Up to 50,000 (as per para 5.2 to 5.4 of WB Guidelines)**
	Use of UN Agencies	**As per para 3.15 of WB Guidelines**
	Use of NGO	**As per para 3.16 of WB Guidelines**
	QCBS **(i) International shortlist** **(ii) Shortlist may comprise national consultants only**	**QCBS (or QBS/FBS if agreed with World Bank) for all other cases** **>500,000** **Up to 500,000**

World Bank's SBD and Standard RFP, as agreed with the World Bank, will be used for all procurement of goods and consultancy under the project. In addition to the World Bank's Procurement and Consultants' Guidelines and SBD/RFP Documents, Malaria Tool Kit published by the World Bank may also be referred for procurement and supply management. The use of WHO pre-qualified suppliers or suppliers recommended by WHOPES for use or application

[30] If bids are called concurrently for several lots/ schedules in a package and cross discounts are invited, the aggregate value of the total package will form the basis to determine the procurement method as well as the review requirements

in public health (as described in the Tool Kit) may also be considered provided it does not adversely affect the competition and is cost effective.

National Competitive Bidding (NCB) will be conducted in accordance with paragraph 3.3 and 3.4 of the WB Guidelines and the following provisions:

- Only the model bidding documents for NCB agreed with the GOI Task Force (and as amended for time to time), shall be used for bidding;
- Invitations to bid shall be advertised in at least one widely circulated national daily newspaper, at least 30 days prior to the deadline for the submission of bids;
- No special preference will be accorded to any bidder either for price or for other terms and conditions when competing with foreign bidders, state-owned enterprises, small-scale enterprises or enterprises from any given State;
- Except with the prior concurrence of the World Bank, there shall be no negotiation of price with the bidders, even with the lowest evaluated bidder;
- Extension of bid validity shall not be allowed without the prior concurrence of the World Bank (i) for the first request for extension if it is longer than four weeks; and (ii) for all subsequent requests for extension irrespective of the period (such concurrence will be considered by World Bank only in cases of Force Majeure and circumstances beyond the control of the Purchaser/Employer);
- Re-bidding shall not be carried out without the prior concurrence of the World Bank. The system of rejecting bids outside a pre-determined margin or "bracket" of prices shall not be used in the project;
- Rate contracts entered into by Directorate General of Supplies and Disposals will not be acceptable as a substitute for NCB procedures. Such contracts will be acceptable however for any procurement under National Shopping procedures;
- Two or three envelope system will not be used.

12.3.5 Use of Procurement Agent

Until such time the procurement and supply management capacities of the implementing agencies are developed to the satisfaction of the World Bank, all ICB/LIB and NCB procurement[31] will be carried out by a qualified procurement agent or through a UN agency hired to do so on turn-key basis (viz. from receipt of the indent till the delivery of the goods to consignees). In this regard, the MOHFW has already selected UNOPS to act as procurement agent for central health sector projects including NVBDCP. The procurement agent

[31] Procurement of pharmaceuticals and medical supplies shall be taken up only through ICB/LIB until the concerns regarding revised Schedule M have been addressed in a way that is satisfactory to the Bank

(commercial or UN agency acting as procurement agent) will follow the World Bank Guidelines dated May 2004 and other procurement arrangements agreed for the project. The Procurement Support Agencies (PSA) are not to be used at any level until otherwise agreed by the World Bank. The procurement of services (both consultancy and non-consultancy) will also be handled by the Procurement Agent till the implementing agencies develop their in-house capacity. However, in procurement of services the role of the Procurement Agent will be limited up to finalizing the contract award recommendations, while the contract shall be signed and managed by NVBDCP. NVBDCP will directly handle the low value procurement below NCB threshold.

12.3.6 Procurement MIS

Until such time the computerized MIS system (in which contract database would be a module) becomes operational, the manual system of collecting contract data would be put in place. The format and frequency for collecting the contract data would be agreed with the World Bank based on the post review plans.

12.3.7 Borrower's Procurement Audit

Following procurement audit will be conducted by the NVBDCP/MOHFW for the project:

- Procurement Audit by GOI**:** NVBDCP/MOHFW will hire an independent agency for undertaking yearly post review of the contracts awarded by the program implementing agencies at all levels to cover a minimum of 10% of the contracts issued during the year. The TOR for this agency shall be shared with the World Bank for No Objection. The report submitted by the consultant would be part of the consolWorld Bank ted audit reports to be submitted to the World Bank.
- CAG Audit: The Comptroller and Auditor General (CAG) of India conduct the procurement audit (as part of the financial audit) of MOHFW. In case there is any procurement related observation made by CAG in its audit report, the same shall be shared with the World Bank along with the comments of MOHFW.

12.3.8 Procurement Staff

With most of the procurement to be handled by the procurement agent, the role of NVBDCP Directorate would be to directly handle low value procurement (below NCB threshold), coordinate with the procurement agent, monitoring the stock position and quality of supplies; development of specifications, supply chain management, quality management, procurement planning, implementation of risk mitigation plan and service procurement (as and when capacity is built up for this), monitoring the decentralized procurement (as and when allowed) etc. For playing this role effectively the directorate of NVBDCP has recruited one procurement consultant in 2007 under retroactive financing

and another procurement consultant (financed by GFATM) is also working for both the World Bank and GFATM funded projects. Another procurement consultant is likely to join NVBDCP Directorate by October 2008 in the proposed project. These consultants will also be required to be deputed to appropriate training program.

12.3.9 Disclosure

Invitation for Bids (IFB) for goods and equipment for all ICB contracts and advertisement for calling of Letters of Expression of Interest (EOI) for short listing of consultants for services costing more than $200,000 equivalent will be published in UNDB and dgMarket as well as procurement agent's website. Apart from this the World Bank's disclosure requirement as listed in Appendix 2.

12.3.10 Procurement Supervision

The frequency of supervision missions will be as per the existing guidelines and the Designated Procurement Specialist (DPS) will be part of the implementation supervision missions. It is estimated that the contracts worth approximately US$ 140 Million will be subject to prior review by the World Bank while the remaining (with cumulative value of US$ 34 Million) will be post reviewed. The prior review and post review arrangements are described below:

Prior Review

Thresholds for prior review by the Bank are:

Goods:	All contracts more than US$1.0 million equivalent
Services: (*other than consultancy*)	All contracts more than US$1.0 million equivalent
Consultancy Services:	> US$200,000 equivalent for firms; and > US$50,000 equivalent for individuals

In addition, all consultancy contracts to be issued on single-source basis exceeding US$ 50,000 in value to consultancy firms shall be subject to prior review by World Bank. In case of single source contract to individuals, the qualifications, experience, terms of reference and terms of employment shall be informed to World Bank for review.

The procurement plan will be updated keeping actual project implementation needs and institutional capacity.

12.3.11 Post Award Review by the World Bank

All contracts below the prior review threshold procured will be subject to periodic post review (in accordance with Paragraph 5 of Appendix 1 to the World Bank's Procurement Guidelines) on a sample basis. This also includes those contracts handled by the procurement agent (or the UN agency acting as

procurement agent) which are not prior reviewed by the World Bank. These reviews are meant to ensure that the agreed procurement procedures are being followed. The percentage of the contracts to be reviewed shall be based on the risk rating (20% based on the current "high" risk rating of the project but may change in future if risk rating is revised) and the sample shall be representative viz. various procurement methods and sizes of the contracts shall be proportionally included in the sample to the extent possible. The sample size may be increased or decreased based on the findings of the post reviews.

The ex-post review by the World Bank will be conducted either by World Bank staff or by consultant hired by the Bank. NVBDCP will implement a document management and record-keeping system to ensure that the data and documentation pertaining to all the contracts are kept systematically by the implementing agencies and shall be provided to the World Bank in a timely manner.

Appendix 1: Procurement Plan for the first 18 months of the Vector Borne Disease Project

A) Goods, Commodities, Equipment and Non-Consultancy Services (ICB and DC)

Package No.	Description	Method of Procure-ment	Quantity (Number)	Estimated Cost (Million USD)	Preparation of Specifications and Bid Document	No Objection of Bid documents by the World Bank	Publication of IFB in Newspapers and UNDB/ dgMarket and beginning of sale of bid document	Receipt and Opening of Bids	Submission of BER to Bank for No Objection	Receipt of No Objection of Bank for BER	Signing of the contract	Issue of contract award notice	100% delivery complete
1	Malaria Kits	ICB	4,838,000	2.658	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
2	Combi-Pack	ICB	868,000	2.713	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
3	Arteether Inj.	ICB	240,000	0.463	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
4	Synt. Pyre. Liq.	ICB	321,600 liters	1.673	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
5	Synt. Pyre. Wdp.	ICB	780 MT	3.000	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
6	RDK Kala Azar	DC	211,000	0.533	15-Aug-08	30-Aug-08	--	20-Sep-08	15-Oct-08	25-Oct-08	05-Nov-08	05-Nov-08	31-May-09
7	Capsule Miltefosine (50 mg)	DC	1,066,000	2.150	15-Aug-08	30-Aug-08	--	20-Sep-08	15-Oct-08	25-Oct-08	05-Nov-08	05-Nov-08	31-May-09
8	Capsule Miltefosine (10 mg)	ICB	120,000	0.135	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
9	LLINs	ICB	1,077,000	6.328	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
10	Artesunate Tab. (50 mg)	ICB	1,920,000	0.192	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09
11	Tab. Sulpha-pyremethamine	ICB	480,000	0.238	15-Aug-08	30-Aug-08	05-Sep-08	20-Oct-08	15-Nov-08	25-Nov-08	05-Dec-08	05-Dec-08	30-June-09

B) Consultancy Services (>US$200,000)

Pack-age No.	Description	Method of Selection	Estimated Cost (Million USD)	TOR, EOI SPN drafted	Bank's No Objection to TOR, EOI SPN	Publication of SPN in UNDB and Newspapers	No Objection of Bank for Shortlist and RFP document	Issue RFP to short listed consultants	Receipt of proposals and opening technical proposals	Evaluation of technical proposals and submission of report to the Bank	Bank's No Objection to technical evaluation report	Opening of financial proposals and financial evaluation	Bank's no objection to contract award recommendations	Contract Signed	Contract Completed
1	IEC/BCC Agency (1 contract)	QCBS	15.00	15-Aug-08	25-Aug-08	30-Aug-08	30-Sep-08	05-Oct-08	05-Nov-08	20-Dec-08	30-Dec-08	05-Jan-09	15-Jan-09	20-Jan-09	31-Mar-13
2	Procurement Agent (1 contract)	QCBS	6.00	15-Aug-08	25-Aug-08	30-Aug-08	30-Sep-08	05-Oct-08	05-Nov-08	20-Dec-08	30-Dec-08	05-Jan-09	15-Jan-09	20-Jan-09	31-Mar-13
3	Supply Chain and Logistics Agency (1 contract)	QCBS	3.00	15-Aug-08	25-Aug-08	30-Aug-08	30-Sep-08	05-Oct-08	05-Nov-08	20-Dec-08	30-Dec-08	05-Jan-09	15-Jan-09	20-Jan-09	31-Mar-13
4	Software Implementation (extension of existing contract)	SSS	0.70	--	--	--	--	--	--	--	--	--	15-Aug-08	20-Aug-08	31-Mar-10
5	Implementation and assessment of pilots (1 contract)	QCBS	2.50	15-Aug-08	25-Aug-08	30-Aug-08	30-Sep-08	05-Oct-08	05-Nov-08	20-Dec-08	30-Dec-08	05-Jan-09	15-Jan-09	20-Jan-09	31-Mar-13
6	NGOs for service delivery, consultation, social marketing, capacity building of smaller NGOs, monitoring and social mobilization (multiple contracts)	SSS	22.00	15-Aug-08	25-Aug-08	30-Aug-08	30-Sep-08	05-Oct-08	05-Nov-08	20-Dec-08	--	--	15-Jan-09	20-Jan-09	31-Mar-13

Appendix 2: Procurement disclosure Requirements as per World Bank's Guidelines

1. Contract Awards for ICB and LIB: Within two weeks of receiving the Bank's No Objection to the recommendation of contract award, the Borrower shall publish in UNDB on-line and in dgMarket the results identifying the bid and lot numbers and the following information:

(a) name of each bidder who submitted a bid;
(b) bid prices as read out at bid opening;
(c) name and evaluated prices of each bid that was evaluated;
(d) name of bidders whose bids were rejected and the reasons for their rejection; and
(e) name of the winning bidder, and the price it offered, as well as the duration and summary scope of the contract awarded.

In the publication of Contract Award referred above, the Borrower shall specify that any bidder who wishes to ascertain the grounds on which its bid was not selected, should request an explanation from the Borrower. The Borrower shall promptly provide an explanation of why such bid was not selected, either in writing and / or in a debriefing meeting, at the option of the Borrower. The requesting bidder shall bear all the costs of attending such a debriefing.

If after publication of the results of evaluation, the Borrower receives protest or complaints from bidders, a copy of the complaint and a copy of the Borrower's response shall be sent to the Bank for information. If as result of analysis of a protest the borrower changes its contract award recommendation, the reasons for such decision and a revised evaluation report shall be submitted to the Bank for no objection. The Borrower shall provide a republication of the contract award.

2. Contract awards for National Competitive Bidding: Publication of results of evaluation and of the award of contract consisting of the same information as mentioned above for ICB and LIB.

3. Contract Awards for Direct Contracting: After the contract signature, the Borrower shall publish in UNDB on-line and in dgMarket the:

(a) name of the contractor
(b) price
(c) duration, and
(d) summary scope of the contract.

This publication may be done quarterly and in the format of a summarized table covering the previous period.

4. Contract Awards for Consultancies: After the award of contract, the borrower shall publish in UNDB on-line and in dgMarket the following information:

(a) the names of all consultants who submitted proposals;
(b) the technical points assigned to each consultant;
(c) the evaluated prices of each consultant;
(d) the final point ranking of the consultants;
(e) the name of the winning consultant and the price, duration, and summary scope of the contract.

The same information shall be sent to all consultants who have submitted proposals.

5. Contract Awards for Selection Based on the Consultants' Qualifications (CQS) and Single Source Selection (SSS): The Borrower shall publish in UNDB on-line and in dgMarket the

(a) name of the consultant to which the contract was awarded,
(b) the price
(c) duration, and
(d) scope of the contract.

This publication will be done quarterly and in the format of a summarized table covering the previous period.

Chapter 13

Governance and Accountability Action Plan (GAAP)

Introduction

MOHFW is fully committed to improve the governance and accountability in all centrally sponsored programs including the NVBDCP by ensuring efficient program design and management, sound financial management and better competition and transparency in procurement and supply of health sector goods and services required to deliver high quality services.

13.1 Scope and Purpose

MOHFW has developed this Governance and Accountability Action Plan (GAAP), in consultation with World Bank to address critical operational concerns related to program management, financial management and procurement in NVBDCP. The key issues and actions to address these concerns are included in the matrix below.

The GAAP applies to NVBDCP supported by World Bank articulating the specific roles and responsibilities of different stakeholders (public, private and civil society institutions).

The GAAP will be a dynamic document and will be strengthened, as necessary, based on lessons learned during the implementation of NVBDCP

Directorate of the NVBDCP will be responsible for implementing program specific actions listed in the attached Matrix and will also act as a nodal point to co-ordinate with the states and other agencies for effective implementation of the GAAP. Project States will be responsible for implementing the relevant actions by district and sub-district level implementing entities.

This GAAP for NVBDCP incorporates a number of agreements previously reached with the GoI as part of the Joint Action Plans of March 2008 developed in response to the Detailed Implementation Review (DIR) of health sector projects in India.

Various institutional mechanisms - NVBDCP technical teams with state focal points (for technical guWorld Bank nce, program management and implementation oversight), Financial Management Group (for financial management), NVBDCP Procurement Unit (for procurement of services,

monitoring of procurement undertaken by procurement agent and supply chain management) and the Empowered Procurement Wing of MOH (for establishment and updating of broader procurement policies and standards for the sector including procurement capacity building of states) - have been established for this purpose.

Approximately 85% of the value of the NVBDCP will be reimbursements by World Bank for expenditures, most of which are for procurement which will be carried out based on agreements in the Joint Action Plans to address risks of fraud and corruption and poor quality in pharmaceuticals, medical supplies, and other health sector goods and services. Many of these agreements are already implemented. The MOHFW is carrying out all ICB through an internationally qualified procurement agent and has put in place a number of quality assurance and disclosure mechanisms as detailed below.

Table 1 summarizes GAAP provisions for NVBDCP which reflect agreements already reached, being implemented, or planned for implementation. Almost all expenditures planned under components 1 and 2 will be covered by these arrangements.

13.2 Monitoring of GAAP

GAAP will be monitored as part of the implementation Support Missions.
NVBDCP will submit six monthly updates on GAAP to World Bank.

Table 1: Governance and Accountability Action Plan (GAAP) Matrix

Topic	Type of risk	Mitigating Action	Agency	Timeline
Procurement	Poor market response, procurement delays and higher costs.	Finalizing future lot size, estimated prices and qualification criteria for procurement of commodities, pharmaceuticals and medical supplies based on market surveys (either through collection of primary or secondary data) about availability of products, prices and production capacities of manufactures.	MOHFW/ NVBDCP	Continuous

Topic	Type of risk	Mitigating Action	Agency	Timeline
		Ensuring no splitting of the requirement into smaller packages to avoid prior review or use of more competitive procurement procedures.	MOHFW/ NVBDCP	Continuous
		Use generic and broad technical specifications, build a database of technical specifications, and use clear and concise bid evaluation criteria.	MOHFW/ NVBDCP	Continuous
	Submission of forged documents to win contracts	Seeking "list of references" in the form of an affWorld Bank vit in case of supplies made to public sector in past contracts. In the case of supplies made to the private sector in the past, affWorld Bank vit as well as supporting evidence will be sought.	MOHFW/ NVBDCP	Continuous
	Collusion among bidders and between bidders and purchasers	Including a qualification requirement of a minimum share of at least 20% revenue to be derived from non-Bank financed contracts in bid documents.	MOHFW/ NVBDCP	Continuous
		Including "independent experts" in the bid evaluation process (also applicable for procurement not handled by procurement agent).	MOHFW/ NVBDCP	Continuous
		Establishing a procurement monitoring database/MIS to monitor the procurement. This database could be online with restricted access.	MOHFW/ NVBDCP	By October 1, 2008

Topic	Type of risk	Mitigating Action	Agency	Timeline
		Sharing record of public opening of bids for all contracts with the Bank within two working days.	MOHFW/ NVBDCP	Continuous
		Develop and deploy software for early identification of indicators of fraudulent and corrupt practices.	MOHFW/ NVBDCP	By October 1, 2008
		Moving to e-procurement.	MOHFW/ NVBDCP	By December 2009
	Delay in bid evaluation, Inadequate/improper bid evaluation	Use of procurement agent for handling ICB and NCB contracts above US$100,000.	MOHFW/ NVBDCP	Continuous
		Include technical experts in the bid evaluation process	MOHFW/ NVBDCP	Continuous
		Include listing and discussion of all complaints received and actions taken in the bid evaluation report.	MOHFW/ NVBDCP	Continuous
Project Execution and Contract Management	Poor quality of commodities	WHO GMP (TRS 863) certification mandatory for ICB	MOHFW/ NVBDCP	Continuous
		Ensure 100% validation of existing WHO GMP certificates of all successful bidders recommended for award of the contract.	MOHFW/ NVBDCP	Continuous
		Agree on specific actions for GMP certification and implementation arrangements satisfactory for the Association for non-ICB procurement of pharmaceuticals and	MOHFW/ NVBDCP	Before non-ICB procurement is agreed

Topic	Type of risk	Mitigating Action	Agency	Timeline
		medical supplies under the project.		
		Ensure Pre-dispatch, post-dispatch and field level inspection for the commodities procured under the project.	MOHFW/ NVBDCP	Continuous
		Disclose available information on deregistered pharmaceutical companies on NVBDCP/MOHFW website and initiating a process for systematically collecting the data on deregistration from other agencies for future updates.	MOHFW/ NVBDCP	By October 1, 2008
	Delays in release of payment	Ensuring payment within 30 working days of receiving the bill with supporting documents from the suppliers or communicating deficiency in the bill within 15 working days.	MOHFW/ NVBDCP	Continuous
	Sub-optimal use of commodities provided under the project	Improving the procurement documentation including recording of receipt and distribution of goods.	MOHFW/ NVBDCP	Continuous
		Conducting periodic quality and quantity review for drugs, pharmaceuticals and medical supplies.	MOHFW/ NVBDCP	First survey by October 1, 2008
Transparency and disclosure in procurement and program implementation	Inadequate disclosure of project information and citizen oversight	Making publicly available all annual procurement schedules for ICB and NCB promptly after finalization on the NVBDCP website.	MOHFW/ NVBDCP	Continuous

Topic	Type of risk	Mitigating Action	Agency	Timeline
		Posting all bidding documents and Notice for inviting Expressions of Interest for all procurements above US$100,000 on the NVBDCP website.	MOHFW/ NVBDCP	Continuous
		Making available to any member of the public promptly upon request all shortlist of consultants and in case of pre-qualification, list of pre-qualified contractors and suppliers.	MOHFW/ NVBDCP	Continuous
		Disclosing information on prequalification, all bids received reasons for rejections, and award of contracts on the NVBDCP website.	MOHFW/ NVBDCP	Continuous
		Posting annual progress (program and financial information), audit reports and Mid Term Review reports of the program on the NVBDCP website.	MOHFW/ NVBDCP	Continuous
	Weak mechanisms for client feedback and program accountability especially for tribal and vulnerable groups.	Contracting at national level with NGO's to develop appropriate methods and processes for clients feedback and accountability community, block and district level with pilots and scale-up plan before early review.	MOHFW/ NVBDCP	Contract in place by December 1, 2008 for 18 months.
Monitoring and Evaluation	Weak Complaints handling mechanism	With support from technical assistance agencies as needed, develop and announce on project website which has robust and transparent procedures	MOHFW/ NVBDCP	By October 2008

Topic	Type of risk	Mitigating Action	Agency	Timeline
		receiving any complaint/feedback availability and quality of essential supplies under the project from village level functionaries and end beneficiaries.		
		Reviewing the current protocols for complaints handling and record keeping in NVBDCP and finalize action plan for further improvement, if needed.	MOHFW /NVBDCP	By December 2008
		Updating the complaint database on a monthly basis.	MOHFW /NVBDCP	Continuous
		Reporting the status of investigation of complaints and measures taken in quarterly progress reports to MOHFW	MOHFW /NVBDCP	Continuous

13.3 New Areas Specific to NVBDCP GAAP

In addition to risk previously identified and being addressed as part of the World Bank -GoI Joint Action Plans, there are several new areas specific to NVBDCP where agreements have been reached to strengthen governance and accountability. These are: decentralized project inputs to be financed by World Bank, some additional issues related to procurement and quality of goods and supplies, and strengthened monitoring and evaluation processes.

Regarding decentralized expenditures, World Bank has agreed to finance state level and below state level contractual staff, their mobility, and training costs. As detailed in Chapter 11, these will be financed based on normative unit costs for these inputs at state and district level. World Bank disbursements will not be based on detailed audited accounts from sub-national units, as it has been found that it is not feasible to maintain separate records for World Bank funding and get them audited. For these expenditures, some risk of improper

use, fraud, corruption may still remain. To mitigate this risk, World Bank and GoI have agreed on an intensified effort of field level input and output monitoring for a sample of project districts on a semi-annual basis, coupled with a review of project implementation after 18-21 months and possible redesign of the local activities. These arrangements apply largely to component 3 of the project where such expenditures account for a little more than 50% of the proposed project costs. States will sign MOU's with the NVBDCP to receive project support. These indicate that states accept the project terms and conditions including those of this GAAP.

NVBDCP may pose some additional specific risks in relation to procurement of pharmaceuticals and goods, such as insecticides and LLINs. Additional measures in the context of the agreed Joint Action Plans will be put in place to address these specific risks. Some additional mitigation measures are also agreed in relation to strengthening M&E (Chapter 9).

Table 2 below places these new actions for GAAP.

Table 2: Governance and Accountability Action Plan (GAAP) Matrix

Topic	Type of risk	Mitigating Action	Agency	Timeline
Financial management processes for national programs are weak. Financial Management System and internal controls inadequate to mitigate	Late and incomplete financial reports Inadequate financial management which cannot be used to monitor implementation progress.	New Financial Management unit created under NRHM. New Financial management manual being completed and rolled out. World Bank Bank will only reimburse contractual staff, mobility, and training costs at state and district level. Reimbursement will be based on normative cost estimates for state and districts as units of	MOHFW/ NVBDCP NVBDCP for HMIS and contracting with external review agency and survey agencies.	New manual ready by Oct. 1, 2008. Additional reviews will be done covering 6 of the first 18 districts (year 1)16 of the 80 districts in phase 2

Topic	Type of risk	Mitigating Action	Agency	Timeline
fiduciary risks of decentralized expenditures fiduciary risks of decentralized expenditures	Lack of compliance with established financial and internal controls leading to risks of misappropriation of funds.	implementation. Additional dedicated review of availability of these inputs and project outputs at state level and significant sample of project districts using multiple measures, including HMIS data,		(year 2) Bank/GoI will consider possible redesign based on performance after year 2 16 of 139 districts in phase 3 (years3-5)
	Varied quality of audit reports received from external auditors.	external review organization, survey data using Lot Quality Assurance Sampling. If, based on these reviews and project's early review at 18-21 months, results are not satisfactory, redesign of local component to satisfaction of the Bank is necessary or state and district cost disbursements can be terminated.		
Procurement	Time taking registration process for insecticides	Establishing an effective coordination mechanism with the Central Insecticides Board to accelerate registration process for insecticides and LLINs in India approved by WHOPES.	MOHFW/ NVBDCP	By January 1, 2009
		Issue advance General Procurement Notice asking prospective bidders to get their products registered in India	MOHFW/ NVBDCP	Completed
	Bidders trying to win contracts by submitting	Seek investigation and prosecution for bidders submitting forged	MOHFW/ NVBDCP	Continuous

Topic	Type of risk	Mitigating Action	Agency	Timeline
	forged documents	documents and/or for any other legal offence.		
	Delay in bid evaluation, Inadequate/ improper bid evaluation	Complete the bid evaluation strictly within the initial validity of bids	MOHFW/ NVBDCP	Continuous
		Reduce time and steps required for internal procurement and financial clearance mechanism in MOHFW	MOHFW/ NVBDCP	By October 1, 2008
Topic	Type of risk	Mitigating Action	Agency	Timeline
	Weak service procurement processes due to inadequate capacity	Use of an appropriate agency (acceptable to WB) for supporting the procurement of services	MOHFW/ NVBDCP	Continuous
Project Execution and Contract Management	Poor quality of commodities.	Prepare a protocol for ensuring the quality of medical kits and consumables, which are not governed by WHO GMP	MOHFW/ NVBDCP	By October 1, 2008
	Inadequate supply chain and storage arrangements.	Strengthen the capacity at NVBDCP directorate and states for monitoring the procurement agent, inventory and supply management	MOHFW/ NVBDCP	By December 1, 2008
		Assess the adequacy of storage/warehouses and initiate actions to strengthen them under the National Rural Health Mission (NRHM).	MOHFW/ NVBDCP	Assessment by March 31, 2009, strengthening based on assessment needs.

Topic	Type of risk	Mitigating Action	Agency	Timeline
Monitoring and Evaluation	Weak Complaints handling mechanism.	Notifying one senior official at district, state and NVBDCP/MOHFW levels for receiving any complaint/feedback availability and quality of essential supplies under the project from village level functionaries and end beneficiaries.	MOHFW/ NVBDCP	By October 2008
	Loss of opportunity to apply mid course correction /efficiency gains.	Designating state focal points for all project states from NVBDCP officers with clear terms of reference to provide technical support and implementation oversight.	MOHFW/ NVBDCP	Continuous
		Ensuring bi-annual program reviews satisfactory to the association.	MOHFW/ NVBDCP	Continuous
	Reliance on routine projects monitoring data	Use of more data sources such as regular HH surveys and LQAS.	MOHFW/ NVBDCP	Continuous (baseline survey to be completed within six months of effectiveness).

Chapter 14

Economic and Financial Analysis

14.1 Economic Analysis

The project seeks to reduce malaria burden in selected, highly endemic areas as well as eliminate kala-azar. This project supports certain very important interventions such as the introduction of a new diagnosis and treatment protocol, strengthening service delivery mechanisms which are necessary for the effective implementation of the new protocol, a different strategy for effective surveillance, strong emphasis on the availability and use of long lasting insecticidal nets for vector control and so forth. The known interventions in both these diseases are highly cost-effective.

Available evidence suggests that all malaria interventions are highly attractive (cost-effective) using a cutoff of US$150 per DALY averted.18 There are two broad types of interventions in Malaria control: case management and prevention. On the prevention side, the review of worldwide trials of ITNs and IRS by Curtis and Mnzava's suggests that ITNs and IRS have equivalent effectiveness. Similar conclusion is reached also by Lengeler and Sharp (2003) who notes that choosing between IRS and ITNs is "largely a matter of operational feasibility and availability of local resources than one of malaria epidemiology or cost-effectiveness." Given cost-effectiveness of both the strategies, choice between ITNs and IRS then essentially reduces to operational and logistical challenges in a given context.

A number of studies from Sub-Sahara Africa, particularly, in the Gambia, Ghana, and Kenya have shown the provision and insecticide treatment of bed nets to be highly cost-effective under varying conditions.19 A study by Goodman et al. (2001) compared the cost and cost-effectiveness of insecticide-treated bednets and IRS KwaZulu-Natal in South Africa. The study concludes, "In view of the greater effectiveness of ITBN, policy makers may view ITBN as a cost-effective use of resources, even if the economic costs are higher."20

[18] Breman, J.G. et al, Conquering malaria, Chapter 21 in Disease Control Priorities in Developing Countries 2006, pages 413-432.
[19] Goodman CA., and Mills AJ, (1999), The evidence base on the cost-effectiveness of malaria control measures in Africa, Health Policy and Planning, Review Article, **14**(4): 301–312.
[20] Goodman CA., et al. (2001), Comparison of the cost and cost-effectiveness of insecticide-treated bednets and residual house-spraying in KwaZulu-Natal, South Africa Tropical Medicine and International Health, Volume 6, No. 4, pp 280-295 April 2001.

Similar conclusions are reached by a recent publication21 in which the authors study five insecticide-treated net programs (Eritrea, Malawi, Tanzania, Togo, Senegal) and two indoor residual spraying programs (Kwa-Zulu-Natal, Mozambique). The study concludes, "In any case, all these vector control programs are excellent public health investments and more such investments should be made as soon as possible. This is a time of unprecedented opportunities for malaria control, with expanding global interest and resources, and also increased commitment by endemic country governments. It is time to substantially bring down the unacceptable burden of disease due to malaria."

On the case management side, the project supports a shift from the current presumptive treatment with chloroquine to treating all confirmed P falciparum malaria cases with ACT. A review of international evidence suggests that a switch from chloroquine to ACT is highly cost-effective at all initial levels of chloroquine resistance above 37 percent. However, this analysis does not take into account non-health related benefits, especially evidence of income gains or prevention of income losses. Nor does it takes into account the costs of health systems strengthening required to make effective use of ACT. Inclusion of non-health related benefits only increase the attractiveness of switching to ACT. The health systems strengthening costs, on the other hand, may be significant but given the current Indian context in which public health services are being strengthened under NRHM, the system strengthening costs should be relatively low.

On the second disease covered in the project, kala azar affecting the poorest segments of rural populations in southern Asia, eastern Africa, and Brazil (Yamey and Torreele 2002).22 In India, kala azar is confined mainly to 52 districts across 4 states of India. In 2006, around 39,000 kala azar cases were reported in the country. However, the joint monitoring mission, carried out by several national and international agencies in 2 of the 9 most endemic districts in 2007, found about 10 fold underreporting of kala azar!

About 60-70% of kala azar cases access private sector for the diagnosis and treatment. In addition to wage loss for a significant period, the high cost of diagnosis and treatment tend to impoverish families. JMM team reported that a household spends anywhere between INR 7000 and 10,000 for the diagnosis and treatment of kala azar. Similar findings have been reported in other studies as well. For example, a study examining the epidemiologic, social, and economic impact of KA in a village in Bangladesh found the high cost of

[21] Yukich, J. et al. (2007), "Operations, costs and cost-effectiveness of five insecticide-treated net programs (Eritrea, Malawi, Tanzania, Togo, Senegal) and two indoor residual spraying programs (Kwa-Zulu-Natal, Mozambique)," Swiss Tropical Institute, Basel, Switzerland.
[22] Yamey G, Torreele E., (2002). The world's most neglected diseases. BMJ 325: 176-177.

diagnosis and treatment, causing substantial emotional and economic hardship for affected families (Ahluwalia et al 2003).23

With effective case management it is possible to eliminate kala azar, and case management is more cost-effective than vector control. Recent studies24 show kala azar treatment to be extremely cost-effective as it costs US$315 per death averted and US$9 per DALY gained.25

To gain a perspective on cost-effectiveness of malaria and kala azar interventions we present cost-effectiveness of a few comparators. Improved case management and immunization (currently undergoing clinical trials) for dengue costs US$ 587 to US$ 1440 per DALY averted. Similarly, among interventions against diarrheal disease during the first year of life, oral dehydration therapy costs US$ 132 to US$ 2570 per DALY averted and cholera immunizations costs US$ 1658 to US$ 8274 per DALY averted. Malaria and kala azar interventions, in comparison, are highly cost effective.

A small exercise on cost-effectiveness of introducing ACT using Indian data suggests that under the proposed policy, the unit cost of both diagnosis and treatment will be over ten-fold higher than that of current policy (Rs.7.5 vs. Rs. 77.8). Even though the new protocol may appear to be expensive, the real benefits accrue in terms of reduced transmission and reduced mortality. The steep reduction in hospitalizations and mortality as well as the reduction in transmission (as seen in other parts of the world) will more than compensate for the initial increase in costs. With the estimated reduction in transmission, after five years of implementation, the cost of the new policy will only be around 68% more than the current policy (Rs. 1073 million vs. Rs. 1633 million in the 100 districts), but will avert around 66,000 estimated hospitalizations and about 13,200 deaths (see the analysis below).

Cost benefit analysis of switching from the current to the new protocol for the diagnosis and treatment of malaria

MOHFW/NVBDCP has implemented Artemisinin derivative Combination Therapy (ACT), in all the World Bank's 50 project districts and districts under GFATM. ACTs have high efficacy but are also much more expensive - up to 10-20 fold. Still, the cost of adopting ACT needs to be assessed and compared with the cost of current protocol being followed in India. Studies have linked the

[23] Ahluwalia I B et al. (2003). Visceral leishmaniasis: consequences of a neglected disease in a Bangladeshi community. Am. J. Trop. Med. Hyg., 69(6), pp. 624-628.
[24] For example, Laxminarayan, R., et al, Intervention Cost-effectiveness: Overview of Main Messages, Chapter 2 in Disease Control Priorities in Developing Countries 2006, pages 35-86.
[25] One DALY (Disability-Adjusted Life Year) represents a lost year of healthy life due to poor health or disability and potential years of life lost due to premature death.

cost of switching from Chloroquine (CQ) to ACT with the level of drug resistance reached. For example, it has been estimated that switching from chloroquine to ACT becomes cost-effective as Chloroquine (CQ) resistance reaches around 37%. Similarly, switching from Sulfadoxine Pyrimethamine (SP) to ACT becomes cost-effective as SP resistance reaches 12 percent. This low threshold for SP is due to the high growth rate of resistance to SP when it is used as a first line therapy.26

The current diagnostic and treatment protocol involves (i) active surveillance with collection of blood smears for all cases with history of fever (both current and those in the past 15 days) (ii) presumptive treatment for all cases with history of fever (iii) microscopy of all blood smears collected, and (iv) use of CQ and PQ/ ACT for confirmed Pf cases.

In Table 1, 2 and 3 below, estimate the cost of current protocol, the cost of new protocol, and incremental costs and benefits of phased transition to new protocol in 93 malarious districts from 2008 to 2012 respectively.

[26] Disease control priorities in Developing Countries, 2nd edition, edited by Dean T. Jamison et al., Disease control priorities project (2006), Conquering Malaria, Chapter 21, pp 413-431.

Table 1: Estimated Costs of Current Protocol in 100 Endemic Districts, 2008 to 2012											
					Units	2008	2009	2010	2011	2012	Total 2008 to 2012
(i) Number of new fever cases in 100 districts					Mil. cases	26.60	26.42	28.45	29.24	30.20	140.92
[is the same as no. of blood slides collected (BSC);											
this data pertains to actual BSC from 2001 to 2005]											
(ii) Number of new fever cases residing in areas where											
reported chloroquine resistance is above 25%					Mil. cases	0.05	0.05	0.05	0.05	0.05	0.25
[assumed to be 50,000 cases in the 100 districts]											
(iii) Number of new fever cases residing in areas where											
reported chloroquine resistance is below 25%					Mil. cases	26.55	26.37	28.40	29.19	30.15	140.67
(iv) Cost of treatment for cases in (ii)					Mil. Rs.	3.2	3.2	3.2	3.2	3.2	16.22
(suspected Pf malaria cases; treated with ACT as											
first-line treatment; cost is Rs. 64.86 per case treated)											
(v) Cost of treatment for cases in (iii)					Mil. Rs.	66.4	65.9	71.0	73.0	75.4	351.67
(these cases are given presumptive treatment for											
malaria, at Rs. 2.5 per case)											
(vi) Total treatment cost					Mil. Rs.	69.6	69.2	74.2	76.2	78.6	367.88
[= (iv) + (v)]											
(vii) Number of slides taken and tested by microscopy											
(10% of all fever cases; for surveillance purposes)					Mil. slides	26.60	2.64	2.85	2.92	3.02	38.04
(viii) Cost of taking and testing slides					Mil. Rs.	133.02	132.12	142.26	146.19	150.99	704.59
(Rupees 5 per slide)											
(ix) Total cost of treatment and testing					Mil. Rs.	202.7	201.3	216.5	222.4	229.6	1072.47
[= (vi) + (viii)]											

Table 2: Estimated Costs of New Protocol in 100 Endemic Districts, 2008 to 2012								
(i) Number of new fever cases in 100 districts [50% of BSC]	Mil. cases	13.30	13.21	14.23	14.62	15.10		
(ii) Phased area coverage of new protocol (50% in the first 2 years and full 100% in 3rd, 4th & 5th year)	% of area	0.5	0.5	1.0	1.0	1.0		
(iii) Total cost of treatment and testing in areas not yet under new protocol	Mil. Rs.	101.3	100.6	0.0	0.0	0.0		
(iv) Number of new fever cases in areas under new protocol [the number of new fever cases declines by 30% and 50% (over the level of the third year) in the fourth and fifth year respectively]	Mil. cases	6.65	6.61	14.23	10.23	7.55		
(v) Total cost of testing in areas under new protocol [Assumptions: (a) all new fever cases are tested by either laboratory or via RDKs; (b) 40% are tested through laboratory and 60% through RDKs; [c] costs per case are Rs. 5 and Rs. 18 respectively]	Mil. Rs.	85.1	84.6	182.1	131.0	96.6		
(vi) Number of confirmed Pf cases in areas under new protocol [Assumed to be one-third of all new fever cases in these areas]	Mil. cases	2.2	2.2	4.7	3.4	2.5		
(vii) Cost of treating all confirmed Pf cases with ACT (at Rs. 64.86 per case)	Mil. Rs.	143.8	142.8	307.6	221.3	163.2		
(viii) Number of confirmed P Vivax cases in areas under new protocol [Assumed to be two-thirds of all new fever cases in these areas]		4.4	4.4	9.5	6.8	5.0		
(ix) Cost of treating all confirmed P Vivax cases (with chloroquine, at Rs. 2.5 per case)	Mil. Rs.	11.1	11.0	23.7	17.0	12.6		
(x) Total cost of treatment and testing in areas under new protocol [= (v) + (vii) + (ix)]	Mil. Rs.	240.0	238.4	513.3	369.3	272.4		

Table 3: Estimated Incremental Costs and Benefits of Phased Transition to New Protocol, 2008 to 2012											
(i) Estimated incremental costs of phased transition					Mil. Rs.	37.4	37.1	296.8	146.9	42.8	561.0
(ii) Number of severe cases averted					Cases	5,500	11000	16500	19250	13750	66,000
(iii) Number of deaths averted					Deaths	1100	2200	3300	3850	2750	13,200
(iv) Economic benefits from averted severe cases					Mil. Rs.	16.5	33.0	49.5	57.8	41.3	198.0
(Assuming that about Rs. 3,000 is spent on treating a severe case of malaria)											
(v) Economic benefits from averted deaths					Mil. Rs.	396.0	792.0	1188.0	1386.0	990.0	4,752.0
(Assuming each averted death results in 15 years of additional life, valued at Rs. 24,000 per year)											
(vi) Total incremental economic benefits [= (iv) + (v)]					Mil. Rs.	412.5	825.0	1237.5	1443.8	1031.3	4,950.0
(vii) Net Incremental Economic Benefits [= (vi) - (i)]					Mil. Rs.	375.1	787.9	940.7	1296.9	988.4	4,389.0

14.2 Financial Analysis

Expenditure on NVBDCP has increased at the rate of 51% over 8-year (period 1997-98 to 2004-05), but in the last three years alone (2005-08) the expenditure has gone up by 77%. Looking at the past years data on budget allocations and utilization it is clear that both Domestic Budgetary Support (DBS) and Externally Aided Component (EAC) are important funding sources for the program.27 Cumulatively 51% of total budget allocations came from DBS whereas EAC contributed 49% between 1997-98 and 2007-08. On the utilization side, 61% of expenditure was done under DBS and only 39% was under EAC. Looking at the gap between total budget allocations and actual utilization of funds, it turns out that allocations have been higher than the actual expenditure for all the years (refer the table below). The cumulative shortfall in utilization has been around 20%. This shortfall is only 3.3% in case of Domestic Budgetary Support (DBS) while as high as 36.8% for the Externally Aided Component (EAC). The reason for such high shortfall in utilization of EAC allocations has been due to the inability to complete the planned procurement of commodities on account of certain procurement-related issues. As for DBS, in certain years, the expenditure has in fact been higher than the allocations (refer the table 3 below), implying that MOH can enhance resources on its own account even beyond the budgeted amounts if the program so demands.

[27] The Bank support has been the most important support under Externally Aided Component. In the last 2-3 years, GFATM has also been funding on control of malaria in India.

Table: 3 Budget Allocations to and Actual Expenditure under NVBDCP (INR in million)							
Years	Budget Allocations			Actual Expenditure			Diff. between Allocation & Expenditures
	DBS	EAC	Total	DBS	EAC	Total	
97-98	1500	500	2000	1380	40	1430	570
98-99	1470	1500	2970	1290	350	1640	1330
99-00	1300	1200	2500	1160	610	1770	730
00-01	1550	1000	2550	1110	790	1900	650
01-02	1250	1000	2250	1380	810	2190	60
02-03	1090	1260	2350	1080	980	2070	280
03-04	1350	1100	2450	1430	580	2010	440
04-05	1460	1230	2690	1500	670	2170	520
05-06	1940	1540	3490	1550	1060	2610	880
06-07*	1380	2340	3720	1670	1520	3190	530
07-08*	1420	2570	3990	1644	2209	3854	136
Total	15710	15240	30960	15194	9619	24834	6126
08-09	3219	1504	4723	N/A	N/A	N/A	N/A

Source: Budgets of Directorate of Vector Borne Disease Control Program.
DBS = Domestic Budget Support, EAC = for Externally Aided Component.
* Expenditure figures are provisional.

Chapter 15

Safeguard Policy Issues
Vulnerable Communities' Plan

15.1 Legal and Institutional Framework

The term 'vulnerable community' describes groups with social, cultural, economic and/or political traditions and institutions distinct from the mainstream or dominant society that disadvantage them in the development process. 'Indigenous people' (known as 'Scheduled Tribes' (ST) or 'tribal groups' in India are recognized as vulnerable communities, and so too are the 'Scheduled Castes' (SCs) and economically poor ('Below Poverty Line' or BPL), including those among minority religions. 'Scheduled Castes ' are those who remain outside the four Hindu castes, and include some professing Buddhism or Sikhism who continue to be socio-economically deprived. Around 8% of India's total population is ST and 17% is SC; about 27% of the total population is BPL. The Indian Constitution (Article 342) recognizes several communities as STs and SCs and confers a special status on them to make up for their disadvantages. A number of provisions in the Constitution aim to abolish all forms of discrimination against them, and many public programs target SC/STs and/or BPL people. The majority of STs and SCs continue to be vulnerable as reflected by their socio-economic characteristics, (e.g., low literacy, prevalence of poverty - 46% of rural STs are BPL and 35% of urban STs).

The Indian Government designates areas where more than 50% of the population is tribal as 'Scheduled Areas' or 'Tribal Sub-Plan' (TSP) areas. In these areas, the interests of STs are especially protected and various tribal development programs targeted to them. Many districts or parts of districts in the states in this Project, notably Andhra Pradesh (A.P.), Chhattisgarh, Gujarat, Jharkhand, Madhya Pradesh (M.P.), Maharashtra and Orissa, are Scheduled Areas (Table 1) and others are TSP areas.

There are no specific laws mandating provision of health care to STs and SCs. However, they are a key focus of the National Health Policy as it is recognized that improving their health is critical to achieving national health goals. As tribal habitations are concentrated in remote, forest or hilly areas the Government has enhanced the facility: population norms for health care infrastructure: one health Sub-centre staffed by an Auxiliary Nurse Midwife (ANM) is to be provided for every 3,000 people in tribal areas (instead of 5,000 people), a Primary Health Center (PHC) with two doctors for 20,000 (instead of 30,000) and a Community Health Center (CHC) with four medical specialists for

80,000 (instead of 100,000). The National Rural Health Mission (NRHM) launched in 2005 seeks to improve access to health care by strengthening the public health system notably with a village-based worker known as the ASHA, greater engagement of the private sector, and increased and flexible finances. It also seeks to enhance community demand for and ownership of services, and coordinated planning and implementation across related sectors such as Women and Child Development and Tribal Affairs. Currently all sectors are mandated to allocate and spend 'population percentage proportionate' funds on ST and SC programs.

15.2 Baseline Information

Information on the major tribes inhabiting the project states and salient demographic and developmental indicator levels are presented in Table 1. There is great diversity in their ethnic and cultural identities, and the environmental and geographical conditions in which they live. Their unique myth and belief systems, family and kinship structures, food and dress habits, housing conditions, political organization and economic pursuits and status influence their concepts of health and sickness, health-seeking behavior, and the pace and magnitude of their acceptance of 'outside' interventions.

In many tribal areas, traditional panchayats and Tribal Councils deal effectively with tribal issues. In addition to these traditional leadership systems, special legislation, the Panchayat Extension to Scheduled Areas Act, has introduced the 'modern' system of panchayats to scheduled areas. The NRHM has enhanced the ability of local panchayats to address local needs and priorities to improve health by providing untied funds to Village Health and Sanitation Committees (VHSCs). Additional funds are provided to the ANM and local panchayats have been mandated to ensure optimal resource utilization.

Table 1. Number of Project Districts, Scheduled areas within Project, Important Tribes, ST Population and Development Indicators *

State/Union Territory	Number of Project Districts (a)	Number of Scheduled Areas (b)	Number of Important Tribes in Project Districts	ST Percent of Total Pop.	Development Indicators		
					Sex Ratio	IMR	Literacy Rate
Andhra Pradesh	M: 5	M: 4	10	60.0	972	104	37.0
Chhattisgarh	M: 16	M: 10	15	31.8	1013		52.1

State/Union Territory	Number of Project Districts (a)	Number of Scheduled Areas (b)	Number of Important Tribes in Project Districts	ST Percent of Total Pop.	Development Indicators		
					Sex Ratio	IMR	Literacy Rate
Gujarat	M: 12	M: 7	12	14.8	974	60	47.7
Jharkhand	M: 10, KA: 6, M + KA: 5	M: 7, KA: 1, M + KA: 5	10	26.3	987		27.5
Karnataka	M: 7	None	12			85	
Madhya Pradesh	M: 19	M: 11	17	20.3	975	101	41.2
Maharashtra	M: 5	M: 2	16	8.9	973	74	55.2
Orissa	M: 13	M: 11	17	22.1	1003	99	22.3
West Bengal	KA: 11, M + KA: 1	None	15	5.5	982	85	43.4

Notes: (a) M: number of districts for malaria control; KA: number of districts for kala azar elimination. (b) Scheduled areas are districts or parts of districts with more than 50% ST population.
* Number and specific location of districts may still be revised

15.3 Summary of Social Assessment

A Social and Beneficiary Assessment (SABA) was carried out by an independent agency during project preparation to enable tribal communities to participate in preparation of the VBDCP and ensure that the Project is designed and implemented in accordance with their health and socio-cultural needs. It also aimed to achieve a clearer understanding of tribal communities to facilitate their informed participation, assess whether the Project would have any adverse impacts on them, and help with the preparation of an indigenous peoples' plan. The SABA was undertaken in four project states: A.P., Chhattisgarh, M.P. and Orissa. It included a synthesis of available information, interviews with relevant workers and officials, and a household survey using a mix of open- and close-ended questions. In addition tribal groups were consulted through focus group discussions. The key findings and

recommendations of the SABA are summarized below, and additional inputs from the consultations are provided in the next section.

15.3.1 Surveillance, Case Diagnosis and Management

Personnel at health Sub-centers, village volunteers, functioning laboratories at PHCs/CHCs, and mobile vans are contributing to improvements in health services and disease surveillance. Rapid Diagnostic Kits (RDKs) and anti-malarial blister packs have also contributed to quick diagnosis and treatment compliance. However, in difficult locations there are deficiencies in supplies, personnel and monitoring which steer the care-seeker to traditional healers or the unorganized private sector. These often dispense non-standardized diagnosis and treatment and may entail greater expenditure. Filling up critical vacancies at peripheral health centers (qualified practitioners, lab technicians, health workers), ensuring that drugs are not stocked out, and frequent monitoring and evaluation are needed to ensure timely diagnosis and effective treatment.

15.3.2 Public-private partnerships (PPP)

PPP have been initiated in many areas. Private nursing homes and clinics report malaria cases to the District Programme Officer on a monthly basis and in the event of increases remedial measures are taken by the public health system. This system requires scaling up. The risk of VBDs varies seasonally. A Seasonality-based Action Plan was recommended at district level to ensure adequate coverage with drugs/ITNs and reduce the risk of epidemics. Intensified surveillance and information to the public (about what is being done and what it needs to do) using various communication channels were recommended.

15.3.3 SWOT analysis

The role of health workers/volunteers in implementing programs with a focus on women and children was seen as major strength. It was suggested that they be better skilled and equipped and provided performance-based incentives to enhance effectiveness. Active involvement of panchayats was also seen as strength. Weaknesses to be addressed included: inadequacies in health care system, inter-sectoral coordination, monitoring, and stakeholder involvement in planning, implementation and monitoring. The NRHM was viewed as an opportunity to improve health infrastructure, stakeholder participation, community empowerment, capacity of health/non-health sector staff to address local needs and priorities, use of resources, and M&E. Potential threats were: inappropriate treatment by unqualified service providers, inadequate community mobilization and capacity-building, sub-optimal use or misuse of available resources and staff, and adverse impacts of unplanned development projects.

15.3.4 Capacity building

Training and regular reorientation were emphasized as ways to remove some of the deficiencies noted in service delivery especially in tribal areas. This would also prevent indiscriminate use of drugs, incomplete treatment and drug resistance. Health worker training to support the efforts of doctors in developing local strategies and planning was also mentioned.

15.3.5 Integrated Vector Management

Insecticide-Treated Bed-Nets (ITNs) have been distributed free of cost to the very poor by the Government. The BPL and APL (Above Poverty Line) populations were charged highly-subsidized costs of USD 0.25 and 0.50 respectively. Along with health workers and volunteers, panchayats were involved in ITN distribution and in educating communities about the use of nets, precautions and re-treatment of nets. However, bed-net use ranged from about one-third to two-thirds of those who received them. In tribal communities, the use was particularly low on account of the habit of sleeping in the open, and the traditional belief that forbids sleeping under a 'foreign' object such as a roof or net. Because of crowded housing conditions (families have an average of five members), sleeping under one bed net was infeasible. There was also a lack of perceived benefits. Nevertheless, during a malaria epidemic in some villages, children were encouraged to sleep under bed nets. Although bed-nets were reportedly purchased from the market as well, there was very little information on community-owned bed-nets. About one-half of community members expressed their willingness to pay for ITNs supplied by the government. It was recommended that areas be prioritized for bed-net distribution on the basis of risk, a high proportion of Pf cases, and inaccessibility for indoor residual spraying.

Social marketing was recommended to increase access to ITNs and other health products and services.

Some positive traditional practices were mentioned such as driving away mosquitoes by burning neem leaves, other forest herbs, cow dung or paddy stubble. Some tribes use repellant body oils.

Although it was widely known that mosquitoes cause malaria, there was little knowledge of mosquito breeding habits. Only in one study area were people aware of the need to cover stored water, spray kerosene oil over stagnant water, etc. Given open drainage systems, garbage disposal and 'toilets', the need to address environmental sanitation and personal hygiene to reduce vector-borne diseases was discussed.

Some villages had not been sprayed for a year or so. Lack of advance information for IRS reduced its coverage. However, tribal people were also

reluctant to allow their homes to be sprayed as tradition holds that family deities and ancestors' souls live inside and protect surviving children. The entry of strangers is considered polluting. The involvement of PRIs, however, has led to improved acceptance. In addition to IRS, some villages (especially in Chhattisgarh) are using biological control measures (e.g., larvivorous fish).

15.3.6 Community Awareness, Attitudes, Beliefs, Practices

In inaccessible villages with deficient services, the dependence of tribal people (particularly 'primitive' tribes) on tribal medicine men is absolute. However, traditional knowledge about herbs, plants, etc. is eroding with time. About half of the tribal people interviewed/consulted voiced a dependence on traditional beliefs, customs and practices, including tribal priests and medicine men. They mentioned consulting public health staff or local doctors only when they were not able to get any relief. However, this is changing gradually in villages that are close to PHCs or have qualified health workers/doctors.

Awareness generation campaigns by the government in the past few years did not reach about half of the sample villages. Not unexpectedly, therefore, about half of all respondents continue to have traditional beliefs about the cause of malaria [e.g., the 'wrath of God' (20%), witchcraft (15%), strolling in the forest (4%), eating stale food (2%), drinking bad water (1%), etc.]. Although a majority of respondents recognized fever as a symptom of malaria, around one-sixth did not. Similarly, vector breeding sites, prevention and treatment measures, etc. were not widely known. The most common route of information was counselling (inter-personal communication) by health workers or doctors. Tribal people had limited access to radio/TV and posters/newspapers also had minimal reach. Intensified campaigns and improved access to facilities were recommended.

15.4 Summary of the Consultations with Affected Indigenous Peoples

Free, prior and informed consultations were held with tribal communities in the proposed project areas during project preparation. The project background, objectives and purpose of the discussions were explained to the target groups to set the context for consultation. Focus group discussions and individual interviews were conducted. Interactions were also held with non-governmental organizations (NGOs) and community-based organizations (CBOs) such as Self Help Groups or women's groups (Mahila Mandals), Panchayati Raj Institutions (PRIs), Tribal Councils, etc. that represented tribal groups and were working on public health related programs or issues. Their main points and recommendations are given below. The suggestions made at the consultative workshop held to review the draft VCP and finalize it have also been included.

15.4.1 Surveillance, Case Diagnosis and Management

Service delivery related to VBDs is inadequate in many tribal areas. During the monsoon many PHCs are unable to handle the patient load and replenish stocks. Examination of blood smears for malaria and treatment are often delayed (for three days or more), and hence there is always a risk of the disease spreading. □In some PHCs delays occur on account of the lack of a laboratory technician. Multi-purpose Health Workers collect blood smears and provide treatment, but their domiciliary visits are somewhat irregular, owing to the need to cover a large dispersed population. Their capacities and efforts to sensitize and mobilize communities are often limited. The effectiveness of Fever Treatment Depots (FTDs) is also inadequate. Radical treatment is started as soon as fever cases are confirmed positive for malaria, but only at PHCs. Treatment compliance is frequently a challenge as tribal communities tend to take low dosages and resort to local herbal medicines. The Anganwadi Workers (AWWs) under the Integrated Child Development Services Scheme give VBD activities lower priority as they are heavily engaged in maternal and child care.

Faster and better quality services should be ensured, partly by filling up staff vacancies. The focus of PHCs, Health Workers (HWs) and Volunteers on VBDs needs to be reinforced from time to time through reviews. Information campaigns could help to build people's trust in HWs and FTDs and should be intensified along with the workers' capacity building. Stock outs of drugs should not be allowed. Laboratory technicians should be posted full-time in tribal PHCs. Fever detection camps and clinics should be conducted regularly during monsoon months. The roles and responsibilities of AWWs need to be review and prioritized, especially in view of the engagement of ASHAs under NRHM.

NGOs could be involved in the program, especially to improve access to tribal populations. Their workers would need training and equipment (e.g., with RDKs).

15.4.2 Integrated Vector Management

Preventive measures such as insecticide spraying are delayed even when a malaria positive case is diagnosed due to inadequacies in resources, storage space, spraying equipment, etc. Spraying should be timely as well as focal. Spraying activities are undertaken with DDT, malathion or synthetic pyrethroids (in keeping with insecticide policy) but synthetic pyrethroids are preferable because of their quick knockdown effect against vectors. Malathion leaves stains on walls and furniture and is not favored. Micro-planning should be done to ensure timely resource mobilization, adequate infrastructure and

equipment, optimal coverage and quality of IRS. The insecticide policy should be reviewed in view of community resistance/acceptance of different types.
The supply of free or subsidized ITNs to BPL households in highly endemic areas is inadequate. Bed-nets are used only by those who realize their benefits and can afford to buy them. Tribal people, especially the poor, are yet to understand the benefits of bed-nets in the absence of a sustained information campaign. Health care personnel are uncertain that even free bed-nets would be used. The demand for free or subsidized ITNs to BPL households in highly endemic areas should be met and coupled with promotional activities involving PRIs, Tribal Councils, NGOs, CBOs and/or volunteers in communicating the benefits. APL families should also be encouraged to use nets.

The importance of biological control using larvivorous fish is being understood increasingly. However, tribal communities expect the initiative to be program-driven with support from the Fisheries Department. PHCs should map water sources and implement biological control measures, possibly as a planned seasonal activity.

Verification of IRS and of the distribution of ITNs/LLINs could be undertaken fortnightly by Village Health and Sanitation Committees.

15.4.3 Community Mobilization

Behaviour Change Communication (BCC) or even Information, Education and Communication (IEC) activities are yet to be optimally implemented. BCC/IEC strategies and activities should take into account the social and cultural background of tribal communities to ensure effectiveness. NGOs could be involved in collecting local information, providing BCC (in local languages, using folk media, etc.), and mobilizing communities and community leaders, school teachers and volunteers should be involved in BCC activities.

Community participation in the program is weak. The constitution of VHSCs and engagement of women from the villages as ASHAs are positive steps in involving communities. They will be trusted while mobilizing their people and supporting village health planning and action. However, the burden of work on ASHAs needs to be reviewed and rationalized from time to time for effective implementation. The necessary tasks could be redistributed among health workers and others at the village level. ANMs and other departments' village workers (e.g., AWWs) should support ASHAs, and ANMs should be involved in village planning to enhance community participation. These and other grassroots workers need to be trained in community interaction, and local NGOs or CBOs should also be involved in community mobilization. Inclusion of community-based groups, community leaders and NGOs in consultations will help improve participation in the program.

15.5 Framework for Consultations with Vulnerable Communities during Project Implementation

The framework for consultations with tribal people and other vulnerable communities in the project areas during project implementation is presented in Table 2. It indicates the, the possible facilitators at different levels, methods they could use and frequency of consultation. These consultations are expected to give 'real time', experience-based feedback from clients, local leaders, staff and NGOs on how the project is functioning in tribal areas and/or for vulnerable communities, including suggestions for improvement of any aspect of the program. They will also contribute to the design and implementation of BCC efforts, operational pilots, and NGO involvement, to help ensure need- and demand-based, culturally-acceptable approaches, plans and service delivery.

Table 2. Framework for Consultations with Vulnerable Communities during Project Implementation

Consultation	Facilitator	Methods	Frequency
Village level	VHSC/ASHA/FTD with NGO	Community meeting and key client visits	Once in six months
Sub-Centre and APHC	MTS/MO-PHC with NGO	Staff meeting, community meeting, and key client visits	Once in six months
BPHC and CHC	District VBD Officer/Consultant/ Social Development Professional	Meeting with staff, Panchayats, key client visits	Once in six months
District	District VBD Officer/Consultant/ Social Development Professional and BCC Consultants	Workshop with key stake- holders (incl. tribal reps, staff, clients, NGOs, PRIs)	Annually
State	State Program Officer, State Social Development and BCC Consultants	Workshop with key stakeholders (as above)	Annually
National	National Program Officer National	Workshop with key stakeholders (as	Annually

	Social Devpt. and BCC Consultants	above)	

15.6 Action Plan

As most of the project areas ("high prevalence areas") are tribal or backward, and many of its intended beneficiaries are tribal or other vulnerable people, its intervention strategies are designed to address the constraints faced in these areas and by these people in prevention, diagnosis and treatment of malaria and/or kala-azar. The strategies include supply-side improvements; increasing access according to need; communication for demand-generation, informed decision-making and improved practices; socio-culturally appropriate and gender-sensitive planning and implementation; and monitoring by dedicated VBD experts and Social Development specialists.28 Table 3 shows those activities in the project that would ensure that vulnerable communities receive maximum benefits and that VBDs are reduced among them in the form of a 'step-by-step' Action Plan. As a guide to implementation, it shows the action, where it would primarily take place, the persons who would be chiefly responsible for its implementation, and a likely timing or frequency of action. Thus, the 'Vulnerable Communities' Plan' (VCP) is integral to the Project's overall implementation, and is part of the GOI's Project Implementation Plan (PIP) and forthcoming Operational Manual. It would be implemented in all project districts in keeping with the Project's planned phasing, as needed and feasible.

The VCP will also guide Bank project supervision, and includes the indicators that would be used when feasible to assess implementation effectiveness for vulnerable communities. Data providing information on project outputs and outcomes for tribal and other vulnerable groups (including women and children) will be generated initially from routine program monitoring, project reports and surveys. Over time better data are expected to become available

[28]. The consultations at the client and sub-district levels of the health system would focus on whether the program is reaching vulnerable groups, and cover all aspects of service delivery related to this project, including the cultural acceptability of interventions, BCC activities and grievance redressal mechanisms. In kala-azar areas they will also include discussions of the village environment, hygiene in homes, cattle-sheds, etc. At district level and above, the consultations would focus on whether tribal people and the most backward areas are receiving due attention in all aspects of program planning, management and implementation, including capacity-building and monitoring of private providers; and monitoring by Panchayats. Any issues arising will be investigated and addressed, and 'Action Taken Reports' presented at the next consulta

from a strengthened Health Management Information System (HMIS). When disaggregated by age, sex, SC/ST/General population, and Tribal/Non-tribal areas they will provide information on the equity being achieved by the Project, and facilitate remedial responses where necessary.

15.8 Institutional Arrangements and Capacity Building for Implementation of the Action Plan

The institutional arrangements for implementation of the Vulnerable Communities' Plan are given below in Table 3.

Table 3: Actions for Vulnerable Communities

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
Component 1: Improving Access and Use of Malaria Prevention and Control Services				
Sub-component 1A: Improving Malaria Case Management				
1. Case detection and treatment				
Mapping high risk tribal/non-tribal areas with no microscopy facility within 3 km	District	DVBDO	Annually	Percent of Pf+ cases treated with ACT in 24 hrs (excl. first trimester pregnant women) (disag. by M/F, age, SC/ST/ Genl and Tribal/ Non-tribal areas). Initially from surveys, then MIS
Calculating need for RDT, ACT and no stock out/expiry for high-risk tribal areas	District w CHC/PHC	DVBDO, DMO, MOs	Quarterly	
Mobilizing village health workers and MPWs for case detection with RDT	Village, SC	DVBDO, MTS	Annually	
Case detection with RDT	Village	MPW, MTS	Continuous	
Case treatment with ACT	Village and health facilities	VHW, MPW, MO(a)	Continuous	
2. Arranging referral to avert deaths				
Identifying/mapping referral centers (RC) in tribal and other backward areas	District	DVBDO, DMO	Annually	Number of cases and deaths (disaggregated by M/F, age, SC/ST/ General and Tribal/Non-tribal
Equipping RCs with necessary anti-malarials,	District	DVBDO, DMO, MO	Twice annually	

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
supportive drugs, supplies				areas) when available from sentinel surveil-lance data
Mobilizing VHWs, MPWs, MOs for identification of severe cases	District, Block	DVBDO, MO, MTS	Annually	
Arranging referral of severe cases to RCs in tribal areas	Village, SC, PHC	VHW, MPW, MTS	Continuous	
Orienting RC staff to manage severe cases	Block, District	DMO, MO	Annually	
Trained staff managing severe malaria	RC	DMO, MO	Continuous	
Sub-component 1B: Strengthening malaria surveillance				
1. Active case detection (ACD)				
Ensuring staff in position at health facilities in tribal areas	State, District	SPO, DVBDO, DMO	At start and continuous	Number of cases detected by ACD (disaggregated as above). From surveys and HMIS
ACD of Pf+ cases in tribal areas with RDTs	SC, Village	MPW, VHW	Continuous	
Compiling and transmitting reports upto district for analysis and feedback	SC, PHC, CHC, DH	SC, PHC, CHC, DHS, DVBDO	Monthly	
2. Passive case detection (PCD) and Sentinel surveillance				
Identifying and equipping Sentinel Sites (SS) in tribal areas	State, District	SPO, DVBDO	Year 1, 3, 5	Number of cases detected by PCD (disaggregated as above). From sentinel surveil-lance data.
Ensuring staff at SS in tribal areas	State, District, SS	SPO, DVBDO, DMO, SS-in chge	At start and continuous	
Passive case detection	Hlth facilities	MPW, MO	Continuous	
Compiling and transmitting reports up to District for analysis and feedback	Hlth facils., SS and District	MTS, MO, SS-in-charge,	Monthly	

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
		DVBDO		
3. Rapid response				
Setting up response teams in tribal areas	State, District	SPO, DVBDO	At start	Percent of Tribal/ Non-tribal districts with active response teams
Identifying outbreaks in tribal areas, reporting, working with IDSP	Hlth facility, SS and District	MTS, MO, DVBDO	Continuous	
Investigating outbreak; following up	Village, Block	DVBDO, SS,MTS	Continuous	
Sub-component 1C: Effective vector control				
1. Indoor Residual Spraying				
Identifying high risk tribal areas	District	SPO, DVBDO	Annually	Percent of houses targeted for IRS that received full, quality spraying in each round (disag. by Tribal/Non-T areas); from program reports, then MIS
Supplying insecticide and equipment	PHC	SPO, DVBDO	Annually	
Storing insecticides safely	PHC	MO, MTS	Annually	
Orienting spray teams to safety, quality	PHC	DVBDO	Prior to IRS	
Organizing BCC & involving community	Village	MTS, BCC cons.	Prior to IRS	
Conducting spraying with concurrent and post quality assessments	Village	Teams, MTS, DVBDO	Per schedule	
2. Use of Long Lasting Insecticide Treated Bed Nets (LLINs)				
Identifying tribal villages for full coverage	Village	DVBDO, MTS	Annually	Percent of LLINs delivered to people of those planned by the district (disag. by Tribal/ Non-T areas); from reports, then MIS
Inviting NGOs/PRIs/Tribal Councils, etc. to participate in storage and distribution	Village	MTS, MPW, MO	Annually	
Supplying LLINs and storing safely prior to distribution	District, Village	NPO,SPO ,DVBD, MTS, local group	Annually	

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
Distributing LLINs and monitoring proper use	Village	MTS, MPW, local group	Annually	
Component 2: Supporting Elimination of Kala-azar				
Sub-component 2A: Improving KA Case Management				
Mapping high risk areas	District, Block	SPO, DVBDO	Annually	Percent diagnosed Kala-azar patients completing new/ standard treatment (disag. by M/F, age, SC/ST/ Genl, and Tribal/Non-T areas); reports, and gradually HMIS
Calculating need for RDT (rk39), and ensure no stock out/expiry	District, Block	NPO, SPO, DVBDO, MO	Quarterly	
Mobilizing MPWs for case detection	Village, SC	KTS, MO	Annually	
Case detection with RDT	Village, SC	MPWs	Continuous	
Completing treatment (new/standard), treatment cards, provision of food support for patient/attendant	PHC, SC	MO, KTS, MPW	Continuous	
Sub-component 2B: Strengthening Kala-azar surveillance				
1. Active Case Detection				
Identifying areas for active case search	District, Block	SPO, DVBDO, MO and others	Twice a year	Number of cases detected through ACD (disag. by M/F, age,SC/ST/G, T/NonT areas); surveillance data
Mobilizing and orienting health teams	Block, Village	KTS, MPW	Twice a year	
Maintaining case register; compiling reports and transmitting up to District for analysis and feedback	Village, Health facilities	Health teams, KTS, MO	Monthly	
2. Passive case detection (PCD) and Sentinel surveillance				
Identifying, staffing and equipping Sentinel sites	District	SPO, DVBDO	Years 1, 3, 5	Number of cases detected by PCD (disag. by M/F, age, SC/ST/Genl
PCD (standard method) and case treatment	Sentinel sites	SS in charge	As needed	

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
Compiling reports and transmitting up to District for analysis and feedback.	Sentinel sites, District	SS in charge, DVBDO	Monthly	and Tribal/Non-T areas); reports, then surveillance data
Sub-component 2C: Effective vector control (Indoor Residual Spraying)				
Identifying high risk areas	District, Block	SPO, DVBDO	Annually	Percent of houses targeted for IRS received complete quality spray in each planned round (disag. by T/Non-T areas); reports
Supplying and storing DDT, equipment	Block	NPO, SPO, DVBDO, KTS	Annually	
Orienting teams in safe, quality spraying	Block	DVBDO, KTS	Prior to IRS	
Organizing BCC & involving community	Village	BCC Cons, KTS	Prior to IRS	
Conducting spraying with concurrent and post quality assessments	Village	Teams, KTS, DVBDO	Per schedule	
Component 3: Policy and Strategy Development, Capacity Building and Monitoring and Evaluation				
Sub-component 3A: Policy and strategy development				
Conduct workshops to identify pilots to assess operational feasibility and impact of approaches to improve services for vulnerable groups (at least 2 each for Malaria, KA) and prepare TORs	National	N SD Prof. with NIMR, other research instituts, medical colleges, NGOs, etc.	Years 1, 3	Number of studies identified, designed and conducted for Malaria, Kala-azar; from project reports
Contract pilots (with TORs)	National	N SD Profsnl.	Years 1, 3	
Conduct pilots; provide reports	Per TORs	Consultants	Per schedule	
Take follow-up action as recommended	Per Recoms.	NPO, SPO	Year 3 on	

Action to be Taken	At what Level	By Whom (Implem enter)	Time point/ Frequency	Output/Outcome Indicator
Sub-component 3B: Program management and capacity building				
1. Program management: Position national and state Social Development Professionals; form and orient multidisci-plinary team (anthropology, communica- tions, public health) at national level	National, State	NPO and SPOs	At start of project and sustained througho ut	Staff in position
2. Engage NGOs for Service Delivery and Social Mobilization				
Developing appropriate TORs and engage NGOs to work in states	National	NPO and SD Prof. with states	Year 1 and as needed	Number of villages covered by NGO activities (disag. by T/NonT areas); project reports
Develop plans and implement activities	Villages	NGOs	Per Plans	
Obtain lower level feedback, review and revise plans, and plan expansion	National, State	N+S SD Profs, NGOs	Year 2 onwards	
3. BCC for Malaria control and KA elimination				
Developing TORs and engage BCC Consultant agency for project	National	NPO, BCC and SD Specialist s	At start of project	Percent of indivi-duals/HH who - slept under ITNs, - allowed full IRS - sought D&T in 24 hrs of fever (disag for Tribal/ Non-T areas); survey data
Doing assessments, develop strategy and plans for BCC activities per TORs	All levels	BCC Agency and others as needed	Per TORs	
Implementing activities according to plans	All levels	BCC Agency + others per plans	Per Plans	
Obtaining lower level feedback, reviewing,	National, State	N+S BCC + SD	Year 2 onwards	

Action to be Taken	At what Level	By Whom (Implementer)	Time point/ Frequency	Output/Outcome Indicator
revising, planning expansion		Profs, Agency		
4. Training				
Engaging Training consultant agency/ies	National	NPO and SD Prof. with states	Year 1 and as needed	Percent of staff trained at each level of those estimated to require specific training (disag. by T/Non-T areas); project reports
Assessing special training needs to ensure culturally appropriate efforts for tribal people and women, developing and carrying out training	As needed	Training agencies	Per schedule (prior to transmission season)	
Evaluating training (incl. quality, using suitable indicators); following up	As needed	NPO, SPO, SD Profs, DVBDO	Annually	
Sub-component 3C: Monitoring and Evaluation				
Examining Routine Program Monitoring reports from Tribal/Non-tribal areas	District and above	M&E Officers, SPO, NPO	From start	Analysis differentiating these areas
Using GIS to map high-risk areas, health facilities, and other issues in tribal areas	District, State	NPO,SPO, M&E Officers, Conslts	Per agreed schedule	Availability of relevant maps
Developing HMIS to generate data disag. by M/F, SC/ST/G, and T/NonT areas	All levels	NPO,SPO, M&E Officers, Conslts	Per agreed schedule	Availability of disaggregated data
Population-based LQAS survey	PHC	NPO,SPO, M&E Officers, Conslts	Annual	Availability of disaggregated data
Cross-sectional household surveys (mid-term and endline)	Village	NPO, M&E Officer, Conslts.	Year 2, 5 (2010, 2013)	Availability of disaggregated data

Note: (a) "MO" includes CHC MOs, BPHC MOs, PHC MOs and APHC MOs as relevant.

National Level: As the Borrower is the Government of India, responsibility for overseeing implementation of the Action Plan will lie with the national Directorate of National Vector-Borne Disease Control Program (NVBDCP) in the Ministry of Health and Family Welfare (MOHFW). The Directorate will engage a full-time Social Development (SD) professional with a social science background to provide technical assistance and monitor the VCP. S/he will coordinate with State Program Officers, state-level SD professionals, and partner organizations. For efficient and effective implementation of the activities in the Plan, other program officers and professionals responsible for BCC, Training, M&E, etc. will also be consulted as needed.

State Level: The state NVBDCP Manager will be primarily responsible for the program and the VCP which is an integral part of it. A full-time Social Development professional will provide technical assistance and monitor the VCP. S/he will coordinate with the national level and provide support to the District VBD Officers and consultants. As above, program officers and consultants responsible for BCC, Training, M&E, etc. will be consulted as needed.

District Level: In all VBD endemic districts, the Project will primarily be the responsibility of the District VBD Officer. An additional program manager will be appointed at district level to increase managerial effectiveness, and three Integrated Vector Management Supervisors to improve quality and effectiveness of vector control operations. The VCP will be implemented by the District VBD Officer with the support of the District VBD Consultant. This team will coordinate with the sub-district levels, and report on progress, constraints and resource requirements to the state team.

Capacity Enhancement: The NVBDCP has an on-going training program to enhance the capacities of health workers and technical personnel at all levels. To build the knowledge and skills to implement and manage the VCP, the curriculum and modules will be expanded to include topics such as: socio-cultural (including gender) issues; the political and self-governance structures of vulnerable communities, their rights and policies; methods to assess and address their needs and priorities; approaches to achieve and sustain vulnerable communities' access to VBD control services and products; and so on. Social mobilization, counseling and motivation skills will be stressed. Training on the VCP will be integrated into the overall NVBDCP training. Reorientation will be carried out after assessment of capacities during project reviews. A database of experts with social science backgrounds and knowledge of tribal people and other vulnerable communities will be developed to ensure the availability of appropriate trainers and technical resources.

15.8 Measures to Address Potential Adverse Effects

The Vulnerable Communities' Plan will address any unintended or unforeseen effects of the Project that may increase peoples' vulnerability to VBDs or its control operations. The potential adverse impacts could be related to vector management or case management and include insecticide resistance, drug resistance, poor health and environmental contamination caused by improper use, handling, storage, etc. of treatment agents. The program includes several activities to reduce these risks such as integrated vector management and case management, which are described in Annex 4: Detailed Project Description and in the Environment Management Plan below.

In addition, micro-planning of all interventions will be undertaken at the district level to ensure that local needs are addressed appropriately. Health volunteers, PRIs, Tribal Councils and other CBOs will be sensitized, participate in planning and implementation, and take responsibility for monitoring vector control, treatment interventions and effects. BCC activities will be targeted to make the affected and surrounding communities aware of the causes and methods of VBD prevention, diagnosis and treatment options, and to stimulate appropriate behavioral responses. The BCC will also build in information on the potential adverse consequences of use, non-use and improper use of drugs and insecticides. Capacity building, supervision and monitoring activities planned under Project will also help to avoid, minimize, mitigate or compensate for adverse effects.

A situation analysis of kala azar will be carried out at the commencement of the project to identify additional interventions that could be undertaken in the project or in other government programs to address the disease and its underlying causes. Similarly, studies to assess operational needs to address the disease burden of tribal and other vulnerable populations will be conducted during the project to strengthen program strategies.

I. <u>Activities, responsibilities, timeframe and costs for Vulnerable Communities' Plan (VCP)</u>

A focus on vulnerable communities is an integral part of the Project and its key activities were indicated in the Action Plan above. As such, the costs of most activities for vulnerable groups are included in the costs for the population at large. However, to ensure the effective provision of services to vulnerable groups some special efforts will be made to focus the attention of program managers; support action by the health system; facilitate community consultations, action, and oversight; and pilot innovative approaches to

vulnerable groups. Table 4 summarizes these provisions, including cost estimates.

Table 4. Special Activities for Vulnerable Communities, Responsibility, Time-frame and Estimated Costs

Action	Responsibility	By When	Cost (INR)
Salaries for staff dedicated to supporting preparation and implementation of VCP (National and State SD Professionals)	NVBDCP and State Directorates	From start of project and sustained throughout	20,000,000
Development of training modules for preparation and management of VCP, and of booklets to sensitize existing community institutions (e.g., VHSCs)	NVBDCP with consultant agency	Within three months of project start	2,000,000
Sensitization workshops for VHSCs, PRIs, RKSs and State and District Health Societies	District VBD Officers and SPOs	Once every two years (Year 1, 3, 5)	40,000,000 (a)
Conducting/facilitating and preparing summaries of periodic consultations, including annual district, state and national summaries	NVBDCP and consultant agency/ies	As shown in Table 2	5,500,000
Engaging NGOs in tribal and other difficult areas for social mobilization and special activities focused on vulnerable communities	National with State	According to need	Upto 70,000,000
Workshops and consultations to design pilots to assess operational feasibility and impacts of innovative approaches to improve services for vulnerable people	NVBDCP working with NIMR and IDA	Early in Years 1and 3	Upto 50,000,000
Implementation of pilots and assessing their impacts (at least 2 each for Malaria and Kala-azar)	NVBDCP and consultant agency/ies	Years 1 to 4	

Note: (a) Estimated on the basis of Rs. 10,000 per Block plus Rs. 25,000 per District

15.9 Grievance Redressal Procedures

In India, rural and tribal areas are disadvantaged in terms of access to quality health care on account of their remoteness, difficult terrain, weak infrastructure including health facilities, inadequate service providers, and so on. Furthermore, the social, cultural and economic characteristics of tribal and other vulnerable communities, coupled with social exclusion even of their leaders, and deficient health promotion and outreach activities, contribute to gross under-utilization even of available services.

In view of the specific needs of such areas, the Project will establish systems to bring out and redress grievances related to the lack of access to or availability of curative and preventive VBD services and information. Within the health

system, cases and outbreaks, stock-outs of drugs, backlogs of unexamined blood slides, unavailability of bed-nets, poor coverage and quality of insecticide spraying, inadequate biological control, inadequate/ineffective BCC/IEC activities, and so on, will be reported upward from village to sub-district, district, state and national levels. In addition to this internal monitoring and reporting, individuals, community volunteers (such as ASHAs, FTDs, AWWs), local self-government (VHSCs/PRIs/Tribal Councils), NGOs/CBOs, the autonomous societies managing health facilities (Rogi Kalyan Samitis, RKS), and District and State Societies will be able to express their grievances through a variety of means. Tribal and other vulnerable community representatives will be included in stakeholder committees to recognize and address issues. Contact information for core program/project staff (such as telephone/mobile phone numbers and addresses for postcards/written communication) will be provided at the community level. No less than annual review meetings will be held with stakeholders at community, block and district levels. The Project will give wide publicity to inform vulnerable communities and others about all grievance redressal procedures.

15.10 Mechanisms and Benchmarks for M&E and Reporting

Specific performance indicators to monitor the Vulnerable Communities' Plan were given above. , The mechanisms available to monitor the Plan are described below.

At the start, mid-term and end of the project, cross-sectional household surveys will provide information on individuals disaggregated by age, sex, and SC/ST/General categories and at the household and community levels. The baseline survey has been completed, and mid-term and end-line surveys will be carried out in 2010 and 2013 (Years 2 and 5), respectively, by an independent agency. The surveys will include participatory methods and approaches to provide a comprehensive picture of service delivery to, acceptance of interventions by, and accrual of project benefits to the vulnerable communities.

Rapid Population-based Surveys: using the 'lot quality assurance sampling' method (LQAS) will be undertaken annually in each project district to track coverage and use of RDTs, ACT, LLINs (for malaria), rk39, medicines and treatment completion (for KA), and IRS (for both diseases). Information will be available at the PHC level, and will be fine-tuned over time, to provide estimates for outcome indicators at the district and overall project levels. It is expected that these data would be examined by area and possibly by community or household characteristics.

Routine Program Monitoring: At the state and district levels, service-related data collected regularly provide information about program inputs (e.g., staff, supplies and financial resources), processes (e.g., training, communications) and outputs (services delivered). Over time this routine information provides a picture of increases or decreases, improvements or gaps, achievement of stability, and so on. Data for tribal districts/areas will be examined separately.

Geographic Information System (GIS): The Project will facilitate GOI's efforts to introduce GIS to map high-risk areas and health facilities, monitor the distribution of VBDs in tribal areas, analyze time trends, ensure available health resources, and forecast epidemics. GIS data (in the form of maps) will also help to plan appropriate actions at the local level, for example, to identify high-risk areas for IRS. The availability and use of 'tribal maps' would be examined during Bank reviews

Health Management Information System (HMIS): The Project will support revamping of the VBD MIS, and enable monitoring of the use of services by vulnerable groups and women, and timely and appropriate responses by the health system. Data is expected to be disaggregated by M/F, age, SC/ST/General, and Tribal/Non-tribal area by the early implementation review.

15.11 Environment Management

The Environmental Management Plan (EMP), prepared by the NVBDCP,[through National Institute of Malaria Research] consists of a set of mitigation, monitoring, capacity development and institutional measures to be taken during implementation and operation of the project, to address the adverse environmental and social impacts, offset them, or reduce them to acceptable levels. The EMP also includes an implementation schedule and the capital and recurrent cost estimates for its implementation. This budget estimated for the EMP will be integrated into the total project cost.

15.11.1 Legal Framework

NVBDCP, through this project recommend and support the country in updating the various regulations related to its activities. The key activities include review of compliance of Insecticides Act to meet minimum essential international standards. Also the EMP recommends revision of the national guidelines (based on FAO's Pesticides Guidelines on Storage, Labeling, and Disposal), to include monitoring, efficacy evaluation for the registration of plant protection products; and compliance and enforcement of a pesticide regulatory program.

15.11.2 Procurement:

Insecticide procurement is highly specialized and complex due to time-lag of delivery between production and usage. While the NVDCP will utilize the services of UNOPS as a procurement agent, the real challenge still remains in effective implementation of the program on the ground ensuring that quality services reach the most needy populations in time and appropriate pesticide management practices are followed. The EMP recommends a number of activities such as modification of specifications /contracts with insecticide producers to include guidelines for pesticide application and disposal of used bags/containers, measures for quality control and adequate labeling of products, including translation in local language of destination. The manufacturers should include instruction leaflets in local languages before dispatching the goods to destination. Pre and post dispatch certification is necessary for all insecticide based products. Materials and quality of packaging by insecticide manufacturers shall be reviewed periodically by NVBDCP to ensure efficacy, shelf-life, human and environmental safety and manufacturers should provide independent certification of chemical and physical analysis, product and formulation acceptability to NVBDCP. The NVBDCP will ensure that insecticide producers may provide protective gear along with their products.

15.11.3 Storage and transport:

Due to poor storage and conditions currently existing in the states, the EMP recommends that funds be allocated from the program for construction and/or up-gradation of appropriate storage areas for district HQ and PHC facilities. Training needs to be provided in proper stacking and utilization is essential for minimizing damages, leakages and accumulation of stocks.

Safe transportation of insecticides requires trained drivers, well-labelled vehicles, checking of quality of packaging and pesticide load during transit and at point of delivery. The NVBDCP shall ensure that DDT packaging from gunny bags may be replaced with fibre-board drums to reduce ruptures, spills and also loss of efficacy during storage. Licensing of insecticide manufacturers, distributors, retailers, and pest control operators is an important aspect of pesticide management. Annual procurement and distribution cycles between states and the Directorate need to be synchronized to allow timely delivery and usage prevent stockpiling. States will also provide information on amount of stockpiled insecticides in larger storage areas particularly at district and PHC levels. A systematic tracking system of volumes of insecticide from factory to point of delivery needs to be established by the manufacturers, along with a system for reporting spills and leakages during transit. NVBDCP will include this requirement in their contracts to be monitored by the consignee state governments.

15.11.4 Application activities:

Safe and environmentally sound application of insecticides (space spraying and IRS, impregnation of bed-nets, larviciding etc) can be achieved by intensive training of all the spray workers and handlers and by timely availability of protective gear. Equipment management is important and states have to review all spray equipment and protective gear before start of each spraying season and keep appropriate records. Close supervision of application activities is essential and district and PHC level officials should be provided adequate funds and training to ensure good practices are being followed. Manufacturers are stipulated to provide instructions for disposal of pesticide containers including plastic wrappings and one way of reducing wastage is by provision of appropriately sized packages for spraying and impregnation activities. It is also necessary to develop clear pictorial instructions to health and spray workers on use, applications, preparation of suspension and disposal of insecticides, insecticide treated materials, insecticide containers etc.

15.11.5 Integrated Vector Management:

The EMP Action Plan recommends that IVM activities will be piloted in 3 districts (malaria and Kala azar) during first year of the project. The NVBDCP will develop a phase-down plan for gradual decrease in DDT use and promotion of ITMN, biolarvicides and IGR compounds. This plan will be shared with the World Bank. Other activities include mapping of insecticide resistance status of malaria vectors through NIMR and training staff in effective IVM procedures.

15.11.6 Waste Management:

Since the Ministry of Health and Environment, through its various programs, has developed a number of detailed guidelines for implementation of sound infection control and waste management practices, which the NVBDCP can utilize effectively. NVBDCP shall replicate standard protocols for waste management during the first year of the project. This will be developed by the Consultant (Environment). The project will ensure that these protocols are disseminated to the states and training is provided to its field staff.

15.11.7 Occupational Health and Safety:

The EMP proposes that a National Surveillance Committee be constituted to review health and environmental impacts of vector control activities, which can review issues related to worker health and safety and recommend solutions which are applicable and feasible in Indian conditions. Such committees at national, state and district level will conduct periodic review on occupational health safety measures every year during malaria & other VBD transmission season. State and district has one such Task Force committee chaired by Secretary (health) at state level and District Collector at district level for observance of anti malaria month. The same members will monitor the safety

measures at state and district level. State and district shall ensure that the recommendation of committee is followed at all level of the program implementation. The NVBDCP will strengthen liaison with the Ministry of Agriculture for quality control and stocks management of pesticides.

The EMP also recommends that the NVBDCP commission an independent audit for impact of vector control activities after 2 years of project implementation.

15.11.8 Capacity building:

Capacity building for good worker practices is an integral and essential part of integrated vector management. This activity will include provision of rigorous and regular training for different levels and types of workers and certification of staff and operators in the following activities: stock management; good storage practices; proper handling of pesticides during transport and disposal; application of insecticides; surveillance methods; signs and symptoms of poisoning, emergency measures; PPE usage; accident reporting, data management and monitoring and reporting. Such capacity building should target those involved in the production, distribution, use and application of insecticides, householders and health personnel. The NVBDCP will hire an OEHS expert for development of different guidelines on environmental safeguard policies and waste management.

15.11.9 BCC /IEC:

Long-term health education and communication approaches are required to educate the community, create general awareness and provide accurate information to elicit support for sound and effective use of insecticides. Such approaches are absolutely vital for field level activities such as spraying and bed-net impregnation. A village level committee comprising of the village chief, Anganwadi worker/ANM, junior health worker and village teacher could be constituted to supervise the proper storage, spraying, environment management including disposal of used containers etc at sub centre/village. Community should also be educated to understand the importance of IRS and to take necessary steps to ensure maximum efficacy of spraying. Domestic and peri-domestic sanitation may be an important component where individual and community cooperation is essential. The NVBDCP develop new guidelines on sound environmental and OHS issues will be developed and disseminated actively across all states. An Action plan will be developed before commencement of new project by the OEHS expert. Additionally NVBDCP shall utilize GOI's guidelines on Inter-sectoral collaboration and modify them in the context of this program, to ensure IVM activities are successfully implemented.

15.11.10 Institutional Framework:

For effective implementation of the EMP, NVBDCP will strengthen the institutional framework at national and state levels. An Environment Consultant at the national level, one VBD Consultant at district levels and Malaria Technical Supervisors at block level are to be newly recruited. The Accredited Social Health Activist (ASHA) under NRHM at village level is also being envisaged for supporting the implementation of the EMP. To monitor the surveillance outbreak and support the EMP activities, one multi purpose health worker per 5000 population will be assigned at subcentre levels. The Consultant (Environment) will not only provide technical guidance to NVBDCP, World Bank but also monitor the state level activities with regard to the EMP.

All agreed actions defined by World Bank have been reflected in PIP, project budget, legal agreements and contractual documents. The NVBDCP will also hire an OEHS expert to review the occupational health and safety measure being implemented under the project.

15.11.11 Reporting and Monitoring:

While it is recognized that data and information collection in such a decentralized program is quite difficult, but without effective monitoring of the insecticide chain and environmental and health issues, such a program can not be successfully implemented. The EMP recommends that the existing data management system be strengthened considerably and include all levels of the insecticide chain – manufacturer, distributor village, primary, district, and state offices.

The reporting system will include the following: tracking of insecticide movement from production to disposal, records of insecticides utilized in various applications (IRS, spraying and larviciding), records of ITN procured, distributed and impregnated, amounts of insecticides used for impregnation monitoring of spray workers, records of spray equipment, PPE and other tools related to insecticide use, conditions of storage and transportation, records of accidental poisoning etc. The state level surveillance committee should review the above records on an annual basis and recommend corrective measures where necessary. The National Committee should review the findings and recommendations of the state level committees.

15.11.12 Implementation:

Given the scope of the program and the complexity of the environmental and health issues related to insecticide use and IVM practices, it has been agreed between the GOI, NVBDCP and the World Bank that the EMP will be implemented in different phases. The first phase will be a pilot phase for about 18 months and will focus on 3 districts (both malaria and KA). The lessons

learnt from this "pilot" phase will be reviewed after 18months and then replicated in the remaining project sites, as appropriate.

The timing, frequency and duration of mitigation measures and monitoring for the first 18 months are given below. The table also includes cost estimates for both the initial investment and recurring expenses for implementing all measures defined in the EMP, integrated into the total project costs and factored into loan negotiations.

ACTION PLAN FOR EMP IMPLEMENTATION:

Action	Responsibility	By When	Cost (Rs)
Contracting of consultant agency for supporting the NVBCP in development and implementation of EMP	NVBDCP	April 2009	3,000,000
Review the existing legal framework including municipal bye-laws and international guidelines	NVBDCP (through consultant agency)	April 2009	2,000,000
Provision of PPE and pictorial instruction leaflets in local language in individual insecticide packages procured under the project	NVBDCP and Procurement Agent	Initiate in Sept 2008 and continue to end of project	
Survey of current storage and disposal practices of insecticides in year I states and preparation of action plan to improve storage and disposal practices	NVBDCP through NIMR	April 2009	1,500,000
Survey of stockpiled insecticides in larger storage areas and development of plan of action for disposal of these stockpiles, in consultation with IDA	NVBDCP through NIMR (survey) and States (Action Plans)	December 2009	
Piloting of EMP activities in 3 districts covered in first year of the project	NVBDCP through NIMR	Sept 2008 – Aug 2009	2,500,000
Organizing workshops and meeting to update the national guidelines for all aspects of insecticide management	NVBDCP though the Consultant Agency	October 2008	1,500,000

Action	Responsibility	By When	Cost (Rs)
(procurement, storage, use, disposal, OHS, monitoring, quality assurance and inter-sectoral coordination)			
Workshop for training of Trainers in the application of new national guidelines	NVBDCP	November 2008	500,000
Preparation of training Plan, Training modules and facilitator guidelines	NVBDCP through engaging a consultant	Nov-December 2008	500,000
Implementation of decentralized training activities at state and district levels (with completion before spraying season)	State and district Vector Borne Diseases Control Officers	Jan-Feb 2009 and subsequent years	25,000 per district
Development of TOR and establishment of National Surveillance Committee	NVBDCP	June 2008-Nov 2008	
Independent audit of impact of EMP	NVBDCP	EIR	
Plan for DDT usage	NVBDCP	Annual	
Replication and dissemination of Waste Management protocols	NVBDCP	October 2008	
Development of monitoring framework and monitoring the implementation of EMP	NIMR	October 2008 (framework) and subsequent monitoring acc. to plan	2,000,000

Chapter 16

Enhanced Implementation Support

Background:

The Project will enhance Government of India's efforts to control malaria in high burden districts from eight states and eliminate kala-azar from highly endemic districts in three states. The project is expected to contribute to poverty reduction and to achieving the Millennium Development Goals (MDGs). The World Bank has supported an earlier project 'Enhanced malaria control project' for control of malaria which closed in December 2005.

Based on the feedback from the Quality Enhancement Review, the project design has been significantly changed. From the original concept of supporting a nation-wide program covering all vector borne diseases, the project has now been limited to two diseases causing highest burden among the poorest covering the most endemic districts in 11 states. Some of the states having highest burden of malaria and kala-azar, especially the states of Chhattisgarh, Jharkhand, Orissa and Bihar, have weak implementation capacities and fiduciary oversight. This poses a major challenge for the implementation of new diagnosis and treatment policy for malaria control and elimination of kala-azar. Given the weak implementation environment and experience to-date with externally assisted projects in country, close and intensive implementation support will be critical for achieving the development objectives.

16.1 Strategy for the enhanced Implementation Support

The strategy involves a combination of continues oversight and periodic more intensive implementation support and will have specific focus on three broad areas:

(a) Progress in Implementation of agreed technical reforms: The scope of these reviews will include new drug policy, introduction of RDKs and LLINs. This will be done through: (1) improvements in project MIS supported by GIS mapping; (2) World Bank tion of MIS through Lot Quality Assurance Surveys (LQAS); (3) two rounds of household surveys out which first will be during the early implementation review; (4) systematic monitoring of therapeutic efficacy of anti-malarial drugs and vector resistance for insecticides being used in the program; (5) monitoring the quality of pharmaceuticals and commodities

procured under the project; (6) bi-annual program technical reviews led by WHO and (6) impact evaluation studies.

(b) Oversight for decentralized activities: This oversight covers recruitment, availability and functioning of contractual staff supported by the project and implementation of training activities as per the agreed guidelines. This will be done through: (1) semi-annual third party reviews covering 50% of districts included in the first year, 20 % in year II and at least 15% of the districts during the later three years; (2) Early implementation review of the project after 18-24 months of effectiveness; (3) Enhanced field visits during implementation support mission as well as undertaking thematic mini missions and regional reviews.

(c) Implementation reviews of GAAP and Joint DIR action plan: This includes review of the progress in project specific GAAP and DIR joint action plan common. The activities will include: (1) A 6 monthly update on the project specific GAAP will be prepared by the MOFHW; (2) Quarterly reports on implementation progress of the DIR joint action plan to the World Bank management; and (3) 100% post review of all procurements undertaken centrally.

16.2 Stakeholder and partner participation in project implementation oversight

A key issue in centrally sponsored projects is the lack of ownership by the states and weak implementation at that level. While the severity of malaria and kala-azar in the selected states generates concern among the state governments, continued engagement and dialogue with states will be necessary and this will be ensured throughout the project period. In addition to the capacity building measures included in the project, the task team will regularly visit the key states and participate in state level implementation reviews. In addition to the national project launch workshop, state and district launches to create awareness among the concerned officers to ensure better understanding of the project for effective implementation, are planned as part of the supervision strategy.

During the [project preparation technical assistance was sought from WHO, GFATM which is also supporting the NVBDCP program. There will be active engagement of states and other partner agencies working in the area of VBD especially NGOs and social marketing agencies. The other national programme has identified some large NGOs that have strong field presence in the project states and capability to undertake stakeholder consultations as well as help the

districts to prepare the decentralized plans targeting on vulnerable populations. They will be utilized during the project period.

16.3 Implementation Plan

World Bank besides their Task team for technical guidance to NVBDCP for the project will also provide Consultants who will help Task team. These Consultants shall be hired by World Bank and be posted at Bank's Office. In addition to constant technical expertise, these experts will be supporting the task team in reviewing the technical specifications of commodities procured under the project and providing technical comments on procurement complaints. Implementation readiness filters for project districts have been discussed in detail during the pre-appraisal and agreed upon. While the post reviews will be covering 100% of the central contracts, the decentralized activities (limited to contractual staff, training and mobility) will have semi-annual third party reviews carried out by external agencies hired by the World Bank during the first two years. These reviews will cover a sample of the project districts to monitor the availability of staff, their performance and stock situation of crucial supplies (diagnostic kits, ACT and miltefosine) made under the project. This sample will include more than 50% of districts in year one, 20% in year two, and 15 % in year three and five assuming that performance is satisfactory. The sampling can be revised incase of poor performance. The report of the third party reviews will form the basis for district and state visits by the NVBDCP state coordinators and the World Bank supervision teams for enhanced implementation support during the next quarter. The NVBDCP will share the guidelines for selection of contractual staff and the names of the selected candidate with World Bank and this will be disclosed at the web site of the district health mission if such arrangements have been made by the districts. Where possible, the senior staff from MOH, NVBDCP will also be participating in the selection of the contractual staff in states with.

16.5 Implementation Support during the First Year of the Project

The focus of implementation support in the first year would be on working closely with the World Bank and project states to put in place implementation arrangements and institutions for the activities agreed under the GAAP for the VBD project. The ongoing monitoring of the joint action plan by the sector to address deficiencies identified by the DIR will also help the VBD project.

The agreed district readiness filter will be applied and the number of districts included under the project during the first year will be determined on the ability

of each identified district to successfully fulfill these criteria. In addition to the national launch workshop, state-specific launch workshops and district level sensitization meetings will be undertaken to make the staff familiar with the agreed fiduciary arrangements and reporting requirements.

One specific area of focus in the year I will be following-up on actions being undertaken by MOHFW to register more LLIN manufacturers in country and improving the supply chain logistics through hiring state level agencies. The protocols for LQAS will also be finalized and piloted during the first year. During the first year, the task team will have monthly meetings with the NVBDCP Directorate and the MOHFW focusing on these issues with a view to addressing these before they arise or become acute.

16.5 Annual plans

Two full-team joint implementation support missions are proposed every year in which World Bank, WHO and GFATM and other experts will be invited to participate. The missions in addition to technical specialists and M &E expert will include the procurement, financial management, social development and environment specialists. The missions will have clear Terms of Reference. In addition three joint external reviews are proposed and NVBDCP will seek WHO support for this.

The project will support annual Lot Quality Assurance Surveys (LQAS) to validate the programme reports on performance. The protocol for such surveys is described in the M&E chapter and LQAS will form the basis for annual joint project appraisal. Active engagement and participation of other development partners especially DFID and USAID currently supporting health systems strengthening initiatives in some of the malaria/kala-azar endemic project states such as Orissa, Jharkhand and Madhya Pradesh would be ensured to provide additional technical support and implementation oversight.

An early implementation review will be carried out after two years of implementation, i.e., 2009 or 2010 with technical support from WHO to assess the project implementation in phase I districts. Project scale up to the remaining districts would be subject to satisfactory implementation. Planned supervision activities, schedules and expected outputs are in the Table below. The project will become effective by August 2008 and implementation will begin from September 1, 2008. It provides an overview of supervision activities, schedules and outputs:

Activity	2008/09 *	2009/10	2010/11	2011/12	2012/13	Outputs
Launch Workshop	Sept 2008					Workshop Report
Five State Regional Workshops (3 no.s)	October 2008					Three Workshop Reports
Supervision Missions (2nd year)	February 2009	August 2009 Feb. 2010	August 2010 February 2011	August 2011011 February 2012	August 2012 Feb. 2013	Mission Report
Early Implementation Review		Feb. 2010				Review Report
ICR Mission					July 2013	Mission Report
Surveys	Baseline before Feb. 2009	First repeat survey before Feb. 2010			Second repeat survey before Feb. 2013	Survey Report
State/District Visits (no. of visits)	3	3	4	4	4	18 Field Visit's Reports

** GOI Financial Year Apri1-March 31*

All the Outputs report will be shared with World Bank

Annexure 1

MALARIA CASES & DEATHS

STATEs/UTs.	2004				2005				2006 (Provisional)			
	Blood Slide Examination	Malaria cases	Pf cases	Deaths	Blood Slide Examination	Malaria cases	Pf cases	Deaths	Blood Slide Examination	Malaria cases	Pf cases	Deaths
Andhra Pradesh	9793211	35427	19410	2	10040085	39099	22548	0	9442026	34081	20317	0
Arunachal Pradesh	213273	29849	4397	0	258994	31215	7447	0	276074	39182	12854	196
Assam	1853560	58134	41409	54	2050261	67885	45453	113	2743092	126178	82624	304
Bihar	289973	1872	333	0	230139	2733	427	1	240019	2744	428	1
Chhattisgarh	3598383	194256	148775	4	3874911	187950	140182	3	3770468	190590	147766	3
Goa	239043	7839	1471	7	264170	3747	468	1	277989	5010	1196	7
Gujarat	9755255	222759	66440	89	10976750	179023	32382	54	11139833	89835	17932	45
Haryana	2182431	10064	169	0	2527485	33262	238	0	2634814	47142	506	0
Himachal Pradesh	501376	126	7	0	479358	129	0	0	462791	114	8	0
Jammu & Kashmir	371988	250	8	0	395144	268	7	0	396938	156	8	0
Jharkhand	1306554	143722	44238	40	2846684	193144	51676	21	2095291	193888	48388	4
Karnataka	9189910	80961	20472	27	10080290	83181	21984	26	9924797	62842	16459	32
Kerala	1747620	2790	510	12	2118032	2554	337	6	1966325	2111	322	7
Madhya Pradesh	9101655	132094	52292	36	9018326	104317	32250	44	9735974	96160	29053	56
Maharashtra	14690118	68988	29300	61	15177228	47608	16718	104	16937173	54420	17506	133

STATEs/UTs.	2004				2005				2006 (Provisional)			
	Blood Slide Examination	Malaria cases	Pf cases	Deaths	Blood Slide Examination	Malaria cases	Pf cases	Deaths	Blood Slide Examination	Malaria cases	Pf cases	Deaths
Manipur	154202	2736	771	8	141378	2071	770	3	94608	2709	1301	8
Meghalaya	216978	18080	15514	29	218660	16816	14758	41	290111	29924	25907	167
Mizoram	217316	7830	4170	72	218961	10741	6294	74	218072	10644	6956	120
Nagaland	67511	2486	128	1	86470	2987	91	0	91953	3370	585	75
Orissa	4369409	416732	351737	283	4848624	396573	342692	255	4935442	375907	327972	253
Punjab	2435456	1643	21	0	2743340	1883	28	0	2581686	1888	37	0
Rajasthan	7253502	105022	7578	20	7037873	52286	4061	22	8682576	99529	9481	58
Sikkim	9355	160	33	3	8319	69	31	0	7956	93	31	0
Tamil Nadu	7397845	41732	2875	0	7728987	39678	3098	0	6373612	28219	1276	0
Tripura	251146	17453	15182	16	290344	18008	14261	20	307478	23375	19058	31
Uttaranchal	330317	1255	39	0	311916	1242	17	0	288297	1108	6	0
Uttar Pradesh	4186005	87022	2237	0	4223366	105303	3149	0	3892119	91566	1875	0
West Bengal	3821295	220871	60262	184	4408763	185964	41365	175	5271645	159646	43448	203
A.N.Islands	154671	745	119	1	126996	3954	2073	0	131972	2993	1299	1
Chandigarh	72367	199	6	0	92694	432	9	0	75901	449	7	0
D & N Haveli	36009	787	202	0	49664	1166	183	0	130647	3786	0	0
Daman & Diu	20425	118	18	0	18732	104	17	0	28897	140	17	0
Delhi	1028273	1316	28	0	1031488	1133	61	0	940300	928	36	0
Lakshadweep	1479	2	0	0	811	0	0	0	1410	0	0	0
Pondicherry	253615	43	1	0	218563	44	2	0	196371	50	2	0
All India Total	**97111526**	**1915363**	**890152**	**949**	**104143806**	**1816569**	**805077**	**963**	**106584657**	**1780777**	**834661**	**1704**

Annexure 2

KALA-AZAR CASES & DEATHS

State	2004		2005		2006	
	Cases	Deaths	Cases	Deaths	Cases	Deaths
Bihar	17324	107	23383	124	29711	162
Jharkhand	4028	14	6578	12	7508	11
West Bengal	3015	23	2706	15	1843	10
Uttar Pradesh	34	2	73	2	83	0
Delhi	78	9	62	4	31	4
Gujarat	0	0	0	0	2	0
Assam	0	0	1	0	0	0
INDIA	**24479**	**155**	**32803**	**157**	**39178**	**187**

Project costing of National Vector Borne Disease Control Project