



Module for Training of District VBD Consultants On Malariaology



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Foreword

Malaria remains a major public health concern in India. About 80% of malaria reported in the country is confined to tribal, hilly, difficult and inaccessible areas. The north-eastern states having such geographical setting and approximately 4 per cent of country's population contribute 10 to 12 per cent of total malaria cases every year. Towards strengthening the national response for malaria, an Intensified Malaria Control Project-II (IMCP-II) supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Round 9 grant is being implemented by the National Vector Borne Diseases Control Programme (NVBDCP) of Government of India. A non-government consortium led by Caritas India is complementing the efforts of the NVBDCP in selected areas in the North-Eastern states.

Similarly, the Central and Eastern Malaria Endemic States are covered under the World Bank supported National Vector Borne Disease Control Support Project (NVBDCSP) covering 9 States namely, Andhra Pradesh, Chhattisgarh, Jharkhand, Madhya Pradesh, Gujarat, Odisha, Karnataka, Maharashtra, West Bengal.

The overall goal is to achieve impact in terms of reduction in the number of malaria cases and deaths due to malaria through effective and efficient use of interventions and resources in tandem by the public sector and civil society.

To facilitate the programme implementation activities in both these projects, technical manpower in the form of District VBD Consultants (DVBD) and Malaria technical Supervisors (MTS) has been provided. These additional human resources are the key to successfully implement the Malaria control activities as they are the persons directly involved with the programme activities at the district and sub-district level. To make them fully sensitized with the programme policies and guidelines, Dte. of NVBDCP has organized and successfully started the training of these persons with the help of National Institute of Malaria Research (New Delhi) and field stations of ICMR.

For effective capacity building of the people, a comprehensive module is essential to facilitate both the trainees and trainers. This present module is one such component of the training. I wish to thank my officers, namely Dr. G S Sonal Additional Director and HOD Malaria Division, Dr. Avdhesh Kumar, Additional Director and Nodal Officer GFATM Project, Dr. Munish Joshi, National Consultant (Training), Dr. H G Thakor National Consultant (M&E) and Mr. Atul Kumar, Statistician, for their sincere efforts to bring this module. I hope that this will go a long way in helping the trainees to understand the subject and thus prove to be effective implementation personnel for the malaria control programme.

I also wish to thank Dr. Neena Valecha, Director, NIMR and her team especially Dr. B N Nagpal, Scientist F who have taken extra efforts to make these trainings successful.

I wish the trainee District VBD Consultants a successful training and fruitful activities in the field so as to achieve the Goals for malaria Control and finally elimination.

With Best Wishes,

Date: - 3-Sep.-2013
Place: - Delhi

Approval
3/9/2013
Dr. A.C. Dhariwal



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ABBREVIATIONS USED In The Module

ACT	Artemisinin-based Combination Therapy
API	Annual Parasite Incidence
ASHA	Accredited Social Health Activist
CHV	Community Health Volunteer
DMO	District Malaria Officer
EAC	Externally Aided Component
EQA	External Quality Assurance
FEFO	First Expiry First out
HRP2	Histidine-Rich Protein 2
IQC	Internal Quality Control
LT	Laboratory Technician
NVBDCP	National Vector Borne Disease Control Programme
Pf	<i>Plasmodium falciparum</i>
PHC	Primary Health Center
pLDH	Parasite lactate dehydrogenase
Pv	<i>Plasmodium vivax</i>
QA	Quality Assurance
QAP	Quality Assurance Programme
QC	Quality Control
RDK	Rapid Diagnostic test Kits
RDT	Rapid Diagnostic Test
SPR	Slide Positivity Rate
SRL	State Reference Laboratory
TS-VBD	Technical supervisor-VBD

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Chapter-1

Introduction to malaria and Life Cycle of Malarial Parasite

What is Malaria?

Malaria is a disease transmitted by the female anopheles mosquito. The parasite which causes malaria is the plasmodium (a unicellular organism). Malaria is a global health problem; worldwide 300-500 million people develop malaria every year. In India the number of recorded cases is about 1.5 million per year, but it is estimated that the real number may be much higher. About thousand deaths due to malaria are reported every year by NVBDCP, but as many hospitals do not report malaria cases to the programme, the real number is thought to be much higher.

Malaria Control programme in India

Malaria has been a problem in India for centuries. Details of this disease can be found in the ancient Indian Medical Literature like the “*Charaka Samhita*”. In the 1930s there was no aspect of life in the country that was not affected by malaria. The annual incidence of malaria was estimated at around 75 million cases in 1953, with about 8 lakh deaths. To combat this menace, the Govt. of India launched the National Malaria Control Programme (NMCP) in April 1953. The programme was highly successful and within 5 years, the incidence dropped to 2 million cases. Encouraged by this, the programme was changed to a more ambitious National Malaria Eradication Programme (NMEP) in 1958. By 1961 the incidence dropped to a mere 50,000 cases a year. But since then the programme suffered repeated setbacks due to technical, operational and administrative problems, and cases started rising again. In the late 1960’s malaria cases in urban areas started to increase and surges of malaria in rural areas were also widespread. As a result in 1976, 6.47 million cases were recorded by the malaria control programme, the highest since resurgence began. In the year 1995 Malaria Action Programme (MAP) was taken up in high risk areas. The National Malaria Eradication programme was renamed as National Anti Malaria Programme (NAMP) in 1999 covering the concept of effective control. In 2004 the programme was integrated with other vector borne diseases control and was named as the National Vector Borne Disease Control Programme (NVBDCP).

The reported malaria incidence is now about 1.5 million cases per year. Over the last few decades, the proportion of falciparum malaria has increased; and the drug resistance of *P.falciparum* and insecticide resistance of vectors threaten to cause setbacks. Malaria therefore remains one of the most important public health problems of India, despite continuous efforts at its control.

The Strategy of malaria control in India is three pronged comprising of Early Diagnosis and Prompt Treatment (EDPT), Integrated Vector Management (IVM)

and Supportive interventions like Training for capacity building, Behaviour Change Communication (BCC), intersectoral coordination, Public Private Partnerships (PPP), community participation and legislation.

Types of Malarial Parasite

In India two types of plasmodia are responsible for most human malaria.–They are *Plasmodium vivax* (*P. vivax*, PV) and *Plasmodium falciparum* (*P. falciparum*, PF). There are two other plasmodia (*Plasmodium malariae* and *Plasmodium ovale*) that cause malaria in humans, but they are rare and of practically no public health importance in India. *P.falciparum* is the variety which is responsible for almost all the deaths due to malaria. *P. vivax* causes debilitating illness, but vivax malaria is rarely fatal, unless accompanied by some other problem like malnutrition. In many states of India, particularly the North Eastern states, Orissa and Chhattisgarh, a very high proportion of malaria cases are due to *P. falciparum*.

Life Cycle of the Malarial Parasite

The malarial parasite undergoes 2 cycles of development – the human cycle (asexual cycle) and the mosquito cycle (sexual cycle). Man is the intermediate host and mosquito the definitive host.

1) Asexual cycle in human being

The asexual cycle begins when an infected anopheles mosquito bites a person and injects sporozoites. There are 3 phases in the human cycle.

a. Hepatic Phase

The sporozoites disappear within 60 minutes from the peripheral circulation. Many of them are destroyed by phagocytes, but some reach the liver cells. After 1-2 weeks of development (depending upon the species), they become hepatic schizonts, which eventually burst releasing a shower of merozoites. The number of merozoites produced from a single sporozoite varies – as many as 40,000 in *P. falciparum*, whereas only 200 – 15,000 in other species. In *P. falciparum*, the intrahepatic schizonts rupture almost simultaneously and there is no persistent tissue phase (exo-erythrocytic phase). In other species, the hepatic forms may remain dormant (hypnozoites) for long periods, liberating merozoites at various intervals, causing relapses of malaria.

b. Erythrocytic Phase

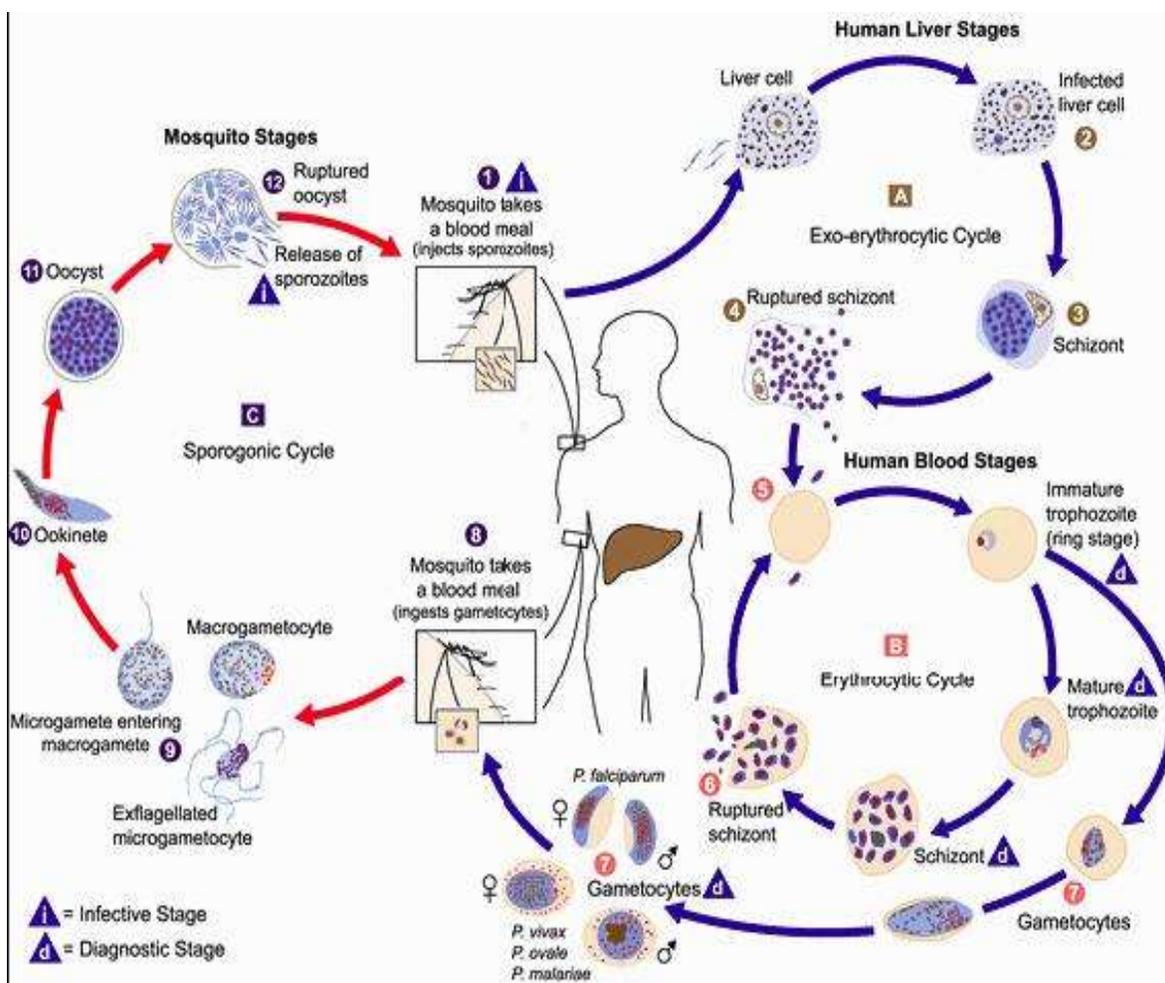
Many of the merozoites released from the liver cells are quickly destroyed, but a significant number attach themselves to specific receptor sites on the RBCs, penetrate them and pass through various stages of trophozoite and schizont. The erythrocytic phase ends with the liberation of merozoites, which infect fresh RBCs. The clinical feature of fever with chills coincides generally with the rupture

of RBCs. The cycle is repeated over and over again until the condition worsens or when it may be slowed down by the immune response of the host. The duration of each erythrocytic cycle varies between species – 48 hours for *P. falciparum*, *P. vivax* and *P. ovale*; and 72 hours for *P. malariae*.

c. Gametogony

Some of the erythrocytic forms of plasmodia do not divide further but develop into male and female gametocytes. Not all **infected** persons are **infectious** (can infect anopheline mosquitoes). The blood of the person has to have mature male and female gametocytes and the density should be minimum 12/ cumm of blood to be infective. These gametocytes take over a week to appear in the blood. Gametocytes do not cause any symptoms in humans. Most drugs like chloroquine kill the asexual forms that cause the fever but leave intact the sexual forms that are infective especially in case of *P. falciparum*. Thus an apparently normal person may harbour the disease and contribute to its spread.

Figure 1. Life Cycle of *Plasmodium* species in man and the mosquito



Spread of malaria

The plasmodia spread from person to person by the bite of mosquitoes. This process is called the **transmission** of the disease, and the mosquitoes are the **vectors** of malaria. However, not all mosquitoes can act as malaria vectors. It is only mosquitoes belonging to the genus *Anopheles* - and that too the female of the species which can carry the parasite and infect. Male *Anopheles* mosquitoes only feed on plant juices and nectar and cannot transmit malaria.

Sexual Cycle in Mosquito

The mosquito cycle (sporogony) begins when gametocytes are ingested by the vector mosquito while feeding on an infected person. The male gametocytes, after reaching the stomach of the mosquito and develop into 4-8 filaments called "microgametes". The female gametocyte undergoes maturation to become a "macrogamete". The microgametes get attracted to the macrogamete, and one of the microgametes fertilizes the macrogamete. The resulting zygote is at first motionless, but within 18-24 hours, becomes a motile ookinete, which penetrates the stomach wall of the mosquito and develops into an oocyst on the outer surface of the stomach. The oocyst further develops into numerous sporozoites, when the oocyst ruptures and releases the sporozoites into the body cavity of the mosquito. Many of the sporozoites migrate to the salivary glands and the mosquito becomes infective to man. The period required for the development of the parasite from the gametocyte stage to sporozoite stage is about 10-20 days depending on atmospheric temperature and humidity. This period is known as the "extrinsic incubation period". The sporozoites (the infective stage of *Plasmodium*) are injected with saliva when the mosquito next feeds.

In falciparum malaria, there may be involvement of the brain and coma in addition to life threatening complications including kidney or liver failure. With early and effective treatment, the case fatality rates in *P.falciparum* malaria can be brought down from above 5% to close to zero. Malaria cases can be classified according to the parasite species causing them and according to the severity of the disease, as either uncomplicated or severe malaria. It should be understood that severe vivax malaria is very rare.

Immunity to malaria

Repeated infections with malaria parasites lead to the acquisition of antibodies directed against various antigens of various stages of malaria parasites as well as cell-mediated immunity. The immunity is to a large extent, but not completely, specific to the species of malaria parasite. It is also to some extent strain-specific, meaning that a person, who has been exposed to malaria in a certain part of the world (or part of a large country like India) will have a higher degree of immunity to local malaria parasites than to those from a distant location. There is no perfect immunity to malaria: nobody acquires such a high level of protective

antibodies that he or she can be certain not to contract malaria. Also, in contrast to many other communicable diseases, the immunity to malaria is time-limited: the person who has acquired a certain degree of immunity through repeated malaria attacks will lose that immunity in a few years, if the exposure is not maintained. For this reason, sometimes the terms semi-immunity or premunition are preferred to immunity.

Typically in areas with very intense transmission, persons who are heavily exposed, acquire some immunity in childhood. Then as adults, they get ill relatively rarely and when they do, the disease is mild and of short duration. It seems that in old age, immunity is lost again, but it is not clear whether this is a result of ageing processes or of old people being less exposed to malaria or both. Typically, people with a certain degree of immunity still harbour parasites: They are **asymptomatic carriers**. It can be difficult to detect such cases and this can have implications for malaria control. If a certain population is heavily exposed to malaria, so that some people have some immunity to the disease and exposure is reduced for some years as a result of control measures, the immunity will largely be lost. If control is then relaxed, malaria may return with occurrence of large number of cases. For this reason, sustainability is important in malaria control.

Scientific work to develop a **malaria vaccine** has taken place for decades. One or two vaccines may well be marketed within the coming 5 years, but they are likely to have only a limited degree of effectiveness and would, at best, only be a supplement to other malaria control tools.

Malaria is a serious disease, which has affected human populations for many thousands of years. It has therefore exerted a selective pressure, favouring certain genotypes in humans with some innate (in contrast to acquired, as described above) immunity to malaria. Among these conditions are sickle cell disease, thalassaemia and glucose-6-phosphate dehydrogenase deficiency, all of which are common in India, especially in populations which are or have in the past been heavily exposed to malaria.

Malaria Control

Malaria control comprises all activities undertaken to reduce the burden of malaria in a given population. It includes the diagnosis and treatment of malaria cases and prevention. Surveillance of the disease, prevention and control of epidemics and field studies to regularly assess the malaria situation and its determinants are essential components in a malaria control programme. The main methods of prevention aim to reduce the risk of humans being bitten by infected anopheline mosquitoes. The aim of malaria control is to reduce morbidity and mortality of malaria to the lowest possible levels locally. In some

cases, the aim may be elimination, i.e. the interruption of transmission, where no new cases occur.

Diagnosis and treatment

Uncomplicated malaria can become severe malaria within 1-2 days (shorter for young children) of onset of symptoms. Early and effective treatment will halt the progression of the disease, thereby preventing deaths from occurring. This could be achieved by treating everybody with a fever as malaria, and this was in fact done until recently as “presumptive treatment”. Nowadays, because of drug resistance, it is necessary to use more expensive and differentiated treatment regimens. The strategy of presumptive treatment has therefore been replaced by early diagnosis (through RDTs or microscopy) followed by prompt, effective treatment. Early effective treatment benefits not only the individual patient, but also has the following advantages:

- a) Lowering the infectivity of infected persons to the mosquito vector will contribute to reducing malaria transmission, and eventually the incidence of malaria.
- b) Early diagnosis is important because in the early stages the infected persons have only asexual forms of plasmodia in the blood, which are not infective to mosquitoes. It takes about 4 - 5 days after the person has developed fever to develop the sexual forms of *P. vivax* in the blood; for *P. falciparum* it takes 8 -10 days. If the blood is cleared of the parasites during this time, then the transmission from that person is prevented.
- c) In low transmission areas, where most infective people are symptomatic, treating all cases within the first week could cut transmission dramatically. In high transmission areas, where there are many asymptomatic carriers, case management alone has relatively little role in transmission control.
- d) Most antimalarial medicines have no significant action on the gametocytes, whereas primaquine can effectively destroy them. Artemisinin derivatives have some effect on gametocytes, but it is not as constant as that of primaquine. Therefore, primaquine is included in the treatment of falciparum malaria, because some patients only report after they have developed gametocytes.

Chapter-2

Measures directed against the transmission by mosquitoes

Transmission dynamics

It is important to have a basic knowledge of the transmission dynamics to understand malaria control. The intensity of malaria transmission in an area is the rate at which people are inoculated with malarial parasites by mosquitoes. It is expressed as the annual Entomological Inoculation Rate (EIR) i.e. the average number of infectious bites by malaria-infective mosquitoes delivered to an individual human resident in that area per year. Annual EIRs range from 500 to 1000 in certain parts of Africa to about 10 to 100 in places where there are seasonal peaks. At levels of about 0.01 or less, malaria transmission is barely and rarely sustained.

The EIR can go down, if:

- a) There are fewer people, who have gametocytes in their blood; so that the probability of a mosquito becoming infected upon biting a human being is reduced.
- b) Total population of mosquitoes has decreased.
- c) People have taken measures to avoid mosquito bites.
- d) More animals are available as sources of blood meals, provided the vectors are zoophilic.
- e) Average life-span of vectors has been reduced, so that only a few of those infected become infective for human beings.

Field studies and mathematical models have shown that in most situations the most effective vector control methods are the ones, which include reduction of life-span of vectors. The explanation is that the average life-span of a female anopheline is only a little longer than the extrinsic incubation period. Thus, a 20% reduction of the average life-span of female anophelines may lead to a situation, where no or very little transmission takes place. In contrast, even if the density of anophelines is reduced by, for example 80%, the remaining 20% will be able to maintain some transmission. In practice, methods which reduce the life-span of anophelines may also reduce their density and the frequency with which they bite humans.

Behaviour Change Communication (BCC)

The NVBDCP envisages strong community participation and behavior change components in the malaria control program to meet the challenges in malaria control. Three interventions of proven value are now being introduced at a large scale into the program, each of which has benefits tangible even to the lay person, and thus having high likelihood of acceptability and utilization:

Diagnosis. In the place of slide tests which involved delay in getting results, rapid diagnostic tests (RDT) for *P. falciparum* are now available. These tests can be conducted at the most peripheral levels by any one with simple training.

Treatment. In place of Chloroquine which was associated with treatment failure due to drug resistance, ACT is now available which is nearly 100% effective and is not associated with any major side effects.

Bed nets. In place of Insecticide impregnated Bednets which required periodic reimpregnation, soon we will have Long lasting bed nets which do not require reimpregnation, remaining effective even after 20-25 washes and lasting for 3-5 years.

A fourth component of the program having high acceptance potential is the establishment of trained ASHAs at village level, known as ASHAs. The malaria control program offers considerable scope for communities to participate in and own the program.

Vulnerable groups

Certain groups are particularly vulnerable to malaria:

Pregnancy increases vulnerability of women to severe malaria, by lowering immunity. Malaria can cause abortion, stillbirth, low birth weight and severe anaemia in pregnant woman. Early and complete treatment of malaria is therefore of the greatest importance in pregnant women.

Young children are at highest risk in those populations, which are exposed to very intense transmission, where older people develop immunity. Even in areas with less intense transmission, severe disease may develop particularly rapidly in young children. Diagnosis may be difficult, as young children can have fever from a number of different causes.

People who do not live in malaria-endemic areas have no immunity. The problem of immigrants may be a lack of knowledge of malaria and about where to go for

treatment if they fall ill. Travellers, tourists and immigrants need information on protective measures against malaria in various locations and situations.

Malaria and Gender

Women are more likely to delay visits to qualified health care providers and more likely to visit traditional healers for their sickness and for their children because of their lesser control over resources and decision-making process in the household. There may be a gender bias towards the male child, who gets preferential attention in getting health care. Studies have shown that women in many situations do not have control over decision making about accessing quality health care. Malaria in pregnant women is associated with more serious complications.

When men have malaria the household becomes severely affected economically. Women's work days become longer and the work load becomes heavier as they have to take care of the ill apart from their routine activities. There may also be times when they have to go for work to compensate for the wage loss of the male members. In households without any male earning member, the economic consequence can be very severe on the entire family.

There is a need to promote women's active participation in leadership and decision-making. It is critical that people at every level come together to create awareness of the magnitude of the problem and on the way gender inequalities lead to a greater impact on women and the girl child in case of sickness due to malaria.

Chapter-3

Malaria Entomology

Malaria entomology is the study of biology and ecology of the mosquitoes that transmit malaria. There are more than 4000 species of mosquitoes in the world of which about 424 belong to Anopheline group, and about 70 are considered to be the main vectors of malaria. In India there are about 53 species of anopheline mosquitoes and of these nine are vectors for malaria; only six of them being important primary vectors. The other three can contribute to spread of malaria but by themselves cannot initiate or sustain transmission (secondary vectors).

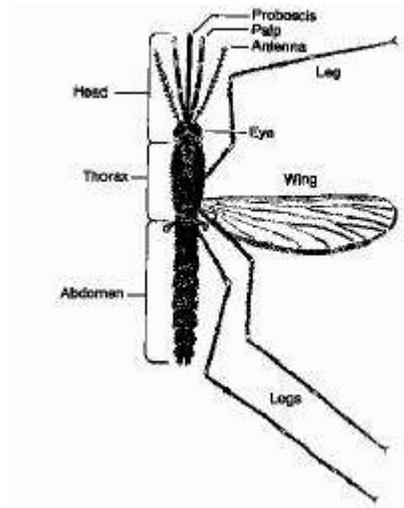
Distinguishing mosquitoes from other insects

Mosquitoes belong to the **class Insecta** – having the following characteristics:

- ☐ The body is divided into three sections—head, thorax and abdomen
- ☐ The head has one pair of antenna, and a pair of compound eyes
- ☐ The thorax has three pairs of legs

The main parts of the adult mosquito are shown in figure given below. Four characteristics can be used to describe adult mosquitoes: only one pair of wings; a long proboscis; the body is covered with scales; and wings have **veins** that show a defined pattern

Main parts of the adult mosquito



Distinguishing anophelines from culicines

Distinguishing characteristics of anophelines and culicines are illustrated in Figs. 2.2 and 2.3.

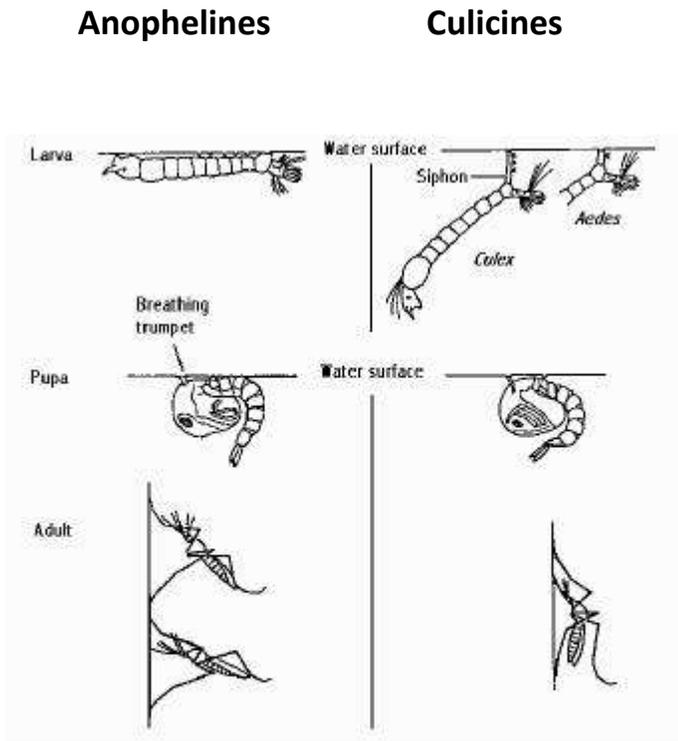


Figure 2.2 Comparison between anopheline and culicine mosquitoes

Eggs

Culicine eggs clump together in a "raft" (*Culex*) or float separately (*Aedes*); anopheline eggs float separately and each of them has "floats" .

Larvae

The **culicine** larva has a breathing tube (**siphon**) which it also uses to hang down from the water surface, whereas the **anopheline** larva has **no siphon** and rests parallel to and immediately below the surface.

Pupae

Pupae of both anophelines and culicines are comma-shaped and hang just below the water surface. They swim when disturbed. The breathing trumpet of the anopheline pupa is short and has a wide opening, whereas that of the culicine pupa is long and slender with a narrow opening. However, it is difficult to distinguish anopheline from culicine pupae in the field.

Adults

Live adult anopheline and culicine mosquitoes, can easily be distinguished by observing their resting postures. Anophelines rest at an angle between 50° and 90° to the surface whereas culicines rest more or less parallel to the surface. Anopheline mosquitoes can also be distinguished from culicines by the length and shape of the palps. The differences (Fig. 2.3) are:

- ☐ In female anophelines, palps are as long as proboscis; in female culicines, palps are very much shorter than proboscis.
- ☐ In male anophelines, palps are as long as proboscis and club-shaped at tip; in male culicines, palps are longer than proboscis, with tapered tips.

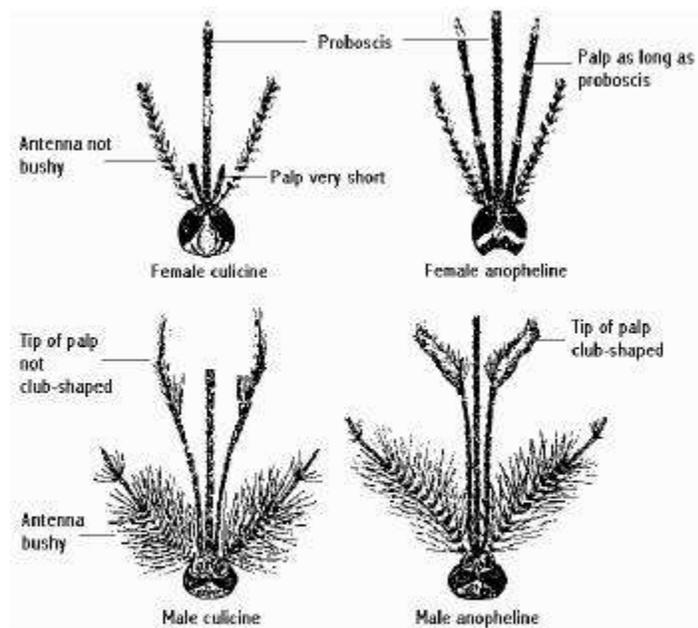


Figure 2.3 Heads of male and female anopheline and culicine mosquitoes

Distinguishing female *Anopheles* from males

It is important to distinguish females from males because only the female *Anopheles* takes blood meals and transmits malaria; on the antennae of the female the hairs are few in number and short (Fig. 2.3). The male has very long hairs on the antennae, which consequently have a bushy appearance.

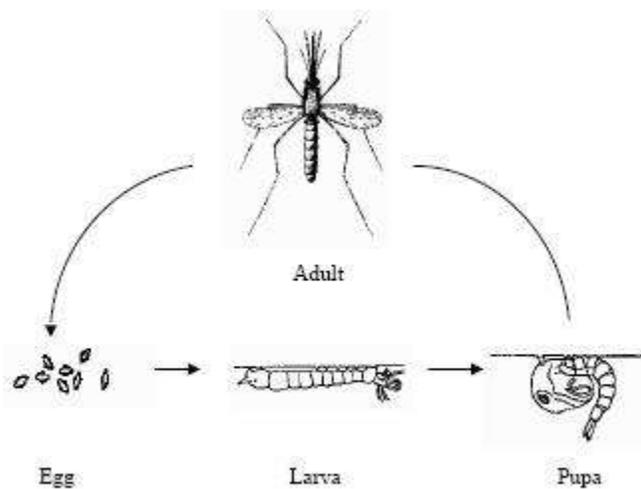
Life cycle of anopheline mosquitoes

All mosquitoes have four different stages in their life cycle: the **egg**, **larva**, **pupa** and **adult**.

Eggs

A female anopheline mosquito normally mates only once in her lifetime. She usually requires a blood meal after mating for development of eggs. Blood meals are generally taken every 2-3 days before the next batch of eggs is laid. About 100-150 eggs are laid on the water surface during oviposition. Oviposition sites vary from small hoof prints and rain pools to streams, swamps, canals, rivers, ponds, lakes and rice fields. The average lifespan of female anopheline mosquitoes is about 3-4 weeks.

Life cycle of an *Anopheles* mosquito



Larva

A larva hatches from the egg after about 1-2 days. The anopheles larva floats parallel under the water surface, since it needs to breathe air. It feeds by taking up food from the water. When disturbed, the larva quickly swims towards the bottom but soon needs to return to the surface to breathe. There are four larval stages or **instars**. The total time spent in the larval stage is generally 8-10 days at normal tropical water temperatures. At lower temperatures, the aquatic stages take longer to develop.

Pupa

The pupa is shaped like a comma and it's a non feeding stage. It stays under the surface and swims down when disturbed. The pupal stage lasts for two to three days after which the skin of the pupa splits. Then the adult mosquito emerges and rests temporarily on the water's surface until it is able to fly.

Adult

Mating takes place soon after the adult emerges from the pupa. The first batch of eggs develops after one or two blood meals, while successive batches usually require only one blood meal. The feeding and resting habits of mosquitoes are of great importance in control programmes and for this reason they must be well understood. Most anopheline mosquitoes bite at night. Some bite shortly after sunset while others bite later, around midnight or the early morning. Some mosquitoes enter houses to bite and are described as being **endophagic**; others bite mostly outside and are called **exophagic**.

After the mosquito takes a blood meal she usually rests for a short period. Mosquitoes that enter a house usually rest on a wall, under furniture or on clothes hanging in the house after they bite and are said to be **endophilic**. Mosquitoes that bite outside usually rest on plants, in tree holes, on the ground or in other cool dark places and are called **exophilic**.

Host preferences are different for different species of mosquitoes. Some mosquitoes prefer to take blood from humans rather than animals and are described as being **anthropophagic/anthropophilic** while others only take animal blood and are known as **zoophagic/zoophilic**. Clearly, those who prefer to take human blood are the most dangerous as they are more likely to transmit malaria from person to person.

Chapter-4

Malaria vectors of India

The important malaria vectors in India are:

- a. *Anopheles culicifacies*: The most common vector in India, especially in rural areas and is widely distributed in India. Occurs sporadically in N.E. India. Not reported in Andaman & Nicobar Islands and Lakshadweep.
- b. *Anopheles fluviatilis*: Important vector in hilly and forested areas. Widely distributed in the foothill areas including both peninsular and North East India
- c. *Anopheles stephensi*: Distributed throughout India except at higher altitudes. Found only sporadically in the North East. Almost all urban malaria is due to this species.
- d. *Anopheles sundaicus*: Typical of seashores; low importance except on islands. Responsible for malaria transmission in Andaman & Nicobar islands only.
- e. *Anopheles minimus*: Of great importance in the north east India, breeding in slow- moving streams with grassy margins, mainly in foothills.
- f. *Anopheles dirus*: Vector in forested and forest fringe area in the north-east. Highly exophilic and exophagic and difficult to). Breed in small, transient, partly shaded pools in forest areas (eg. Elephant footprints)
- g. *Anopheles annularis*: Mainly a secondary vector, which is common in central India and Orissa.
- h. *Anopheles philippinensis*: It is incriminated as a vector in deltaic West Bengal and N.E. India. Breeds mainly in paddy fields.
- i. *Anopheles varuna*: Secondary vector in Andhra Pradesh, Jharkhand and Orissa.

Bionomics of important vector species. The behaviour of the four important vector species is given below:

	<i>An. culicifacies</i>	<i>An. stephensi</i>	<i>An. f/u via tilis</i>	<i>An. minimus</i>	<i>An. dirus</i>
Site of breeding	Water in paddy fields, wells, irrigation wells, step wells, ponds, cattle water storages, cattle foot prints	Clean water in water tanks, water logged in trenches, large clean water puddles, upturned cans, etc	Rock pools, hilly streams, ponds	Shaded slow flowing streams with grassy margins, swamps, ditches, channels	small, transient, partly sh8rlerl pools in forest areas (eg. Elephant footprints)
Zoophilic anthropophilic	Zoophilic; Occasionally anthropophilic	Zoophilic/ Anthropophilic according to availability	Anthropophilic	Highly anthropophilic	Highly anthropophilic
Seasonality	Peaks during monsoon months	Rainy months	Peaks in late monsoons and early winter months	Perennial	Rainy months
Peak Time of biting	Varies - (1900 to 0400)	Varies- (2200 to midnight)	Late night (2300 to 0300)	1800 to 1900 (Outdoors); Midnight to 0200 (Indoors)	2100 - 03:00 Hrs
Preferred place of biting	Endophagic	Endophagic	Endophagic & exophagic	Endophagic & Exophagic	Primarily Exophagic & Endophagic as well
Resting behaviour	Endophilic	Endophilic	Endophilic/ Exophilic	Endophilic/ Exophilic	Exclusively Exophilic
Biological efficiency as vector	Low	Low	High	High	High

Chapter-5

Case detection, Case Management and Chemoprophylaxis

The objectives of malaria case management are:

- ☐ To prevent severe disease and death in patients presenting with uncomplicated malaria
- ☐ To shorten the duration of symptoms
- ☐ To reduce malaria transmission
- ☐ To prevent relapses of vivax malaria

Recognition of malaria

People living in malaria-endemic areas need to be informed that any febrile disease might be malaria and that malaria can rapidly become a very dangerous disease. They also need to be informed about where they can obtain qualified care for malaria. This is particularly important for migrants to endemic areas (for example temporary labour), who may be ignorant both of what malaria is and where treatment is available.

Diagnosis of malaria

A patient with fever and no other obvious cause is considered a case of *suspected malaria*. A more elaborate definition is presented in the table *Case definitions applied in NVBDCP*. In practice the ascertainment of an “obvious cause” can only be expected from well-trained and experienced health staff. A volunteer or health activist working in a high-risk area should be taught to consider any fever case in the absence of specified symptoms as suspected malaria.

Any volunteer, health worker or health professional observing a case of suspected malaria must immediately initiate a diagnostic test by

1. Microscopy of blood for malarial parasites and/or
2. Rapid Diagnostic Test¹ for *Pf*

If a microscopy result can be made available to the provider managing the patient within 24 hours (in practice on the day, when the patient presents or the day after), only microscopy is done. Antimalarial treatment is given only on the basis of a positive slide-result. If a microscopy result cannot be available within 24 hours, the procedure depends on the risk of *P.falciparum*. RDTs are to be supplied and used for diagnosis in villages (or subcenter areas, where village data is not available) where

- ☐ Pf % > 30 and SfR > 2%:
- ☐ Consistently high API and deaths are reported
- ☐ Inaccessible areas - cut off during transmission season
- ☐ Limited road and public transportation facility for treatment of severe and complicated malaria requiring immediate medical attention

An RDT is done in front of the patient and a slide is taken. If the RDT is negative, the slide is sent for microscopy. If it is positive, the patient is treated for falciparum malaria,

Currently, the program uses HRP2 based rapid diagnostic tests and the slide is discarded in order to reduce the load on the microscopy services. Mixed infection cannot be ruled out in such cases, but the risk is low. The ACT treatment for *P.falciparum* is also effective for the blood stages of *P.vivax*. If the patient should have a *P.vivax* relapse later, he or she is expected to return and then be diagnosed and treated with primaquine.

Wherever a microscopy result **can** be made available within 24 hours, microscopy should be maintained as the only routine method. RDTs should be used in PHC and other health facilities only in emergencies in the absence of the laboratory technician (LT).

It should be noted that these tests have a shelf-life of only 12 months and that they may deteriorate at high ambient temperatures.

Interpretation of rapid diagnostic tests

HRP2-based tests for *P.falciparum* detect a circulating antigen excreted by asexual plasmodia. The tests have a sensitivity of about 95%, when the asexual parasite density is above 100/ μl . Malaria patients are rarely symptomatic at lower densities. If a suspected malaria patient has a negative RDT, it can therefore be assumed that the patient does not have malaria and another cause of the symptoms should be sought. If no other cause can be found and the clinical suspicion is high (e.g. intermittent fever with rigors and sweats), the test should be repeated after about 24 hours and special efforts should be made to obtain the microscopy result rapidly.

HRP2 antigen can persist for up to 4 weeks after clearance of asexual parasitaemia through treatment. False positive tests are therefore common, especially in patients with a recent history of treatment. RDTs should therefore **not** be used for following up patients after treatment. They are not useful to monitor prognosis. If a patient, who has been treated, is febrile within one month after the treatment and the RDT is positive, the patient **may** have malaria. If possible, the diagnosis should then be confirmed by microscopy.

Quality microscopy remains the best method of diagnosis. Functional microscopy facility should therefore be strategically positioned in all PHCs, especially in high risk areas. If needed, laboratory staff under NRHM & RNTCP should be trained on malaria microscopy. Where an LT position is vacant, contractual recruitment should be undertaken.

Chapter-6 Treatment

Antimalarial drugs used in public health in India

- Schizonticidal drugs - Chloroquine, quinine, sulfadoxine-pyrimethamine, artemisinin derivatives: artesunate, arte-mether, arte-ether (artemotil).
- Gametocytocidal and anti-relapse drug - Primaquine

Selection of drugs

All fever cases diagnosed positive by either RDT or microscopy need to be promptly started on effective treatment. The treatment will depend upon the species of *Plasmodium* diagnosed.

Treatment of uncomplicated falciparum malaria

Artesunate 4mg/kg daily for 3 days plus sulfadoxine-pyrimethamine 25mg/kg + 1.25 mg/kg as a single dose on the first day (ACT) plus primaquine (PQ) in a single dose on the first day. For North Eastern States where late treatment failure have been reported, SP-ACT is being replaced by ACT-AL (Artemether + Lumefantrine). Treatment Details are given below:

For malaria control, the main thrust of the National Vector Borne Diseases Control programme (NVBDCP) is on early diagnosis and prompt, complete and effective treatment. Malaria diagnosis is carried out by microscopic examination of blood films collected by active and passive agencies. Health agencies and volunteers treating fever cases in inaccessible areas are being provided with Rapid Diagnostic Test (RDT) kits (Pf specific so far and now Bivalent RDT) for diagnosis of Malaria cases so as to provide full radical treatment to the confirmed cases. It is stressed that all fever cases should be suspected of malaria after ruling out other common causes and should be investigated for confirmation of malaria by Microscopy or Rapid Diagnostic Kit (RDK) so as to ensure treatment with full therapeutic dose with appropriate drug to all confirmed cases. Presumptive treatment of malaria with a single dose of chloroquine has been stopped. In all cases of suspected malaria which cannot be immediately confirmed by tests, full treatment with chloroquine for 3 days should be given. The malaria case management is very important for preventive serious cases and death due to malaria. So, the

private healthcare providers should also follow the common National Guidelines for treatment of malaria as per the Drug Policy 2010.

The aims of the Malaria case management are:

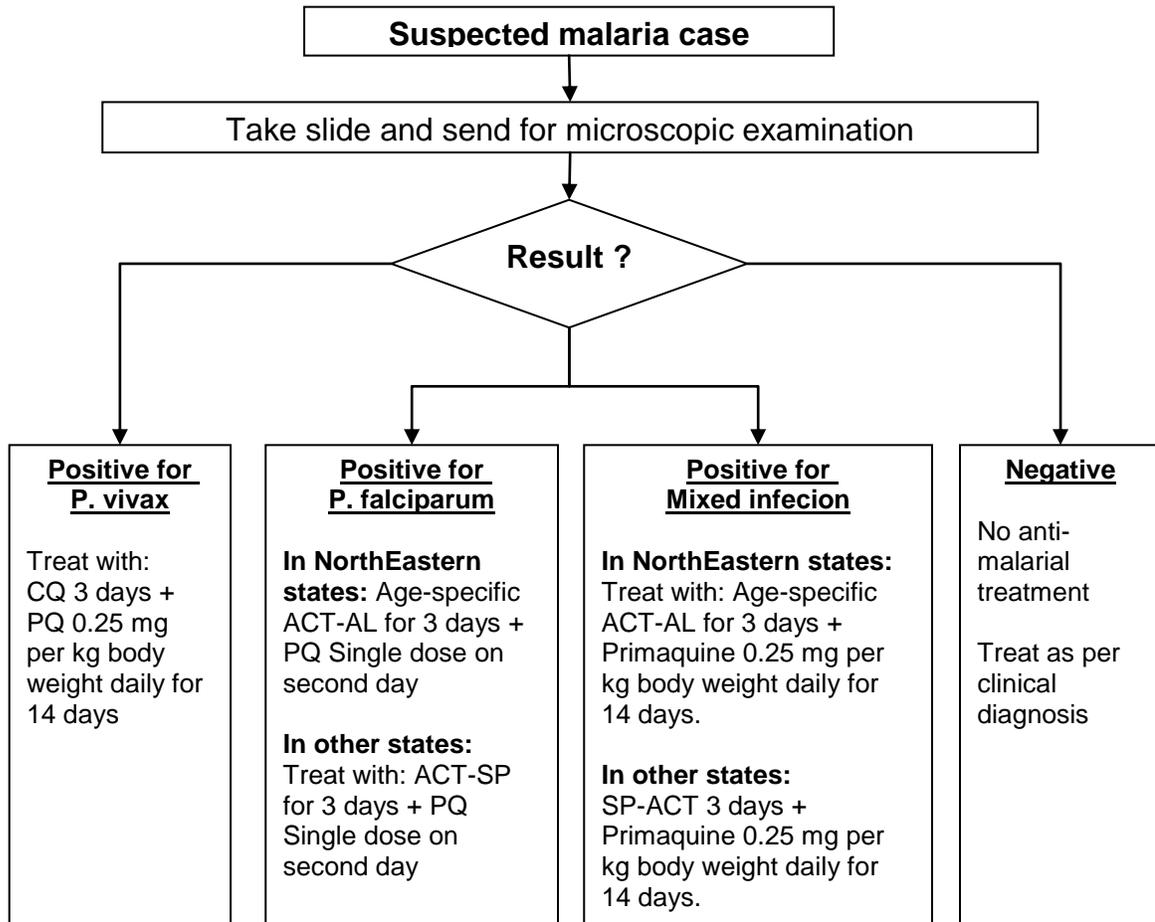
- To provide prompt and complete treatment to all suspected/ confirmed cases of malaria
- To prevent progression of mild cases of malaria in to severe or complicated from of malaria
- To prevent deaths from severe and complicated malaria
- To prevent transmission of malaria
- To minimize risk of spread of drug resistant parasites by use of effective drugs in appropriate dosage by everyone.

Diagnosis and Treatment for Malaria

Diagnosis & Treatment

All fever cases diagnosed as malaria by either RDT or microscopy should be promptly given effective treatment. The medicine chosen will depend upon whether the patient has vivax malaria or falciparum malaria as diagnosed by the blood test. The flow charts in different settings for diagnosis and drug selection for the treatment of malaria are as under:

Where microscopy result is available within 24 hours



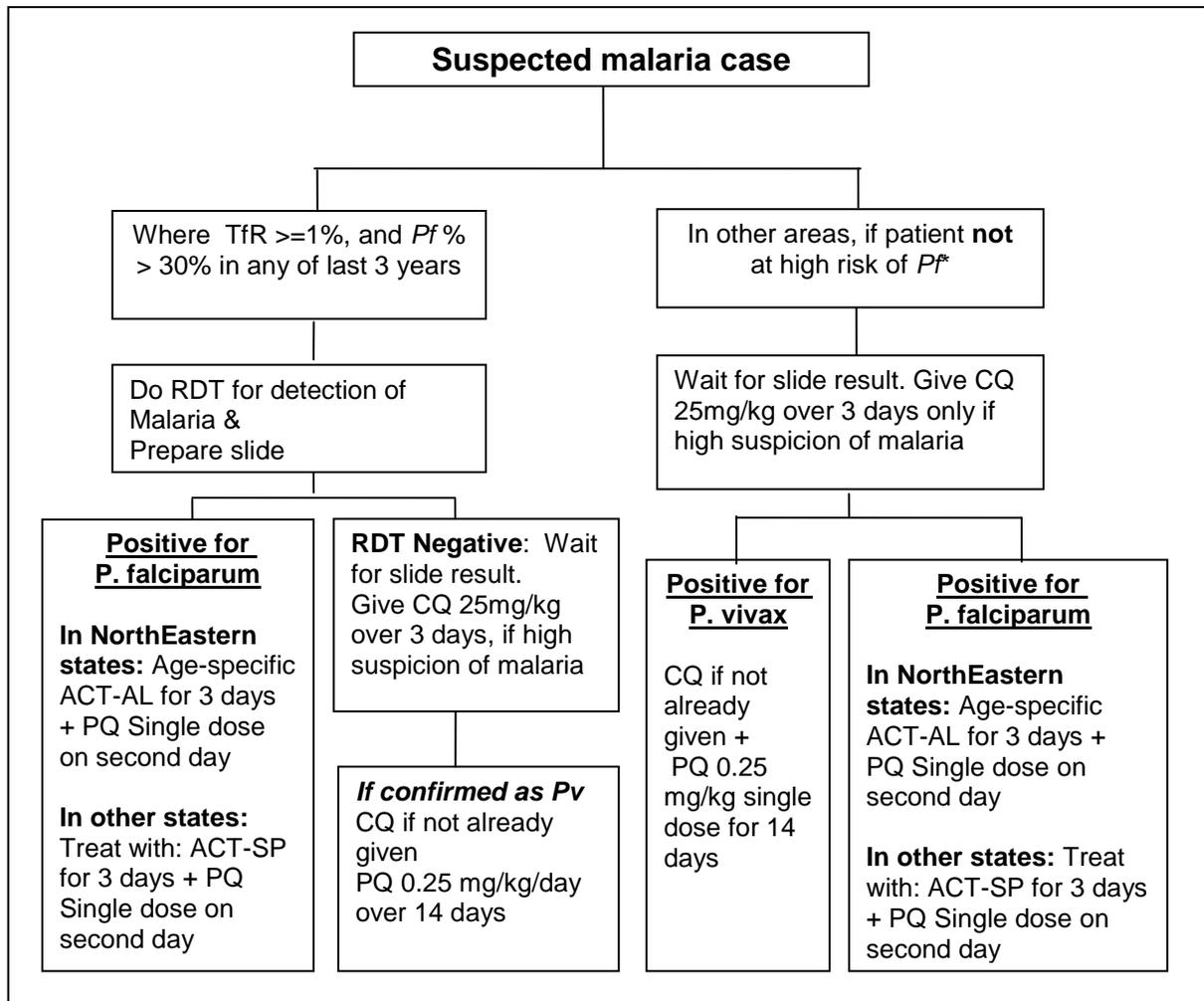
ACT-AL - Artemisinin-based Combination Therapy- Artemether - Lumefantrine

ACT-SP- Artemisinin-based Combination Therapy (Artesunate+Sulfadoxine-Pyrimethamine)

CQ - Chloroquine

PQ - Primaquine

Where microscopy result is not available within 24 hours and Monovalent RDT is used



TfR= Test falciparum rate

Note: if a patient has severe symptoms at any stage, then immediately refer to a nearest PHC or other health facility with indoor patient management or a registered medical doctor.

Note: PQ is contra-indicated in pregnancy and in children under 1 year (Infant).

ACT-AL - Artemisinin-based Combination Therapy- Artemether - Lumefantrine

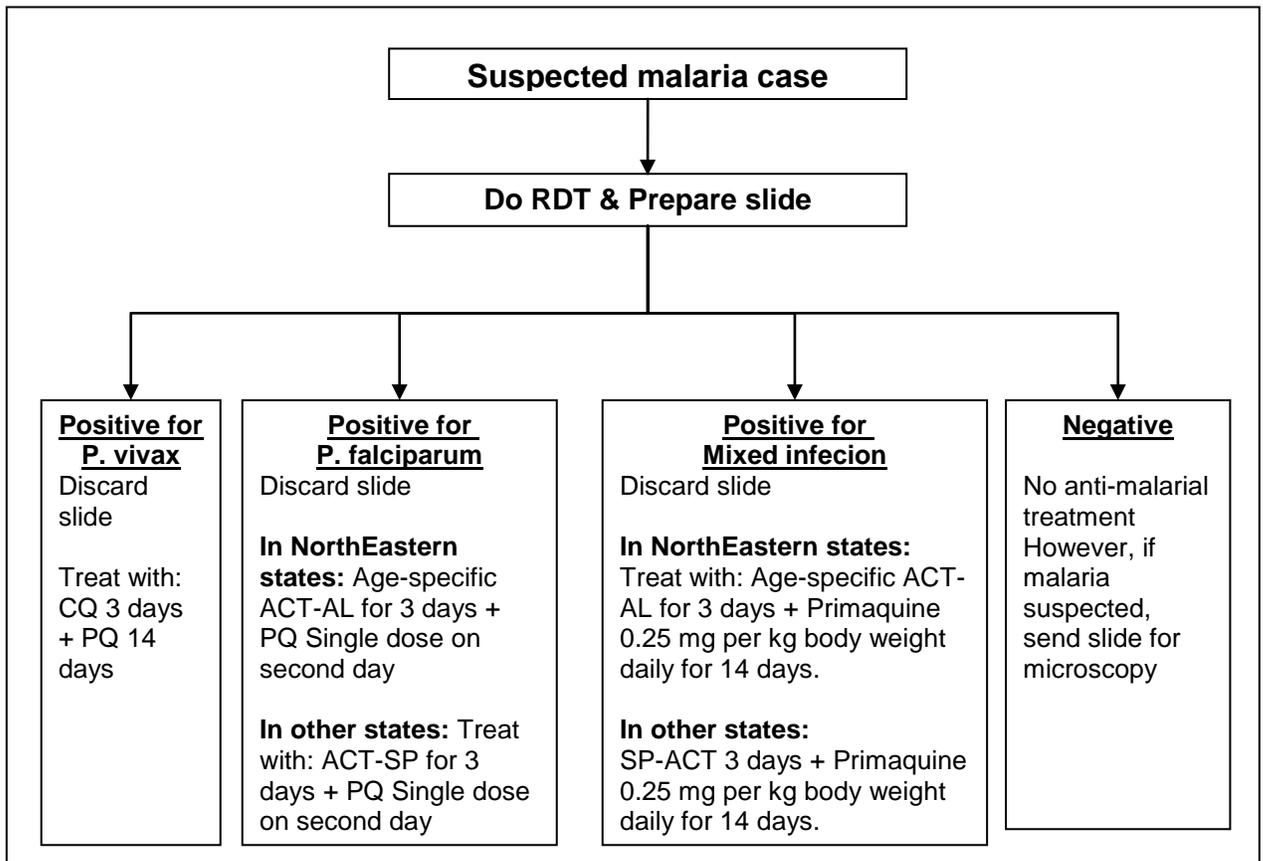
ACT-SP- Artemisinin-based Combination Therapy (Artesunate+Sulfadoxine-Pyrimethamine)

CQ - Chloroquine

PQ - Primaquine

Where microscopy result is not available within 24 hours and Bivalent RDT is

used



Note: if a patient has severe symptoms at any stage, then immediately refer to a nearest PHC or other health facility with indoor patient management or a registered medical doctor.

Note: PQ is contra-indicated in pregnancy and in children under 1 year (Infant).

ACT-AL - Artemisinin-based Combination Therapy- Artemether - Lumefantrine

ACT-SP- Artemisinin-based Combination Therapy (Artesunate+Sulfadoxine-Pyrimethamine)

CQ - Chloroquine

PQ - Primaquine

Treatment of *Vivax* Malaria

Diagnosis of *vivax* malaria may be made by the use of RDT (Bivalent) or microscopic examination of the blood smear. On confirmation following treatment is to be given:

Drug schedule for treatment of *P vivax* malaria:

1. Chloroquine: 25 mg/kg body weight divided over three days i.e.
 10 mg/kg on day 1,
 10 mg/kg on day 2 and
 5 mg/kg on day 3.

2. Primaquine*: 0.25 mg/kg body weight daily for 14 days.

Primaquine is contraindicated in infants, pregnant women and individuals with G₆PD deficiency.

14 day regimen of Primaquine should be given under supervision.

Dosage Chart for Treatment of *Vivax* Malaria

Age	Day 1		Day 2		Day 3		Day 4 to 14
	CQ (250 mg)	PQ (2.5 mg)	CQ (250 mg)	PQ (2.5 mg)	CQ (250 mg)	PQ (2.5 mg)	PQ (2.5 mg)
Less than 1 yr	½	0	½	0	¼	0	0
1-4 years	1	1	1	1	½	1	1
5-8 years	2	2	2	2	1	2	2
9-14 years	3	4	3	4	1½	4	4
15 yrs or more*	4	6	4	6	2	6	6
Pregnancy	4	0	4	0	2	0	0

Treatment of *Falciparum* Malaria

Diagnosis of *falciparum* malaria may be made by the use of RDT (Monovalent or Bivalent) or microscopic examination of the blood smear. It is imperative to start the treatment for *falciparum* malaria immediately on diagnosis. The treatment for *falciparum* malaria is as follows:

In North-Eastern States (NE States):

1. ACT-AL Co-formulated tablet of ARTEMETHER(20 mg) - LUMEFANTRINE (120 mg)

(Not recommended during the first trimester of pregnancy and for children weighing < 5 kg)

Recommended regimen by weight and age group

The packing size for different age groups based on Kg bodyweight.

Co-formulated tablet ACT-AL	5–14 kg (> 5 months to < 3 years)	15–24 kg (≥ 3 to 8 years)	25–34 kg (≥ 9 to 14 years)	> 34 kg (> 14 years)
Total Dose of ACT-AL	20 mg/120 mg twice daily for 3 days	40 mg/240 mg twice daily for 3 days	60 mg/360 mg twice daily for 3 days	80 mg/480 mg twice daily for 3 days
	Pack size			
No. of tablets in the Packing	6	12	18	24
Give	1 Tablet twice daily for 3 days	2 Tablets twice daily for 3 days	3 Tablets Twice daily for 3 days	4 Tablets Twice daily for 3 days
Colour of the pack	Yellow	Green	Red	White

2. Primaquine*: 0.75 mg/kg body weight on day 2

In other States:

1. Artemisinin based Combination Therapy (ACT-SP)*

Artesunate (AS), available as 50 mg tablets are given for three days, and Sulfadoxine-Pyrimethamine (S-P) tablets, containing 500 mg Sulfadoxine and 25 mg pyrimethamine are given for one day, as shown in the dosage chart below. All tablets for a day should be taken together, swallowed with water. In addition, Primaquine (PQ Large) tablets should be given on the second day.

Dose schedule for Treatment of uncomplicated *P.falciparum* cases:

1. Artemisinin based Combination Therapy (ACT-SP)*

Artesunate 4 mg/kg body weight daily for 3 days Plus

Sulfadoxine (25 mg/kg body weight) – Pyrimethamine (1.25 mg/kg body weight) on first day.

* ACT is not to be given in 1st trimester of pregnancy.

2. Primaquine*: 0.75 mg/kg body weight on day 2.

With the introduction of different coloured Blister Packs for different age groups, treatment by the field level staff has been made easy. The colour code for different age groups for Packing of Tablet ACT+SP has been given as follows:

Dosage Chart for Treatment of *falciparum* Malaria with ACT-SP

Age Group (Years)	1 st day		2 nd day		3 rd day
		AS	SP	AS	PQ

0-1 Pink Blister	1 (25 mg)	1 (250 +12.5 mg)	1 (25 mg)	Nil	1 (25 mg)
1-4 Yellow Blister	1 (50 mg)	1 (500+25 mg each)	1 (50 mg)	1 (7.5 mg base)	1 (50 mg)
5-8 Green Blister	1 (100 mg)	1 (750+37.5 mg each)	1 (100 mg)	2 (7.5 mg base each)	1 (100 mg)
9-14 Red Blister	1 (150 mg)	2 (500+25 mg each)	1 (150mg)	4 (7.5 mg base each)	1 (150 mg)
15 & Above White Blister	1 (200 mg)	2 (750+37.5 mg each)	1 (200 mg)	6 (7.5 mg base each)	1 (200 mg)

Treatment of uncomplicated *P.falciparum* cases in pregnancy:

1st Trimester : Quinine salt 10mg/kg 3 times daily for 7 days.

Quinine may induce hypoglycemia; pregnant women should not start taking quinine on an empty stomach and should eat regularly, while on quinine treatment.

2nd and 3rd trimester: Area-specific ACT as per dosage schedule given above.

i.e. **ACT-AL in North Eastern States**

ACT-SP in Other States

Primaquine (PQ) prevents transmission of falciparum malaria to others by its ability to kill gametocytes. PQ tablets should be taken after a meal; not on an empty stomach. Children less than the age of one year and pregnant women should not be given Primaquine. As pregnant women having falciparum malaria require different medicines, they should be directed to go to the nearest PHC or hospital immediately, without delay.

Treatment of mixed infections (*P.vivax* + *P.falciparum*) cases:

All mixed infections should be treated with full course of ACT and Primaquine 0.25 mg per kg body weight daily for 14 days.

In North-Eastern States: Treat with: Age-specific ACT-AL for 3 days + Primaquine 0.25 mg per kg body weight daily for 14 days.

In Other States: SP-ACT 3 days + Primaquine 0.25 mg per kg body wt. daily for 14 days.

Dosage Chart for Treatment of mixed (*vivax and falciparum*) Malaria with ACT-SP

Age	Day 1			Day 2		Day 3		Days 4-14
	AS tablet (50 mg)	SP tablet	PQ(2.5 mg)	AS tablet (50 mg)	PQ (2.5 mg)	AS tablet (50 mg)	PQ (2.5 mg)	PQ (2.5 mg)
Less than 1 yr	½	½	0	½	0	½	0	0
1-4 years	1	1	1	1	1	1	1	1
5-8 years	2	1½	2	2	2	2	2	2
9-14 years	3	2	4	3	4	3	4	4
15 yrs or more	4	3	6	4	6	4	6	6

Treatment of *P. ovale* and *P. malariae*:

In India these species are very rarely found in few places. *P. ovale* should be treated as *P. vivax* and *P. malariae* should be treated as *P. falciparum*.

Treatment of mixed infections:

All cases of mixed infection are to be treated as Pf as per the drug policy applicable in the area plus primaquine for 14 days

Use of paracetamol

Paracetamol tablets are available as part of the ASHA kit also in the health facilities. Paracetamol usually brings down fever from any cause within half an hour. However,

paracetamol does not cure the disease that is causing the fever. So, its effect does not last long. The fever remains low for about 4-6 hours, and then the fever can rise again. Paracetamol can be safely given at any age and even during pregnancy, in the dose shown in the dosage chart. In this dose, it can be given 3-4 times a day if needed. If the fever is not very high, and the patient is able to tolerate the fever, there is no need to give paracetamol.

Dosage chart for use of Paracetamol

Age	No. of Tablets of Paracetamol (500 mg tablets)
Less than 1 yr	$\frac{1}{4}$
1-4 years	$\frac{1}{2}$
5-8 years	$\frac{3}{4}$
9-14 years	1
15 yrs or more	1 or 2

Initiation of treatment and advice to the patient/caretaker

Once a suspected case is diagnosed positive by RDT or microscopy, treatment is started. The first dose is always taken in the presence of the health volunteer/worker. The blister pack with remaining tablets is given to the patient/caretaker to take home with clear instructions.

Caution: If the patient is a child under 5 years or pregnant, ask the patient to wait for 15 minutes after taking the first dose. If it is vomited within this period, let the patient rest for 15 minutes, then give the first dose again i.e. open a new blister-pack and discard what remains of the old. If the patient vomits the first dose again, it is considered a case of severe malaria, refer the patient immediate to the nearest Block PHC/ CHC/ Hospital.

Explain to the patient/caretaker

- That if the treatment is not completed as prescribed, the disease may manifest again with more serious features and more difficult to treat.

- To come back immediately, if there is no improvement after 24 hours, if the situation gets worse or the fever comes back.
- That regular use of a mosquito net (preferably insecticide treated net) is the best way to prevent malaria.

Resistance to anti-malarial drugs.

Resistance can be defined as either the ability of a parasite strain to survive and/or multiply despite the administration and absorption of a drug given in doses equal to or higher than those usually recommended, but within the limits of tolerance of the patient.

In the last two decades, an increasing proportion of *Plasmodium falciparum* infections is proving to be resistant to chloroquine in India. Drug resistance is declared in a study area, when the proportion of treatment failures exceeds 10% of all falciparum infections. In these areas the decision has been taken to treat all Pf cases with the drug ACT instead of chloroquine,

Why does malaria parasite become resistant to anti-malarials?

Drug resistance is a complex phenomenon, where by genetic mutation, a parasite acquires the ability to resist, partly or fully, the effects of one or more anti-malarial drugs. When the resistant parasites are exposed to the drug, they multiply selectively. If parasites are resistant to the drug being used, the patient may not respond to treatment.

One of the commonest reasons for the development of drug resistance is that the parasites are exposed to insufficient amount of the drug due to

- Low prescription dosage
- Lesser amount of drug dispensed
- Incomplete treatment taken by the patient
- Drug vomited out
- Low absorption due to any reason, for example, diarrhoea.

In such cases, most of the sensitive parasites are killed by even these small doses, but resistant parasites survive, multiply and spread to other people by mosquitoes. The new patient then gets infection from the resistant malaria parasites and does not respond to the

drug at all, or responds only partly. Meanwhile, the earlier patient may appear cured because most of the parasites were killed by the drug, and the symptoms abated.

Why is it difficult for parasites to develop resistance to ACT?

ACT contains three drugs: artesunate, sulphadoxine and pyrimethamine. Each drug acts on a different part of the parasite, in a different manner. It is very, very rare for three simultaneous genetic mutations to occur by chance to produce resistance to such diverse drugs. Resistance can be produced in multiple steps, one drug at a time, but this is expected to take many more years. At present, we do not expect resistance to develop to ACT. If resistance develops, it is expected to first develop against sulphadoxine or pyrimethamine, since they have been in use for a longer time. If this begins to happen, some other, newer drug will be used as a companion drug for artesunate, to which resistance has so far not been reported in most malarious areas of the world.

How can one suspect drug resistance in the field? What can one do when faced with treatment failure?

As mentioned above, when a patient fails to respond to treatment (symptoms fail to disappear, or they re-appear), one should think of the possibility of drug resistance. However, there may be many other causes of persistent symptoms:

- the diagnosis might be wrong (the patient had a positive test, but the symptoms were due to some other cause)
- the drug might not have been taken as expected (insufficient dosage was prescribed or swallowed), or may have been vomited out
- the drug was not absorbed in the gut (because of diarrhea, or other reasons), the drug may be of poor quality (past its date of expiry, or poorly stored, or of poor quality when supplied)
- the patient's body might handle the drug abnormally (there are genetic differences in the metabolism of some rare individuals, which may cause the drug to be altered or eliminated quickly)
- the patient might have had a fresh reinfection, or in the case of vivax malaria, there might have been a relapse of the malaria.

In the absence of any of these conditions, if a patient has completed full treatment and is still having symptoms after 72 hours, treatment failure may be suspected.

The course of action when a patient has persistent symptoms is:

- Ask the patient and the family a series of questions to help rule out some of the causes listed above (Did the patient get the drug from an authentic, designated provider? Did the patient get the right amount of the drug? Was all of it swallowed as prescribed? Was the drug vomited out? How many days has it been since drug treatment was begun (if it is not yet 72 hours, one can wait)? Can you see the packing to check the expiry date? Are there symptoms of other obvious causes of fever? If the symptoms had disappeared and then reappeared, how long was the interval (if more than 15 days, it could be a fresh infection)?)
- If it appears that the drug was not adequately taken or retained, a fresh course may be given at home unless the patient has symptoms of severe malaria. Take a fresh blood smear (take two, for checking in different laboratories, if need be), and ask the nearest health care provider to keep an eye on the patient.
- Refer any patient who has symptoms despite taking and retaining a full course of treatment, or who has developed symptoms of severe malaria.

Severe and complicated malaria

A case of uncomplicated malaria usually presents with fever, rigors, headache, bodyache, fatigue, anorexia and nausea.

Serious complications can arise in *P.falciparum* infection and rarely in *P vivax*. They may sometimes develop suddenly over a span of time as short as 12 -24 hours and may lead to death, if not treated promptly and adequately. Severe malaria is clinically characterized by confusion or drowsiness with extreme weakness (prostration). In addition, the following may develop:

- cerebral malaria with generalized convulsions
- pulmonary oedema
- severe anaemia

- renal failure
- hypoglycaemia
- metabolic acidosis
- circulatory collapse/shock
- spontaneous bleeding and laboratory evidence of DIC
- macroscopic haemoglobinuria
- hyperthermia
- hyperparasitaemia

In children, febrile convulsions, repeated vomiting and dehydration are common if the temperature is high due to any cause. Therefore, these symptoms are not necessarily indicative of severe malaria. However, children with such symptoms should be managed as severe malaria in routine program situations, and a diagnosis of malaria should be confirmed at the earliest.

In pregnancy, malaria, especially *P.falciparum* is a serious disease because with each bout of malaria, there is a reduction in haemoglobin and profound anaemia may develop rapidly. They are also at high risk of abortions or intrauterine growth retardation because sequestration of parasites in placenta restricts oxygen and nutrients flow to the fetus.

The management of severe malaria is possible in health facilities which are equipped with the following:

- Parenteral Antimalarials , antibiotics, anticonvulsants, antipyretics
- Intravenous infusion equipment and fluids
- Special nursing for patients in coma
- Facilities for blood transfusion
- Well equipped laboratory
- Oxygen respirator

Often these items are not available at the PHC level. Under such circumstances, the Medical Officer, PHC and paramedical staff should be able to administer emergency treatment and

refer the case without delay to other institutions where such facilities are available.

A list of all health care facilities in the district where emergency care for severe malaria is available should be kept in PHCs and with Community Workers like ASHA. MO-PHC will maintain liaison with all these institutions. For timely referral of severe cases, transportation arrangements should be made with the use of untied funds available under NRHM.

The role of peripheral workers

The community comes in contact with ASHA and MPW (M&F) as a routine. They depend on these persons for advice and treatment of different diseases, malaria being one of them. Therefore, while training these workers the need to recognize a serious case of malaria should be emphasized. These workers should be conversant with the signs and symptoms of malaria and those which are likely to indicate serious complications.

Severe malaria may be suspected, if the patient does not get relief from symptoms of malaria within 24 hours, and/or headache/fever continues to increase. Such patients should be referred immediately to the nearest PHC/CHC/Hospital.

Criteria for immediate referral to Primary Health Centre:

- a) Persistence of fever after 24 hours of initial treatment.
- b) Continuous vomiting and inability to retain oral drugs.
- c) Headache continues to increase
- d) Severe dehydration – dry, parched skin, sunken face
- e) Too weak to walk in the absence of any other obvious reason
- f) Change in sensorium e.g. confusion, drowsiness, blurring of vision, photophobia, disorientation
- g) Convulsions or muscle twitchings
- h) Bleeding and clotting disorders
- i) Suspicion of severe anaemia
- j) Jaundice
- k) Hypothermia

Requirements for management of complications:

The management of severe malaria requires immediate administration of life saving drugs. Therefore essential requirements for management of severe malaria are as follows:

- A person trained in nursing serious/ comatose cases
- Antimalarials which can be given parenterally: Artesunate, arte-ether, arte-mether or quinine
- Supportive treatment: Antipyretics, anticonvulsants, diuretics, antibiotics, Saline/dextrose for intravenous transfusion
- Intravenous infusion equipment
- Facilities for blood transfusion
- Well equipped laboratory: Blood smear examination & parasite count with result within one hour, Routine examination of urine, haemoglobin, blood glucose
- Oxygen respirator, Oxygen

If these items are not available, the patient must be referred without delay to a facility, where such facilities are available. The DVBDCO/ DMO should list all facilities in the district where emergency care for severe malaria is available and this list should be available in PHCs and with all Community Workers like ASHA. MO-PHC should develop links with these institutions. For timely referral of severe cases, transportation is provided from untied funds available under NRHM from Rogi Kalyan samity (RKS).

Treatment of severe malaria cases

Severe malaria is an emergency and treatment should be given as per severity and associated complications which can be best decided by the treating physicians. Before admitting or referring patients, the attending doctor or health worker, whoever is able to do it, should do RDT and take blood smear; give a parenteral dose of artemisinin derivative or quinine in suspected cerebral malaria cases and send case sheet, details of treatment history and blood slide with patient. The guidelines for specific antimalarial therapy is as follows:

Parenteral artemisinin derivatives or quinine should be used irrespective of chloroquine resistance status of the area with one of the following options:

Chemotherapy of severe and complicated malaria

<p>Initial parenteral treatment for at least 48 hours: CHOOSE ONE of following four options</p>	<p>Follow-up treatment, when patient can take oral medication following parenteral treatment</p>
<ul style="list-style-type: none"> • Quinine: 20mg quinine salt/kg body weight on admission (IV infusion or divided IM injection) followed by maintenance dose of 10 mg/kg 8 hourly; infusion rate should not exceed 5 mg/kg per hour. Loading dose of 20mg/kg should not be given, if the patient has already received quinine. 	<p>Quinine 10 mg/kg three times a day</p> <p>with:</p> <p>doxycycline 100 mg once a day or clindamycin in pregnant women and children under 8 years of age,</p> <p>- to complete 7 days of treatment.</p>
<ul style="list-style-type: none"> • Artesunate: 2.4 mg/kg i.v. or i.m. given on admission (time=0), then at 12 h and 24 h, then once a day. • or • Artemether: 3.2 mg/kg bw i.m. given on admission then 1.6 mg/kg per day. • or • Arteether: 150 mg daily i.m for 3 days in adults only (not recommended for children). 	<ul style="list-style-type: none"> • Full oral course of Area-specific ACT: • In NorthEastern states: Age-specific ACT-AL for 3 days + PQ Single dose on second day • In other states: Treat with: ACT-SP for 3 days + PQ Single dose on second day

Note: The parenteral treatment in severe malaria cases should be given for minimum of 24 hours once started (irrespective of the patient's ability to tolerate oral medication earlier than 24 hours).

After parenteral artemisinin therapy, patients will receive a full course of Area-specific oral ACT for 3 days. Those patients who received parenteral Quinine therapy should receive oral Quinine 10 mg/kg body weight three times a day for 7 days (including the days when parenteral Quinine was administered) plus Doxycycline 3 mg/kg body weight once a day or Clindamycin 10 mg/kg body weight 12-hourly for 7 days (Doxycycline is contraindicated in pregnant women and children under 8 years of age) or area-specific ACT as described.

Note:

- Pregnant women with severe malaria in any trimester can be treated with artemisinin derivatives, which, in contrast to quinine, do not risk aggravating hypoglycaemia.
- The parenteral treatment should be given for minimum of 48 hours
- Once the patient can take oral therapy, give:
- Quinine 10 mg/kg three times a day with doxycycline 100 mg once a day or clindamycin in pregnant women and children under 8 years of age, to complete 7 days of treatment, in patients started on parenteral quinine.
- Full course of ACT to patients started on artemisinin derivatives.
- Use of mefloquine should be avoided in cerebral malaria due to neuropsychiatric complications associated with it.

Some don'ts in severe malaria case management

Do not use corticosteroids, give intravenous mannitol, use heparin as anticoagulant, administer adrenaline or overhydrate.

In recent years, increased attention has been drawn to severe malaria caused by P.vivax,

especially in Indonesia and Papua New Guinea, where this parasite has become chloroquine-resistant. Some cases have been found in India, and there is reason to fear that this problem will become more common in the coming years. Historically, *P. vivax* has been an important cause of death in India and in Europe, and this parasite can no longer be considered as “benign”.

Chemoprophylaxis

Chemoprophylaxis should be administered only in selective grips in high *P. falciparum* endemic areas. Use of personal protection measures including Insecticide Treated bed Nets (ITN) / Long Lasting Insecticidal Nets (LLIN) should be encouraged for pregnant women and other vulnerable population including travelers for longer stay. However, for longer stay of Military and Para-Military forces in high *Pf* endemic areas, the practice of chemoprophylaxis should be followed wherever appropriate e.g troops on night patrol duty and decisions of their Medical Administrative Authority should be followed.

Short term chemoprophylaxis (up to 6 weeks)

Doxycycline : 100 mg once daily for adults and 1.5 mg/kg once daily for children (contraindicated in children below 8 years). The drug should be started 2 days before travel and continued for 4 weeks after leaving the malarious area.

Note : It is not recommended for pregnant women and children less than 8 years

Chemoprophylaxis for longer stay (more than 6 weeks)

Mefloquine: 250 mg weekly for adults and should be administered two weeks before, during and four weeks after exposure.

Note : Mefloquine is contraindicated in individuals with history of convulsions, neuropsychiatric problems and cardiac conditions. Therefore, necessary precautions should be taken and all should undergo before prescription of the drug.

Use of chemoprophylaxis is limited to following situations:

Short term travelers/tourists (less than 6 weeks) from non-malarious areas to malarious areas. Drug of choice is Doxycycline 100 mg daily in adults and 1.5 mg/kg bwt in children above 8 years; beginning 2 days before travel – 4 weeks after leaving a malarious area. Doxycycline is contraindicated in children under 8 years and pregnant women, in whom personal protection should be used

In long term travelers where appropriate e.g. military & paramilitary troops on night patrol duty etc. in malarious areas, the decision of respective medical administrative authority is to be followed. Drug of choice in such cases is Mefloquine 250 mg weekly for adults and 5 mg/kg for children once a week; beginning 2 weeks before to 4 weeks after exposure.

In low-risk areas with PV predominance and Pf is sensitive to chloroquine resistance, the Pf cases will be treated with chloroquine and primaquine. Similarly, the clinical cases (unconfirmed cases) will also be treated with chloroquine in situations where diagnosis is not possible within reasonable time, no later than the day after fever is reported to the health facility.

Contra-indications

Primaquine is contraindicated in pregnancy, children under one year and persons with a history of haemolysis following primaquine treatment. Patients belonging to these categories should not receive primaquine.

Precautions

Sulfadoxine-pyrimethamine can, in rare, cases cause serious cutaneous or mucocutaneous eruptions and/or agranulocytosis. Any patients with a cutaneous or mucocutaneous reaction within a month after taking sulfadoxine-pyrimethamine should, if there is not an obvious alternative explanation be considered allergic to sulphonamides and not be given sulfonamide treatment again. Suspected cases of ACT side effects should be reported to NVBDCP with individual case reports.

Artemisinin derivative monotherapy must not be given under any circumstance for uncomplicated malaria, as there is great concern that use of such monotherapy could lead to artemisinin resistance.

Treatment failures

Treatment failures are expected to be very rare with ACT. Most cases of apparent treatment failures will probably be caused by inadequate patient compliance. Therefore, apparent treatment failures should be re-treated with ACT, if they occur at least 14 days after initial

treatment. Earlier treatment failures should be treated with quinine to minimize the risk of side-effects from repeated treatment with sulfadoxine-pyrimethamine. NVBDCP and NIMR jointly monitor the susceptibility to ACT in sentinel sites.

Treatment of uncomplicated vivax malaria

Chloroquine (CQ) for 3 days (Day 1: 10mg/kg + Day 2: 10mg/kg + Day 3: 5mg/kg) plus primaquine 0.25mg/kg daily for 14 days as per prescribed guidelines

Primaquine contra-indications: See above.

Explanation

P. vivax in India remains fully sensitive to chloroquine. This is monitored by NIMR. In recent years, controlled trials have failed to demonstrate any anti-hypnozoite (anti-relapse) effect of primaquine, when given for 5 days. NVBDCP has therefore adopted the 14 day regimen recommended by WHO.

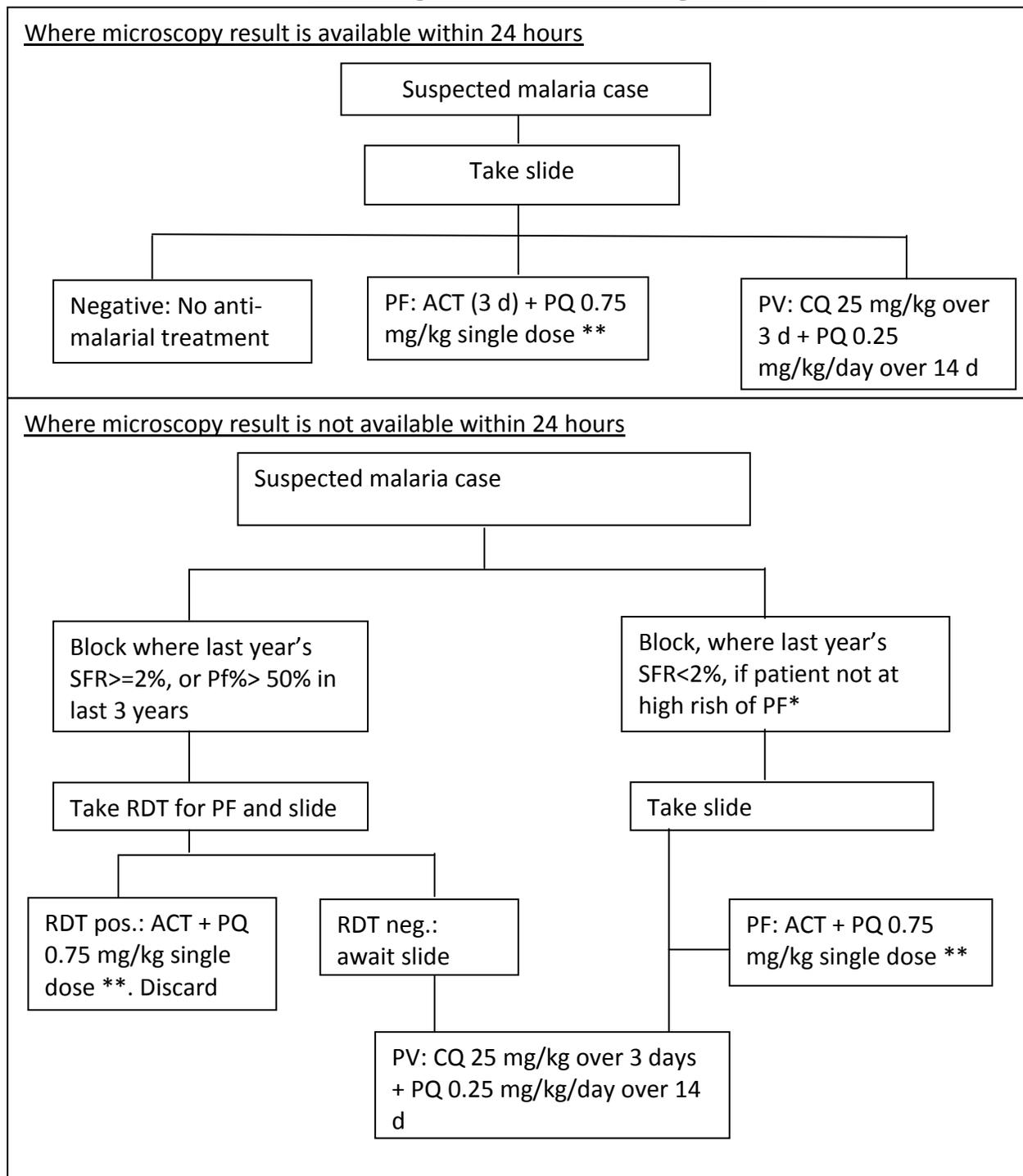
Treatment of uncomplicated mixed infections (of PF and PV)

Artesunate for 3 days plus sulfadoxine-pyrimethamine in a single dose on the first day plus primaquine for 14 days

Contra-indications: See above.

An algorithm for the diagnosis and treatment of fever cases for malaria is given figure:

Fever Diagnosis and Treatment Algorithm



ACT= Artemisinin-based combination therapy (Artesunate + sulfadoxine-pyrimethamine); CQ= Chloroquine; PQ= primaquine

Note that PQ is contra-indicated in pregnancy and in children less than 1 year.

Age-specific Drug Schedules

1. Chloroquine tablets of 150 mg chloroquine base

Age in years	Day 1	Day2	Day -3
	Tab. chloroquine	Tab. Chloroquine	Tab. Chloroquine
<1	'h	'h	%
1-4	1	1	'h
5-8	2	2	1
9-14	3	3	1'h
15&above	4	4	2

2. Primaquine tablets of 7.5 or 2.5 mg base

Age (in years)	<i>P. falciparum</i>		<i>P. vivax</i>	
	Primaquine 0.75 mg/kg on day 1		Primaquine 0.25 mg/kg daily dose for 14 days"	
	mg base	No. of Tablets (7.5 mg base)	mg base	No. of Tablets (2.5 mg base)
<1	Nil	0	Nil	Nil
1-4	7.5	1	2.5	1
5-8	15	2	5.0	2
9-14	30	4	10.0	4
15 & above	45	6	15.0	6

* Primaquine IS contraindicated In children under one year and pregnant women.

3.Artesunate 50 mg tablets + sulfadoxine-pyrimethamine 500 + 25 mg tablets (ACT) combination

Age		1 st Day (number of tabs)"	2 nd Day (number of tabs)	3 rd Day (numbers of tabs)
<1 Year	AS	'h	'h	'h
	SP	%	Nil	Nil
1-4 Yeas	AS	1	1	1
	SP	1	Nil	Nil
5-8 Year	AS	2	2	2
	SP	1'h	Nil	Nil
9-14 Year	AS	3	3	3
	SP	2	Nil	Nil
15 and above	AS	4	4	4
	SP	3	Nil	Nil

* Artemisinin group of drugs is not recommended in pregnancy

3.4.3 Initiation of treatment and advice to the patient/caretaker

Once a suspected case is diagnosed positive by ROT or microscopy, treatment is started. The first dose is always taken in the presence of the health volunteer/worker. If the patient is a child under 5 years or pregnant, ask her or him to wait for 15 minutes after taking the first dose. If it is vomited within this period, let the patient rest for 15

Initiation of treatment and advice to the patient/caretaker

Once a suspected case is diagnosed positive by RDT or microscopy, treatment is started. The first dose is always taken in the presence of the health volunteer/worker. If the patient is a child under 5 years or pregnant, ask her or him to wait for 15 minutes after taking the first dose. If it is vomited within this period, let the patient rest for 15-23 minutes, then give a first dose again (i.e. open a new blister-pack and discard what remains of the old. If the patient vomits the first dose again, it is considered a case of severe malaria (see below).

The remaining part of the treatment is given to the patient/caretaker to take home with clear instructions.

Explain to the patient/caretaker

- That if the treatment is not completed as prescribed, the disease may recur, possibly being more serious and more difficult to treat.
- To come back immediately, if there is no improvement after 24 hours, if the situation gets worse or the fever comes back.
- That regular use of a mosquito net is the best way to prevent malaria.

Recording of treatment

The result of RDT or slide should be entered by ASHA/ Health Worker/ MO in column & 14 of M1. In case of Blood slide the date of receipt of result is to be entered in column 11. This will indicate the time lapse between the date of slide collection and receipt of results. If RDT has not been performed simply mark a cross (X). Now depending upon the species, ASHA/ Health worker/ MO will decide the anti-malarials to be administered. These will be entered in column 15 or 16 of M1. Suppose ACT has been selected then the entry will be made in column 16 while a cross (X) will be put in column 15. The date of starting and completing the treatment will be entered in column 17 and 18. During supervisory visits the time lag between slide collection or RDT and initiation of treatment should be identified.

Severe and complicated malaria

A case of uncomplicated malaria usually presents with fever, rigors, headache, bodyache, fatigue, anorexia and nausea.

Serious complications can arise in *P.falciparum* infection. They may sometimes develop suddenly over a span of time as short as 12-24 hours and may lead to death, if not treated promptly and adequately. These complications are:

- ☒ Cerebral malaria with convulsions, lethargia, coma, paralyses and other

neurologic manifestations

- ☒ Severe anaemia
- ☒ Renal failure, which may be combined with severe haemolytic anaemia in the syndrome of black water fever
- ☒ Adult respiratory distress syndrome, which may progress to pulmonary edema
- ☒ Liver failure with jaundice and haemorrhagic tendency
- ☒ Septicaemia
- ☒ Bacterial pneumonia
- ☒ Hyperpyrexia
- ☒ Dehydration
- ☒ Hypoglycaemia (often caused more by quinine than by malaria)
- ☒ Circulatory shock (rarely with disseminated intravascular coagulation)

In children, febrile convulsions, repeated vomiting and dehydration are common if the temperature is high from any cause. Therefore, these symptoms are not necessarily indicative of severe malaria. However, children with such symptoms should be managed as severe malaria in routine program situations, and a diagnosis of malaria should be confirmed at the earliest.

In pregnancy, malaria, specially *P.falciparum* is a serious disease because with each bout of malaria, there is a reduction in haemoglobin and profound anaemia may develop rapidly. They are also at high risk of abortions or intrauterine growth retardation because sequestration of parasites in placenta restricts oxygen and nutrients flow to the fetus.

The management of severe malaria requires immediate administration of life saving drugs. Therefore availability of the following is essential

- Antimalarials which can be given parenterally.
- Intravenous infusion equipment
- Special nursing for patients in coma
- Facilities for blood transfusion
- Well equipped laboratory
- Oxygen respirator

Often these items are not available at the PHC level. Under such circumstances, the Medical Officer, PHC and paramedical staff should be able to administer emergency treatment and refer the case without delay to other institutions where such facilities are available.

The DVBD/CO/ DMO should list all facilities in the district where emergency care for severe malaria is available and this list should be available in PHCs and with all Community Workers like ASHA. MO-PHC should develop links with these institutions. For timely referral of severe cases, transportation should be provided from untied funds available under NRHM.

The role of peripheral workers

The community comes in contact with ASHA and MPW (M&F) as a routine. They depend on these persons for advice and treatment of different diseases, malaria being one of them. Therefore, Medical Officers **while training these workers should emphasize the need to recognize a serious case of malaria before it is too late.** These workers should be conversant with the signs and symptoms of malaria and those which are likely to indicate serious complications.

They should be **instructed that if the patient does not get relief from symptoms of malaria within 24 hours, and/or headache/fever continues to increase, the patient should report to the nearest PHC/CHC/Hospital.**

Criteria for immediate referral to Primary Health Centre

- a) Persistence of fever after 48 hours of initial treatment.
- b) Continuous vomiting and inability to retain oral drugs.
- c) Headache continues to increase
- d) Severe dehydration – dry, parched skin, sunken face
- e) Too weak to walk in the absence of any other obvious reason
- f) Change in sensorium e.g. confusion, drowsiness, blurring of vision, photophobia, disorientation
- g) Convulsions or muscle twitching
- h) Bleeding and clotting disorders
- i) Suspicion of severe anemia
- j) Jaundice
- k) Hypothermia

Diagnosis

All attempts should be made to confirm the diagnosis using microscopy or RDTs. At PHCs & District level hospitals RDTs should be used in emergency hours only in the absence of technician/microscopist. Wherever possible, treatment should be guided by microscopy. High degree of parasitaemia and presence of stages of the parasite other than ring and gametocyte indicate poor prognosis. Severe malaria in the absence of microscopical evidence of asexual *Plasmodium falciparum* (or *P.vivax*. see below) is exceedingly rare. In such cases, all efforts should be done to identify an alternative cause. If microscopy is negative and RDT is positive for *P.falciparum*, it is possible that the explanation is that antigen is persisting from an earlier infection. However, if the symptoms clearly point to severe malaria and there is no alternative explanation, such a case can be recorded as having severe malaria. Such occurrences are possibly more common in patients, who have started an ACT treatment a few days before. Severe malaria with negative RDT is possible, but extremely rare. A patient with negative microscopy and negative RDT should not be recorded as severe malaria, but may be treated

as such, if the responsible clinician deems it necessary.

Treatment

In severe malaria cases, a parenteral artemisinin derivative **or** quinine is the drug of choice. It has been shown that intravenous artesunate is the most effective treatment for severe malaria in adults in Asia. It is presently being investigated whether this is so for young children also, but there is no reason to assume a priori that it is inferior. If injectable artesunate and the facilities for IV administration are available, this should therefore be the preferred treatment in all patients.

Dosage regimens

Artesunate: 2.4 mg/kg IV/ IM followed by 2.4 mg/kg after 12 and 24 hours then once daily.

Arte-mether: 3.2 mg/kg IM followed by 1.6 mg/kg once daily.

Arte-ether: 150 mg daily IM in adults only for 3 days

Artesunate is dispensed as a powder of artesunic acid. This is dissolved in sodium bicarbonate (5%) to form sodium artesunate. The solution is then diluted in approximately 5 ml of 5% dextrose and given by intravenous injection or by intramuscular injection to the anterior thigh. The solution should be prepared freshly for each administration and should not be stored. Parenteral treatment should continue until the patient is able to take oral treatment. When that is the case, full course of ACT should be administered to patients treated with artemisinin derivatives.

Quinine: 20 mg salt/kg as a loading dose, then 10mg salt /kg 8 hourly in 5% dextrose or dextrose saline. The infusion rate should not exceed 5 mg salt/kg per hour. Loading dose may not be given if the patient has already received quinine or if Clinician feels inappropriate. As soon as the patient is able to take orally, oral quinine should be given. The total duration of treatment should be 7 days including parenteral dose.

Pregnant women with severe malaria should be treated like any other adult patient. In these patients, the benefits of the artemisinin derivatives outweigh the theoretical hazards. Particular attention should be given to the high risk of hypoglycaemia in pregnancy.

Chemoprophylaxis

As chloroquine is no longer considered an effective treatment for falciparum malaria in India, it is no longer used for chemoprophylaxis. In pregnant women, there is no safe and effective alternative to chloroquine, which has been tested in India. Therefore, chemoprophylaxis is no longer recommended as a routine method of prevention in pregnancy. Personal protection should be used in children under 8 years, pregnant women and long term travelers and will now be based on the use of insecticide-treated nets

Use of chemoprophylaxis is limited to following situations:

*a). Short term travelers/Tourists (less than 6 weeks) from non-malarious areas to malarious areas. Drug of choice is Doxycycline 100 mg daily in adults and 1.5mg / kg daily in Children; beginning 2 days before travel – 4 weeks after leaving a malarious area.

*b). Long term travelers where appropriate eg. Military & Paramilitary Troops on night patrol duty etc in malarious areas. The decision of Medical Authority is to be followed. Drug of choice is Mefloquine 250 mg weekly for adults & 5 mg/kg for children once a week; beginning 1 week before - 4 weeks after exposure.

Roles & Responsibilities of District Level Officers and Contractual Project Staff

A. Early diagnosis and complete treatment

- Ensure that FTDs are selected and are functional for the PHC area in consultation with District VBDC Consultant, MO-PHC and the community.
- Ensure that all fever cases are referred to malaria laboratory for blood smear collection and examination before giving final prescription/medicines by repeated sensitization of the MO-PHC. To sensitize the MO-PHC, MPWs and ASHAs on timely referral of severe cases of malaria.
- Ensure that all microscopy centres in the district are functional by positioning of LTs.

B. To ensure sufficient stocks of anti- malarials in PHC and periphery.

- Analyze data for action and prediction of outbreak and also assist in epidemiological investigation based on weekly fever surveillance report.
- Monitor drug failure in malaria cases (failure of response to Chloroquine) and inform the state headquarters immediately.
- Ensure that records of clinically diagnosed cases are maintained.
- Along with MO-PHC and DVBCD consultant to undertake trainings of health supervisors, MPWs and ASHAs in the PHC area.

C. Vector control

- Prepare the district and sub-district micro-action plan with assistance from DVBCD consultant, BMOs and MTSs for control of malaria and other VBDs.
- Supervise IRS micro-planning and implementation to ensure quality and coverage. To ensure that supervisory plan for monitoring of IRS is prepared and followed in each PHC.
- To make arrangements for transport of insecticide to field (dumping stations) well in time.

- To ensure that all spray equipments along with spare parts are purchased/repared in time well before commencement of spray operations. To ensure certification of all spray equipment in the district before IRS rounds.

D. To ensure that sufficient budget is available and spray men get their payment in time.

- Inform the SPO, ROH&FW and Directorate of NVBDCP about the commencement of spray operations.
- Cover all PHCs of the district during spray inspection/supervision in each month. To visit and observe at least 5 to 10 villages every week to check the quality of spray.
- Ensure that complete coverage is achieved in time and space and to submit the spray completion reports within fifteen days of the completion of the respective rounds.

E. Supportive supervision

- Ensure that current programme guidelines for planning, training, service provision, monitoring, supervision, and surveillance of VBDs are applied in all health facilities and by all health workers concerned in the district.
- Work in co-ordination with State and District-level officers to establish good practices of supportive supervision for the control of vector borne diseases. Conduct regular field visits for ensuring quality implementation of the programme and provide technical support to the concerned staff on site, including ongoing on-the job training and supportive supervision of MTSs.
- Visit all sentinel surveillance sites once a fortnight and 50% of PHCs in a month. Visit sub-centres and supervise MPWs, ASHAs and make patient visits.
- To supervise the VBD control logistics of diagnostics, drugs and insecticides so as to ensure against stock-outs. To ensure that FEFO principle is followed in their utilization.

F. IEC / BCC / Inter-sectoral collaboration

- Actively seek involvement of district collector, district administration in the prevention and control of VBDs. To increase participation of NGOs, CBOs and the private sector (health and non-health) under various schemes.
- Prepare the BCC/ IEC plan for the district with special emphasis on IPC tools and innovations in BCC/ IEC with assistance from the district VBDC Consultant and specialized staff at state level.
- Ensure timely data analysis, presentation and interpretation for VBD surveillance at district level.

G. Records and reports

- Timely submit district level reports to the state. To prepare annual report and annual district action plan.
- To ensure that all laboratory records and reports are maintained in the district up to date.
- Participate in all district level and state level meetings held to review the situation of VBDs. To ensure review of the NVBDCP in these meetings.
- Maintain tour diary and vehicle log book for each month.

Roles & Responsibilities

- Attend OPD, inpatients and manage cases of malaria. To ensure diagnosis of all fever cases in malaria laboratory by blood smear collection & examination and/ or by RDT before giving final prescription/medicines.
- Ensure admission of severe & complicated cases of malaria and their treatment as per National Drug policy on Malaria control. To monitor the treatment practices and ensure adherence to treatment guidelines by all treating physicians.
- Provide arrangement of referral services for severe cases of malaria to tertiary Hospital and to arrange for their transportation.
- Assist in the Project Implementation Plan of the District with respect to the Operationalisation of Sentinel sites.
- Ensure maintenance of Line listing of malaria cases seen in OPD and inpatients and submission of fortnightly report to DMO.
- Ensure that the Laboratory Technicians maintains the M3 register and undertakes Laboratory surveillance of Malaria positive cases in the OPD and In-patients.
- Prepare Quarterly Analytical Report in relation to person, time and place distribution and trend of severe cases.

Chapter-7
Work Model for District VBD Consultants (DVBDC)
&
Malaria Technical Supervisor (MTS)

District VBD Consultant is positioned to strengthen the planning, monitoring, supervision and evaluation of VBD control in endemic districts with high burden of malaria and to ensure seamless collaboration between state and district. DVBDC will see:

- District
- Block
- PHCs
- Villages and will provide technical support at all levels.

Depending upon the local infrastructure, geographical terrain and population of the state; each DVBDC will be covering population of 5-25 lakhs

i.e. 5-15 Blocks

i.e. 15-35 PHCs

i.e. 45-75 SCs

i.e. 100-500 villages

Job Matrix of DVBDC

Working days in a month: 22 to 25 days

Distribution of working days:

- 1 day in monthly meeting with DMO/DPM (Caritas)
- 5–6 days visit to Block PHC/CHC (to cover all Blocks once in a month)spend the day there to see reporting, stock position of drugs and diagnostics, interaction with MO I/C and other staff for program review
- 11–12 days- visits to the Additional/ New PHCs , Sub-centre & Villages to review activities at periphery.
- 3-4 days- reporting, follow up action on observations made during field visits
- 1 day in district headquarters to prepare report of the activities of whole month and preparation of next month's ATP

Activity to be done at PHCs/CHCs

- Check the IEC material on display at the HFs
- Check the Patient Attendance Register for OPD/IPD attendance and no of fever cases per day / Month, Year
- Interact with MO I/C and other Medical Staff reg. types of cases, treatment advised , follow-up system, duration of hospital stay (IPD)
- Try to interview the concerned health staff whether they are aware of Drug Health Policy.

- Check for the HR status i:e in position, vacant, trained and untrained staff.
- Check all the reporting formats M2, M3, M4 and V1-V6
- Check the Anti malarial drugs stock register for remaining stock, expiry of the drugs etc.
- **Visit to Malaria Lab**
 - Check the M3 register maintained by the LTs.
 - RDks, Microscopy slides and other Lab equipments.
 - Microscope(s) of the Laboratory.
 - Check the quality of BSE.
 - Staining quality of slides.
 - Other medical equipments; staining chemicals, glass slides etc.
 - Assess time lag between submission of slides for testing and communication of report to the concerned staff

At Sub-center

- Visit SCs during the visit to additional/new PHCs.
- Each sub-centre should be visited at least once in a quarter.
- Review the quality of malaria case management services.
- Promptly bring to the notice of concerned PHC-MO & BMO any delays or poor quality of diagnosis and treatment.
- Monitor and ensure rational use of ACT and RD Kits as per the program guidelines.
- Assess competence of ANM/ASHA/Other Health Workers for deciding on refresher/on the job trainings of the specific components of VBD control program.
- Review the records and reports and take corrective action whenever & wherever needed.

AT Village

- Visit at least 2 adjoining villages during visit to sub-centre.
- To validate and assess the quality of malaria control services being provided by community based workers (ASHAs/AWWs etc)
- Validating the records by interacting with the community by visiting at least 2 malaria cases diagnosed and treated by ASHAs.
- Review the level of awareness about vector borne diseases and its prevention in the community by conducting interviews and group discussions.

➤ **IRS:**

- Ensure that micro plan for IRS has been prepared.
- Check the Spray pumps.

- Stock status of insecticide.
- Required quantity of insecticide is being used.
- Personal protection gear
- Visit the dumping site of insecticides: whether it is far away from the locality or not.

➤ **LLIN:**

- Ensure that LLINs are stored properly in the warehouse.
- Stock status of LLIN.
- Micro plan for distribution of LLINs
- Availability of distribution list as per SC/Village
- Check usage of LLIN during field visits

Other Activities:

- Workout the drugs and other insecticidal requirements
- Check the IEC/BCC activities.
- Check the tour diary of field workers.
- Try to interview health workers whether they carry out malaria cases detection as they are trained.
- Try to interview patients treated by health workers for follow up and feedback.
- Interaction with other program people for coordination in implementation of cross cutting issues

Deliverables

- The consultant will be required to submit a Monthly Activity Report to the DMO/ SPO.
- He / She will also submit year ending Annual Report to DMO/State Programme Officer with a copy to Directorate of NVBDCP.

Role of Malaria Technical Supervisor (MTS)

Purpose

Malaria Technical Supervisor (MTS) is positioned to strengthen supportive supervision and micro-monitoring for malaria prevention and control at sub district level in malaria-endemic districts. The MTS will see:

- Facility centers (sub centre)
- Providers (ASHA, health worker)
- At community level (through IPC)
-

Depending upon the local infrastructure available in the state, each MTS will be covering population of 2, 50 ,000:

- i.e 1-2 Blocks
- i.e 6-7 PHCs
- i.e 40-45 SCs
- i.e 250 villages

Job Matrix of Malaria Technical Supervisor (MTS)

Working days in a month : 22 to 25 days

Distribution of working days:

- 1 day in monthly meeting at Block PHC
- 12–13 days (Monday, Wednesday, Friday) visits to the Sub-centre & villages
- 6–7 days visit to the PHCs (to cover all PHCs once in a month)
- 4-5 days reporting, needed/corrective actions

At District

- Submitting the ATP approved by the designated BMO to the DMO/DVBDC.
- Assist the DMO/DVBDC in planning and monitoring the next/future months activities based on current status and observations.
- Assist the DMO/DVBDC during his supervision visits.
- Submit the Report to the DMO/DVBDC every week along with the tour report and travel (financial) report.
- Assist in any district/block specific VBDC activities (e.g. research)

At Block

- It will be the headquarter (if the blocks covered are more than one, one of them will be the HQ as decided by the district authority).
- Regular liaison with the BMO and assist him in planning the VBDC activities.
- Prepare, submit and get approved, the ATP for the next month and communicate it to the concerned field staff during the monthly meeting.

- After Supervision of VBD activities at the PHC/SC/village he will report to the BMO about his observation and suggest corrective actions.
- Monitor the disease, stock and activity status in the areas covered by him

At PHC

- Visit all the PHCs covered by him at least once in a month
- Supervise and monitor *Malaria Case Management*.
- Review the quality of malaria case management services during the field visits to ensure that the slides collected are being submitted to the designated microscopy centre and results are being conveyed back to concerned Health workers in time for early initiation of effective treatment as per the program service standards.
- Monitor and ensure rational use of ACT and RD Kits as per the program guidelines.
- Supervise and monitor the laboratory services.

Vector Control

- Assist the DVBDSCO & BMO in the development of Micro plan for IRS and would supervise the quality and coverage of IRS rounds as desired by the DVBDSCO & BMO.
- Discuss with the MO about the observations and actions to be taken for the same.
- Record the observation in the visit book and follow up about the taken action at the next visit.
- Block/ Sector meeting: to be attended on rotation basis

At Sub-center

- Visit SC covered by him during the 12-13 days in a month.
- Each sub-centre should be visited at least once in two months period.
- Supervise and monitor *Malaria Case management*.
- Review the quality of malaria case management services: during the field visits to ensure that the slides collected are being submitted to the designated microscopy centre and results are being conveyed back to concerned Health workers in time for early initiation of effective treatment & timely referral as per the program service standards.
- Promptly bring to the notice of concerned PHC-MO & BMO any delays or poor quality of diagnosis and treatment.
- Monitor and ensure rational use of ACT and RD Kits as per the program guidelines.

Vector Control at Sub-center:

- Assist the DVBDSCO & BMO in the development of Micro plan for IRS and would supervise the quality and coverage of IRS rounds as desired by the DVBDSCO & BMO in that SC.
- Discuss with the MPW about the observations and actions to be taken for the same
- Record the observation in the visit book and follow up about the Action taken at the next visit.

At Village

- Visit at least 2 prioritize/selected villages in each sub-centre selected.

- To validate and assess the quality of malaria control services being provided by community based workers (ASHAs/AWWs etc).
- Validating the records by interacting with the community by visiting at least 2 malaria cases diagnosed and treated by ASHAs.
- Review the level of awareness about vector borne diseases and its prevention in the community by conducting interviews and group discussions.
- Network with the village Health & sanitation committee, to help it plan mosquito breeding source reduction activities.
- The MTS would participate in any advocacy event or camps organized in the MU and undertake activities to promote breeding source reduction.

Reporting

- The overall I/c of the MTS would be the DVBDSCO / DMO.
- The MTS will stay at the Block-Head quarters and report to the Block MO on a regular basis.
- In case the monitoring unit (MU) includes 2 Blocks, one block will be designated as Headquarters block.
- For effectively undertaking the above tasks in the malaria unit, the MTS would be provided with a motorcycle & POL expenses

Deliverables

- Monthly advance tour program by 1st of following month and obtain approval of the DVBDSCO/MO officer.
- Supervisory Checklist for each month to the DVBDSCO/DMO & BMO.
- Maintain monitoring register, tour diary, Vehicle log Book and route maps.

Chapter-8

Selection of insecticides, calculation of requirements and safety precautions

Intervention measures to restrict the transmission of malaria by controlling the vector population form the main part of the vector control. Effective vector control strategies are based on the following facts:

- Knowledge and understanding of vector biology
- Surveillance of vector species
- Incrimination of vector species
- Public education and implementation of effective control measures.

Vector control programme in India, as in the case with many anti-malaria programme elsewhere, in the world, mostly rely on usage of natural and synthetic chemical molecules, which have potential to kill the target insects.

Presently different formulations of synthetic chemical insecticides are in use for vector control. Wettable powder (WP) formulations are used for indoor residual sprays while emulsion concentrate (EC) formulations are used for larval control. For IRS, insecticides in use are DDT 50% WP, Malathion 25% WP and synthetic pyrethroids. Synthetic pyrethroids include Deltamethrin 2.5% WP, Cyfluthrin 10% WP, Lambdacyhalothrin 10% WP and Alphacypermethrin 5% WP. The synthetic pyrethroids are also used for impregnation of bednets.

Most of the insecticides having residual effect are sprayed indoors, so that mosquitoes after taking the blood meal from an infective person will rest in the house, pick up sufficient insecticide particles sprayed on the walls and other indoor surfaces of the house and their longevity will be reduced so much that they do not survive long enough to become infective. In areas where the vectors are strongly endophilic, i.e. they tend to rest indoor, IRS of human dwellings can give very effective control. Vectors that are exophilic i.e. they tend to rest outdoors but tend to feed or rest indoors briefly, can be effectively controlled by IRS with insecticides that have good airborne effect. In areas where vectors are strongly exophilic and/or exophagic, i.e. they rest and bite outdoors, other control methods, such as use of ITNs or outdoor space spraying (for emergency control), should be considered.

In practice, the effectiveness of house spraying for malaria control depends on adherence to the specified criteria of the insecticide and application procedure, public acceptance of spraying, the availability of well maintained equipment and adequately trained spray personnel, depends on local circumstances and is influenced by the distribution of malaria and malaria vectors, distance from the active breeding sites, the flight range of the vectors and demographic features.

Selection of insecticides

Several factors need to be considered in the selection of an insecticide for spraying, including availability, cost, residual effectiveness, safety, vector susceptibility and excito-repellency. The insecticides used as adulticides for IRS are DDT, Malathion and different synthetic pyrethroids.

Change of insecticide

If a change of insecticide is warranted, the state government should support their choice of alternative insecticide by documentation of data on vector resistance studies and field observations on epidemiological impact of spray in respect of insecticide in use. The change of insecticide will always be decided in mutual consultation between SPO, ROH&FW and the Directorate of NVBDCP with concurrence of state and central governments. The proposal for any such change of insecticide should follow the following steps:

- The state government submits the proposal for change of insecticide to Directorate of NVBDCP in the month of January-February. All technical data on vector resistance, epidemiological impact of the current insecticide in use, along with financial outlay, quantity of alternative insecticide chosen, with comparative cost difference for spray operations should be included in the proposal. The proposal should be discussed in the annual action plan meeting in Directorate of NVBDCP.
- Mutual consultations between the SPO, ROH&FW and Directorate of NVBDCP in the month of March-April and report prepared in this regard for submission to Technical Advisory Committee (TAC) for approval under the chairpersonship of the DGHS, Gol.
- Approval of MOH&FW should be obtained in the month of April-May.
- Insecticide should be procured for next year's spray operations and fixing of delivery schedule should be ensured so that the insecticide reaches the periphery by March-April next year i.e. well before starting the first round of spray operations.

Insecticides used under NVBDCP

The following formulations/compounds are used under the NVBDCP for control of malaria:

DDT (Dichloro-diphenyl-trichloroethane)

In India, DDT has been in use for malaria control since 1946. Recently there has been a tendency to curb the use of DDT due to its persistence in the environment. It is a fact that if DDT is applied in agriculture, it contaminates water resources, enters the biochain and at each step of the biochain, it gets more concentrated (bio-magnification) till it reaches human beings. In the human body, it is stored in the body fat and is excreted in milk. Since DDT persists for a long time in the environment, there has been apprehension that it will produce adverse effects on human health.

A study group of WHO has recommended that at this stage there is no justification on toxicological or epidemiological grounds for changing current policy towards IRS with DDT for VBD control. DDT may therefore be used for vector control, provided that all the following conditions are met:

- It is used only for indoor spraying
- It is effective
- The material is manufactured to the specifications issued by WHO
- The necessary safety precautions are taken in its use and disposal.

The GoI has constituted a mandate Committee on DDT which reviews the use of DDT in public health and decides its quantity to be released for the NVBDCP every year. DDT has also an added advantage. It is comparatively cheaper than the other insecticides and even in those areas where resistance to DDT has been recorded with WHO test kits the epidemiological impact of good spray operations is seen because of its excito-repellent action.

Requirement of DDT

The requirement of DDT is 150 MT per population of a million for two rounds of spray. In areas where a third round is proposed in selected villages, the additional requirement is estimated to be 75 MT per population of a million.

Malathion

Malathion 25% WP is used under the programme in areas with DDT resistance. The disadvantage of organophosphorous compounds is that unlike their use in agriculture where a farmer uses the organophosphorous compound for crop protection only once or twice a year, the spray squads engaged in spraying residual insecticide in human dwellings work with these compounds for periods extending upto 6 or 7 months. This long exposure results in acute toxic symptoms and if not controlled properly may lead to mortality. Therefore, the spraymen engaged in spraying of organophosphorous compounds is to be provided with more elaborate protective garments and their blood cholinesterase level is to be checked periodically to assess the toxic impact of the compounds. These compounds are also toxic to domestic pets. Under Indian conditions, three rounds of spray with organophosphorous compounds are done as against two rounds of spray with DDT.

In the case of Organophosphate poisoning, the patient should be transported as soon as possible to a doctor to receive an antidote. 2-4 mg of atropine should be given intravenously (for children 0.5 to 2 mg according to weight). Depending on symptoms, further doses of 2 mg should be given every 15 minutes for 2-12 hours in severe cases. Auto-injections are also available for administration of atropine.

Requirement of Malathion 25%

The requirement of Malathion 25% is 900 MT per population of a million for three rounds of spray. In areas where an additional round is proposed in selected villages, the additional requirement is estimated to be 300 MT per population of a million.

Synthetic pyrethroids

These are new insecticides introduced for control of VBDs in India. The cost of these insecticides is higher than the cost of DDT and Malathion. Currently the insecticides of this group registered with Central Insecticide Board for use in the programme are Deltamethrin 2.5%WP, Cyfluthrin 10%WP, Alphacypermethrin 5% WP and Lambdacyhalothrin 10% WP.

In treating synthetic pyrethroid poisoning, vitamin E oil preparations are given for prolonged paraesthesia. Only in cases of definite allergic symptoms should corticosteroids be administered. On occurrence of convulsions after severe intoxication, intravenous injection of 5-10 mg Diazepam (or any other benzodiazepine derivatives) should be given.

Requirement of synthetic pyrethroids

The requirement of Deltamethrin 2.5% WP is 60 MT per population of a million for two rounds of spray. In areas where an additional round is proposed in selected villages, the additional requirement is estimated to be 30 MT per population of a million.

The requirement of Cyfluthrin 10% WP is 18.75 MT per population of a million for two rounds of spray. In areas where an additional round is proposed in selected villages, the additional requirement is estimated to be 9.375 MT per population of a million.

The requirement of Lambdacyhalothrin 10% WP is 18.75 MT per population of a million for two rounds of spray. In areas where an additional round is proposed in selected villages, the additional requirement is estimated to be 9.375 MT per population of a million.

The requirement of Alphacypermethrin 5% WP is 37.5 MT per population of a million for two rounds of spray. In areas where an additional round is proposed in selected villages, the additional requirement is estimated to be 18.75 MT per population of a million.

IRS formulations and dosages

S.No	Name of insecticide	Amount of insecticide to prepare 10 litres of suspension	Dosage per sq. metre of active ingredient	Residual effect in weeks	Area (in sq. m) to be covered by 10 litres of suspension	Requirement of insecticide per million population (in MT)
1.	DDT 50% WP	1.000 Kg	1 gm.	10 -12	500	150.00
2.	Malathion 25 % WP	2.000 Kg	2 gm.	6 - 8	500	900.00
3.	Deltamethrin 2.5% WP	0.400 Kg	20 mg.	10 -12	500	60.00
4.	Cyfluthrin 10% WP	0.125 Kg	25 mg.	10 -12	500	18.75
5.	Lambdacyhalothrin 10% WP	0.125 Kg	25 mg.	10 -12	500	18.75
6.	Alphacypermethrin 5% WP	0.250 Kg	25 mg.	10 -12	500	37.50
7.	Bifenthrin 10% WP	0.125 Kg	25 mg.	10-12	500	18.75

- In the case of Malathion, the requirement shown above, is for the three rounds

General safety precautions

Exposure to insecticides may occur when handling and spraying insecticides as follows:

- When handling the insecticide product during opening of the package, mixing and preparation of the spray.
- When spraying the insecticide, the operator should also wear a protective hat and faceshield or goggles.
- Do not eat, drink or smoke while working.
- Wash hands and face with soap and water after spraying and before eating, smoking or drinking.
- Shower or bath at the end of every day.s work and wear new clean clothes.
- Wash overalls and other protective clothing at the end of every working day in soap and water and keep them separate from the rest of the family.s clothes.
- If the insecticide touches the skin, wash off immediately with soap and water.
- Change clothes immediately if they become contaminated with insecticides.
- Inform the supervisor immediately if one feels unwell.

Protective clothing and equipment

Absorption of insecticide occurs mainly through the skin, lungs and mouth. Specific protective clothing and equipment given below must be worn in accordance with the safety instructions on the product label

- Broad-rimmed hat (protects head, face and neck from spray droplets).
- Face-shield or goggles (protects face and eyes against spray fall-out).
- Face mask (protects nose and mouth from airborne particles).
- Long-sleeved overalls (worn outside of boots).
- Rubber gloves.
- Boots.

Disposal of remains of insecticides and empty packaging

At the end of the day.s work, the inside of the sprayer should be washed and any residual insecticide flushed from the lance and nozzle. The rinsing water should be collected and carefully contained in clearly marked drums with a tightly fitting lid. This should be used to dilute the next day.s tank loads or disposed properly by the supervisor.

Never pour the remaining insecticide into rivers, pools or drinking-water sources. Decontaminate containers where possible. For glass, plastic or metal containers this can be achieved by triplerinsing, i.e. part-filling the empty container with water three times and emptying into a bucket or sprayer for the next application. All empty packaging should be returned to the supervisor for safe disposal according

to national guidelines. Never re-use empty insecticide containers

Storage and transport

Pesticide storehouses must be located away from areas where people or animals are housed and away from water sources, wells, and canals. They should be located on high ground and fenced, with access only for authorized persons. However, there should be easy access for pesticide delivery vehicles and, ideally access on at least three sides of the building for fire-fighting vehicles and equipment in case of emergency. Pesticides must not be kept where they would be exposed to sunlight, water, or moisture which could affect their stability.

Storehouses should be secure and well ventilated. Stocks should be arranged so that the oldest are used first (.first in first out. or, better, .first expired first out. principle) to avoid the accumulation of obsolete stock. Containers should be arranged to minimize handling and thus avoid mechanical damage which could give rise to leaks. Containers and cartons should be stacked safely, with the height of stacks limited to ensure stability.

Pesticides should not be transported in the same vehicle as items such as agricultural produce, food, clothing, drugs, toys, and cosmetics that could become hazardous if contaminated. Pesticide containers should be loaded in such a way that they will not be damaged during transport, their labels will not be rubbed off and they will not shift and fall off the transport vehicle onto rough road surfaces. Vehicles transporting pesticides should carry prominently displayed warning notices. Pesticides should not be carried in the passenger compartments of transport vehicles and should be kept tightly secured and covered at all times during transport. The pesticide load should be checked at intervals during transportation, and any leaks, spills, or other contamination should be cleaned up immediately using accepted standard procedures. In the event of leakage while the transport vehicle is moving, the vehicle should be brought to a halt immediately so that the leak can be stopped and the leaked product cleaned up. Containers should be inspected upon arrival at the receiving station. There should be official reports to the national level and follow-up enquiries in the event of fires, spills, poisonings, and other hazardous events.

Distribution of pesticides should be carried out by trained personnel or under proper supervision. Misdirection or mishandling can result in the product falling into the hands of uninformed recipients or causing human or environmental risk. Proper packaging is also important to ensure the confinement of the product and its safe handling. The original package is intended to ensure safe distribution; when repacking is necessary, the new packing should meet the specifications of the original packaging.

Technique for IRS

Manpower Requirement

The Expert Committee 1995 recommended that 52 squads are required for 5 months spray period to cover a population of one million with DDT / synthetic pyrethroids. 87 squads are required for 4½

months for 3 rounds of Malathion spraying. Each spray squad consists of 5 field workers working with two stirrup pumps and one Superior Field Worker. It is expected that a spray squad can on an average, cover 60 to 80 houses per day. One squad will take 12 to 17 days to cover a subcentre area with an average population of 5,000.

Equipments

Each squad will require the following equipment which must be available well in time before spray operations:

- Stirrup pumps - 2
- Spray nozzle tips for spray pumps - 2
- Bucket 15 litres - 1
- Bucket 5 litres - 1
- Bucket 10 litres - 1
- Asbestos thread - 3 metres
- Measuring mug - 1
- Straining cloth - 1 metre
- Pump washers - 2
- Plastic sheet (3x3 metres) – 1

The squad supervisor must have extra spray pumps, nozzle tips, washers, asbestos threads. A set of tools for minor repairs should also be available which should include a pipe wrench, pliers, screwdrivers and a set of spanners. A good quality nozzle should be used. Each squad must also be provided with personal protection gear including masks and soap to wash.

Preparation of insecticide suspension

The required quantity of insecticide, calculated as indicated in Annexure B, should be issued to the squads each day by the supervisor after checking balance stocks available from previous day supplies.

The preparation of the spray suspension is made just before the start of the spray operations every day. It is important that the suspension is made correctly so that the correct dosage is applied on the sprayed surfaces. The procedure for the preparation of the suspension is the same irrespective of the insecticide. However, the quantity of the insecticide used per 10 litres of water will depend on the insecticide used.

The required quantity of the insecticide is measured with a plastic mug and poured into a 15 litre bucket. A paste is made with a small quantity of water. The remainder of water is then poured slowly into the bucket and the insecticide water mixture is stirred vigorously to obtain a uniform suspension. The suspension is then poured into another bucket through a cloth sieve to remove any particulate matter that might clog the nozzle of the spray pump. The insecticide suspension should be stirred vigorously at least every hour.

Spraying

All food, cooking utensils, bedding and clothes must be protected from the insecticide by taking them outside the house before spraying starts.

The barrel of the stirrup pump is put in the bucket containing the spray suspension. One man operates the pump and the other man sprays. The spray lance should be kept 45 cms (18 inches) away from the wall surface. The swaths should be parallel. Spray is applied in vertical swaths 53 cm (21 inches) wide. Successive swaths should overlap by 7.5 cm (3 inches). Spray is done from roof to floor, using downward motion, to complete one swath; then stepping sideways and spraying upwards from floor to roof. Do not let the spray drip to the floor. Spraying is done only on inner surfaces, including eaves and roofs.

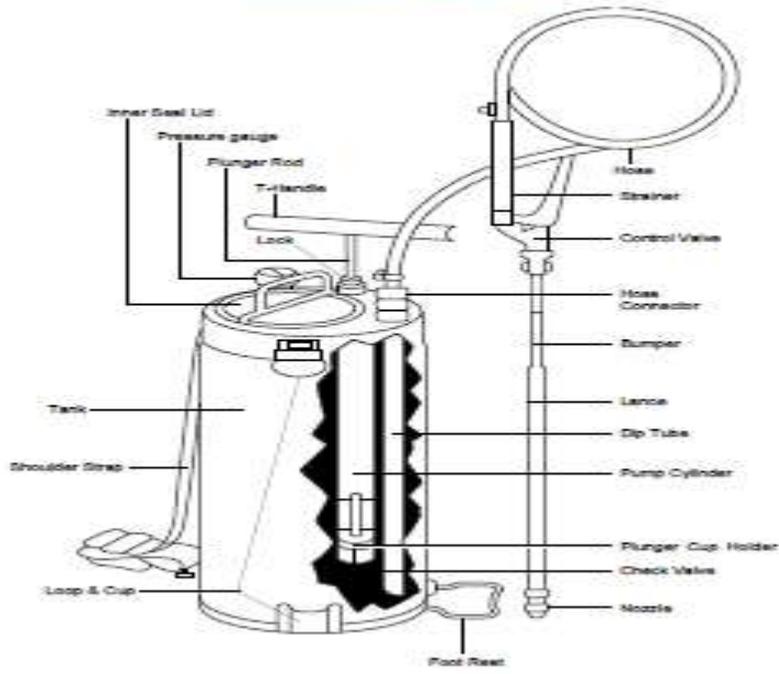
The discharge rate should be 740 to 850 ml per minute. To obtain the above discharge rate, the pump man should give 20 to 26 strokes per minute with 10-15 cms plunger movement at a pressure of 10 PSI (0.7 kg/sq.cm) at the nozzle tip. Spraying into a bucket for one minute and measuring the quantity of the suspension in a graduated mug will check the correct discharge rate (740 to 850ml / minute). The nozzle tip should be discarded if the discharge rate exceeds 850 ml per minute.

If the spray stops due to a blockage in the nozzle, the nozzle cap should be unscrewed to remove the blockage and replaced with a new one. The blocked nozzle should be put in a container with water for a few hours before the blockage is removed with a finer wire.

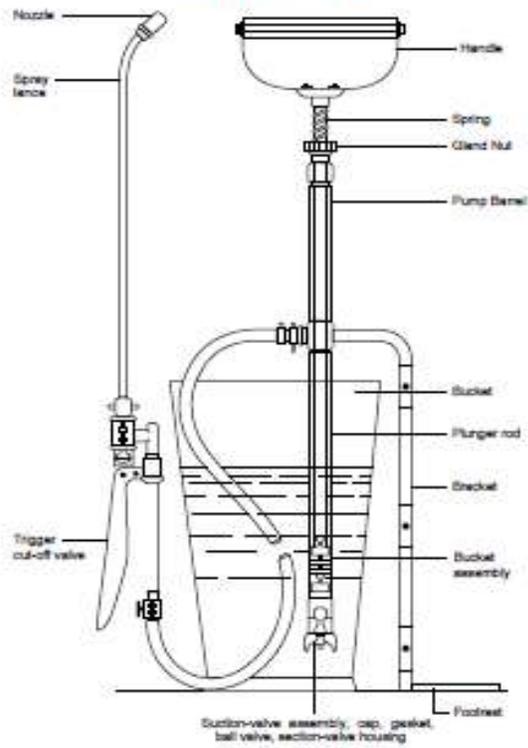
A good quality spray should lead to uniform deposit on walls and other sprayable surfaces. This is easy to verify for DDT and malathion sprays as the insecticide deposits are clearly visible. Deposits of synthetic pyrethroids are visible on wooden structures. The supervisor through physical verification should verify the quality and coverage of spray randomly.

It takes about 5 minutes to spray a house with an average surface area of 150 sq. metres. A summary of spray operations in each village should be maintained by the SFW and verified by the health worker showing the areas covered and room coverage (Form VC-1)

Hand Compression sprayer



Strap pump sprayer



Chapter-9

Technique of Impregnation of bednets - 10 easy steps

Step 1: Collect the necessary equipment

The necessary equipment consists of mosquito nets, insecticide, basin, measuring container, rubber gloves and soap. Make sure the net is washed / cleaned before treatment. The nets should preferably be treated outdoors in the shade. If treatment is to be carried out indoors, a room with open windows should be used. Use basin and gloves that are not used for any other purpose.

Step 2: Put on protective gloves before treating nets

Step 3: Measure the correct amount of water

The amount of water needed depends on the net material. Regardless of the size and shape of net, the amount of water required for one synthetic net (nylon, polyester) is ½ litre (if the net is very large, more water may be needed). If a measuring container comes with insecticide, use it to measure water. Otherwise, use any measuring container that is not used for food, drinks or medicines.

Step 4: Measure the correct amount of insecticide

The amount of insecticide or .dose. needed to treat a net depends on the type of insecticide used. Follow instructions on the container / sachet / packet. Generally, 10-15 ml of insecticide is required to treat one single net. The leftover insecticide should be stored in its original container, in the dark and away from children.

Step 5: Mix the water and insecticide thoroughly by gloved hands in basin

Step 6: Treatment of nets

- Always impregnate one net at a time
- Put the net in the basin containing water and insecticide
- Soak the net long enough to ensure that all parts of the nets are impregnated
- Take out the nets and allow excess liquid to drip back by squeezing it gently, but do not wring it.

Treatment of bed net

Step 7: Drying the nets

- Let the net dry flat in the shade on plastic sheets.
- Later, the net can be hung up to finish drying in the shade.

First phase of drying - On non-absorbent

Second phase of drying-Semi-dry netsflat surface under shade under shade

Step 8: Disposal of leftover mixture of water and insecticide and insecticide containers

- Following the treatment of all available nets, the leftover mixture of water and insecticide,if any, may be used to treat curtains.
- Otherwise, dispose the liquid in the toilet or a hole away from habitation, animal shelters,drinking water sources, ponds, rivers and streams.
- Destroy empty insecticide containers, sachets and packets and/or bury in a hole away from habitation, animal shelters, drinking water sources, ponds, rivers and streams.

Step 9: Washing and cleaning of hands and equipments

- Wash equipments (basin, measuring container) with lots of water while wearing protective gloves.
- Wash gloves (if non-disposable ones are used) with soap and lots of water, or dispose with insecticide containers.
- Wash hands with soap and lots of water.

Step 10: Washing and re-treatment of nets

- Washing removes the insecticide from the net. So, wash the nets as seldom as possible and gently with soap and cold water and dry flat on plastic sheet in shade.
- Do not wash/rinse treated net in or near drinking water sources, ponds, lakes, rivers, streams. Dispose of water for washing/rinsing in the toilet or in a hole away from habitation, animal shelters, drinking water sources, ponds, rivers and streams.
- Nets must be re-treated again after it has been washed three times; or, at least once a year even if it is not washed, preferably just before the rainy season. Nets may be treated twice a year in areas that have a lot of mosquitoes all year long

Remember:

- Use the insecticide-treated net every night, all year round, even if mosquitoes are not seen/their sound not heard.
- Everyone should preferably sleep under a treated mosquito net, or, at least pregnant women and children under five years must sleep under treated net.
- Insecticides used for mosquito nets are not harmful to people, if used correctly.
- Direct skin contact with the insecticide on a still wet net may cause a tingling sensation on the skin. This is not harmful, even for small children.
- After treatment, the net may smell of insecticide. This will go away in a few days and is not harmful to people who sleep under the net.

Chapter-10

Characteristics and logistics of LLINs

LLINs have different weight and volume characteristics as given in the table below:

Characteristics of LLINs relevant to logistics

Characteristics	Multifilament polyester LLIN (deltamethrin-coated)	Monofilament polyethylene LLIN (permethrin-incorporated)
Weight per LLIN	440 g	625 g
LLINs per bale	100	40
Weight per bale	42 kg	29 kg
Volume per bale	0.1727 -0.1894 m ³	0.127 m ³
LLINs per 40-ft container	36,900	16,800

Those with responsibility for logistics must ensure adequate storage capacity and reliable transport at all levels, as well as precise timing. The planning of logistics must include a detailed budget for all transport and storage needs. Most importantly, logistic mechanisms must ensure adequate supervision and control of all operations and full accountability at every stage. It is recalled that LLINs are saleable; their diversion may have adverse effects on the programme at all levels.

Storage

Bales of LLINs are well and securely packed; the nets are essentially non-perishable and are usually individually wrapped in sealed plastic bags. Nevertheless, it is important to ensure that warehouses are clean and dry. The shelf-life of LLIN should be ascertained from the manufacturer.

Bales are relatively easy to handle, being light enough to be moved manually. The principal concern in their storage is one of volume rather than weight. The very large volumes involved make it critical that there is adequate storage capacity at all levels.

The tightly packed and tied bales can be stacked several layers high (up to a height of 5 m) without any damage to the bottom layers. In theory, 5.8 bales of polyester LLINs occupy a volume of 1 m³; in practice, 4 bales / m³ is a reasonable working figure. Thus, if a warehouse space is 10 m x 20 m with storage height of 3 m, available volume is 600 m³, which would accommodate 600 x 4 = 2,400 bales or a total of 240,000 polyester LLINs.

Monofilament polyethylene LLINs can be stored at 6 bales / m³, so that the same warehouse volume of 600 m³ would accommodate 3,600 bales or 144,000 LLINs of this type. Storage space can often be rented, but rental costs would then have to be weighed against the possibly greater cost of staggered delivery.

Stock management is relatively simple because LLINs are well packed and do not deteriorate physically. Stock management should be based on the first in, first out. rule, making a methodical

approach particularly important when containers are off-loaded in a large warehouse. Bales must be stacked in the same way throughout the operation, to create equal piles each identified by a bin card. Bales must be carefully counted by at least two individuals during off-loading of the containers; this provides a double-check of the quantities indicated on the bills of lading.

Transport

Although LLINs are usually individually wrapped and bales robustly packaged, every transport vehicle must be equipped with minimum of a tarpaulin for the protection of its loads. As for storage, the principal consideration in the transport of LLINs is one of volume rather than weight. Travelling on good roads, a typical 25-ton semi-trailer truck can carry the equivalent of the contents of a 40-foot container; correctly loaded, an 8-ton truck can carry 140 bales.

Onward transport of LLINs from district level storage to health facilities could be done, if needed, by the vehicles normally used to carry medicines, vaccines and other supplies within the district – most often bicycles and motorcycles. Initial experiences in some countries indicate that it is possible to transport 4-6 LLINs on a bicycle and 10 on a motorcycle, in addition to a vaccine carrier.

Weight of one LLIN is approximately 650 g. Assumptions for carrying capacity:

- One person with bicycle and vaccine carrier can carry 4-6 LLINs weighing 2.6-4.0 kg depending on various factors.
- One person with motorcycle and vaccine carrier can carry 10 LLINs weighing 6.5 kg
- One 4 x 4 vehicle with mobile team members and vaccines and equipment can carry 150 LLINs weighing 97.5 kg.

Chapter-11

Blood smear preparation and performing RDTs

Blood smear preparation.

For preparation of blood smears, clean glass slides, disposable lancet, and spirit swab for cleaning the finger, cotton, a clean piece of cotton cloth and lead pencil are required. After the patient information has been recorded on the appropriate form, a clean glass slide free from grease and scratches is taken and the finger of the patient is cleaned by using a spirit swab.

	Select the second or third finger of the left hand.
	The site of the puncture is the side of the ball of the finger, not too close to the nail bed.
	Allow the blood come up automatically. Do not squeeze the finger.
	Hold the slide by its edges.
	The size of the blood drop is controlled better if the finger touches the slides from below.
	Touch the drop of blood with a clean slide; three drops are collected for preparing the thick smear.
	Touch another new drop of blood with the edge of a clean slide for preparing the thin smear.
	Spread the drop of blood with the corner of another slide to make a circle or a square about 1 cm.
	Bring the edge of the slide carrying the second drop of blood to the surface of the first slide, wait until the blood spreads along the whole edge.
	Holding it at an angle of about 45o push it forward with rapid but not too brisk movement.

Write with a pencil the slide number on the thin film, Wait until the thick film is dry. The thin film is always used as a label to identify the patient.

- The blood should not be excessively stirred. Spread gently in circular or rectangular form with 3 to 6 movements.
- The circular thick film should be about 1 cm in diameter.
- Allow the thick film to dry with the slide in the flat, level position protected from flies, dust and excessive heat.

- Label the dry thin film with a soft lead pencil by writing in the thicker portion of the film the blood slide number and date of collection.

The lancet and cotton swab should be disposed off as per the standard hospital waste management policy. The SOPs on laboratory work and universal precautions for blood collection are to be followed. Non-disposable needles should not be used and only disposable lancets should be used for finger pricking.

Rapid Diagnostic Test

The materials in the RDT kit are as follows:

- Spirit (alcohol) swab (one for each patient)
- Disposable lancet (one for each patient)
- Capillary tube (one for each patient)
- Test strip (one for each patient)
- One multiple well plastic plate
- Test tube (one for each patient)
- Buffer solution or reagent solution
- Desiccant

Procedure

- Check that the test kit is within its expiry date; if not discard it. Read the instructions of the test kit, as there may be minor variations in the procedure between different kits. Place a small box, jar or bottle for trash next to the kit.
- Open a foil pouch and check that the desiccant inside it is still blue; if not, discard the test.
- Remove the test strip and the small glass tube or loop from the foil pouch and place them on a clean dry surface.
- Take out the buffer solution and the dropper. Place a new test tube in the multiple well plate.
- Clean a finger with the swab and let the skin dry completely in the air. Prick finger on the side with a lancet. Discard lancet in trash container. Let a drop of blood come out on the skin.
- Touch the tip of the glass tube or the loop to the blood drop on the finger and let a small quantity of blood (a small drop) come up in the tube or the loop.
- Touch the tube or the loop to the test strip just below the arrow mark to place the blood there. If there is a paper, where Plasmodiumfalciparum is written, remove it and place the blood where it was. Discard tube/loop in trash container.
- Using the dropper, place 4 drops of buffer solution into a new test tube. After this, place the test strip containing blood in the buffer solution with the arrow pointing down. While waiting, a slide can be prepared.
- Observe after 15 minutes - if no red line appears in the test strip, then the kit is not working; discard it and use another one. If a single red line appears, it is not falciparum malaria. If two red lines appear, the test result is falciparum malaria.

- The test should be read 15 to 20 minutes after blood was taken; earlier or later readings may lead to false results.
- Discard the test strip and test tube in trash container. Make sure this container is kept out of reach of children. When it is full, if in a village, bury it in the ground, or send it with the MPW to the PHC for safe disposal.

Guidelines for Bivalent RDT

Introduction

At present about 100 million fever cases suspected to be malaria are screened for malaria annually under the National Vector Borne Disease Control Programme. In addition to that, 5% of negative slides (about 5 million) and all positive slides (1.5 million) are to be cross checked for quality control. Due to the shortfall of technicians there is delay in reporting the results. Use of Rapid Diagnostic tests (RDTs) for detection of *P. falciparum* (Pf) cases was introduced in the programme during 2004-05 and at present around 14 million RDTs are being procured and used annually.

With the present *Pf* specific RDT there is no reduction in the load of microscopy as all slides for all patients with negative RDT result (around 97% of total slides) are to be sent for microscopy to detect/ rule out *P.vivax* (Pv). Although *Pv* infections usually do not result in fatalities but some mortalities due to *Pv* especially in children are being reported from various parts of the country during recent times. Therefore it has been felt that Introduction of bivalent RDT will be useful in early treatment of *Pv* in areas where microscopy results get delayed.

In the prevailing situation at present, the average efficiency of microscopy may not be more than 60% in many microscopy centers. Microscopy cannot be replaced with RDT at any circumstance and maximum scope for RDT is estimated to be around 40 million (40%) annually and remaining 60% cases will need microscopy for diagnosis. The bivalent RDTs would supplement and help in immediate diagnosis and prompt treatment in areas from where microscopy facility is not readily accessible; but can never replace microscopy which is still considered the gold standard for diagnosis of malaria.

The matter was deliberated by the Experts Group on Chemotherapy and Diagnosis on 18-02-2011 and the following recommendations were made:

- Introduction of bivalent RDTs in the programme right away without waiting for the field trial which may take a minimum of one year or more. It was also opined that at present it may be used in high malaria endemic areas where *Pf* specific RDT is already being used.
- The bivalent RDTs would primarily be used in the remote and hard-to-reach areas where microscopy results cannot be made available within 24 hours. However, RDTs may also be used in PHCs, secondary and tertiary level facilities, for patients arriving in odd hours when the laboratory technician is not immediately available and in emergencies like dealing with severe malaria cases.

- Regarding the criteria for selection of RDTs, the recommendations are as under:
 - i. For Pf: Sensitivity and Specificity should be minimum 95% at parasite density level of 200 asexual parasites/ul of blood
 - ii. For Pv:
 - Sensitivity: $\geq 75\%$ at density of 200 parasites/ul
 - Specificity : $\geq 90\%$
- Type of RDT- Only Histidine-Rich Protein 2 (HRP2) and Parasite lactate dehydrogenase (pLDH) based RDTs to be used and not aldolase based ones.
- In areas where bivalent RDT is introduced, operational research would be conducted and data thus generated will be analyzed for further expansion of bivalent RDT use in the country. The research protocol will include both HRP2 and pLDH based kits in areas with high and low endemicity and in high and low parasitaemia cases.
- The microscopy centers, with the reduced load, would be strengthened by capacity building of the laboratory technicians and better logistic support so as to provide quality microscopy services.

Accepting the recommendation of the committee, the Bivalent RDT is being introduced in the programme with the procurement cycle of year 2012.

Guidelines for its use:

A patient with fever and no other obvious cause of fever is considered a case of suspected malaria. Any Community health volunteer, health worker or health professional observing a case of suspected malaria must immediately initiate a diagnostic test by

1. Microscopy of blood for malarial parasites and/or
2. Rapid Diagnostic Test

Under the programme Slide Microscopy for Malaria is the standard diagnostic tool & wherever a microscopy result **can** be made available within 24 hours, microscopy will be maintained as the only routine method for diagnosis of malaria.

Due to problems of non-availability of Lab Technicians at certain block PHCs & the huge time lag between the slide collection & reporting of results, especially from remote & inaccessible areas, the microscopy result may not be made available within 24 hours. In such areas also, RDTs will be supplied and used for diagnosis. The criteria for selection of these villages (or sub-center areas, where village data is not available) are:

- Pf % > 30 and SPR > 2%:
- Consistently high API (>2) and deaths due to malaria are reported
- Inaccessible areas – i.e. cut off during transmission season, areas with limited road and public transportation facility.

RDTs will be used in PHC and other health facilities only in emergencies for treatment of severe and complicated malaria requiring immediate medical attention in the absence of the laboratory technician (LT).

The limitations on the deployment of RDTs, are meant to avoid wastage of these products. In areas, where the risk of malaria is very low, it is not cost-effective to test every patient with fever. However, in such areas, a small number of RDTs should be available at health facilities to test fever patients reporting during the emergency with a very high suspicion of malaria such as those, who have recently stayed overnight in an endemic area.

Steps for the use of bivalent RDT

A patient with fever and no other obvious cause of fever is considered a case of suspected malaria. Any Community health volunteer, health worker or health professional observing a case of suspected malaria must immediately initiate a diagnostic test as per the guidelines.

Where microscopy result is not available within 24 hours and Bivalent RDT is used

- An RDT is done in front of the patient and a slide is taken. The bivalent RDT detects *Pv*, *Pf* as well as mixed infection. If it is positive, the patient is treated for falciparum or vivax malaria based on the diagnosis and the slide is discarded in order to reduce the load on the microscopy services.
- In the bivalent RDT if line for *Pf* is found present then it is a case of *Pf* and accordingly the full course of ACT for three days and Primaquine on day 2 (second day) is to be given.
- If the line for *Pv* is present, then it is a case of *P vivax* and a full course of Chloroquine for three days and Primaquine for 14 days is to be ensured.
- If both the lines for *Pf* and *Pv* are present, then it is a case of mixed infection and the treatment of mixed infection i. e. ACT for three days and primaquine for 14 days is to be given.
- If the RDT is negative, (i.e. only control line is present) then the slide is discarded.
- If no other cause can be found and the clinical suspicion is high (e.g. intermittent fever with rigors and sweats), the test should be repeated after about 24 hours and special efforts should be made to obtain the microscopy result rapidly.
- Some slides may also need to be preserved for cross checking the results as per the Quality Assurance Guidelines.

However, the worker/ health personnel should refer the product guidelines for any product specific instruction before using it.

Rapid Diagnostic Tests

It should be noted that these tests have a short shelf-life and that they may deteriorate at high temperatures. Some manufacturers are now indicating that their product has a longer shelf-life. Although this is encouraging, malaria control staff and medical officers should

manage rapid diagnostic test kits (RDKs) under the assumption that the shelf-life is 24 months.

Interpretation of rapid diagnostic tests

HRP2-based tests for *P.falciparum* detect a circulating antigen excreted by asexual plasmodia. The tests have a sensitivity of about 95%, when the asexual parasite density is above 200/ μ l. Malaria patients are rarely symptomatic at lower densities.

If a suspected malaria patient has a negative RDT, it can therefore be assumed that the patient does not have malaria and another cause of the fever should be sought. If no other cause can be found and the clinical suspicion is high (e.g. intermittent fever with rigors and sweats), the test should be repeated after about 24 hours and special efforts should be made to obtain the microscopy result rapidly.

HRP2 antigen can persist for up to 4 weeks after clearance of asexual parasitaemia through treatment. False positive tests are therefore common, especially in patients with a recent history of treatment. RDTs should therefore **not** be used for following up patients after treatment. If a patient, who has been treated, is febrile within one month after the treatment and the RDT is positive, the patient **may** have malaria. If possible, the diagnosis should then be confirmed by microscopy.

The above rules for use of diagnostics should be applied at all levels of care and in passive as well as active case detection.

Calculation of the annual requirement of RDT

S.No.	District	No. PHCs where RDTs are to be used in emergency hours	No. of sub-centre areas with SPR >2% and API>2 & Pf > 30% & no microscopy result within 24hr.	No. of blood examinations in those sub-centre/ PHC areas last year (A)	Expected RDT requirement in remote high risk areas and PHCs [A x 0.4 x 1.25] (B)	RDTs for buffer stock and distribution to other areas: [B x 0.25] (C)	Total annual RDT supply [B+C]
1							
2							
3							
Total							

- Villages planned to be equipped with RDTs should have trained ASHA/ CHVs (including Angan Wadi Worker)
- The number of (blood) test examinations is estimated by adding 25% to the 40 % of number of blood examinations during the last completed calendar year, because RDTs may attract additional patients.
- If possible, a buffer stock of approximately 25%, depending on the availability of supplies is added, to cover needs in other areas and health facilities, where impending outbreaks may be suspected or where individual patients may be considered as highly suspect of malaria on account of symptoms or travel history, or where microscopy may be temporarily unavailable and to provide a reserve for supplies to the eligible areas.
- Procurement of RDT is done centrally (mostly for the project states under EAC). However, the state may be required to procure buffer stock of 25 % if the central procurement is delayed due to any reason.

Guidelines for Proper Storage of Drugs and Commodities

The main purpose of storage is to protect the quality of products and its packaging throughout the supply chain and make products available for distribution. The brief guidelines for storage of drugs/commodities are mentioned below:

1. Clean and disinfect the store room regularly and monitor the storage conditions
2. Clean receiving, storage, packing areas and remove the garbage and also keep the stores away from rodents, insects and termites
3. Safely handle the health commodities while loading and unloading from the transport vehicle
4. Clean bins, shelves and cupboards, if needed and
5. Store supplies in a dry, well-lit and well ventilated store room and out of the direct sunlight
6. Ensure adequate ventilation and temperature control (not more than 40⁰ C).
7. Provide the rack storage system in such a way so that gang ways may be created for easy movement of materials and personnel handling the store
8. Stack cartons in steel racks/slotted angles and at least 10 cm(4 inch) off the floor, 30 cm (1ft) away from the walls and other stacks and no more than 2.5 m (8ft) high
9. Store supplies in a manner that is accessible for FEFO, counting, and general management. Use First Expiry First out (FEFO) principle. Please issue the drugs which are going to expire first.
10. Store medical supplies separately, away from insecticides, chemicals, old files, office supplies, and other materials.
11. Arrange cartons so that arrows point up, and ensure that identification labels, expiry dates, and manufacturing dates are visible.
12. Monitor store security and safety to avoid theft/pilferage
13. Secure store room from water penetration and from any seepage in the walls, roof, doors & windows, especially during rainy season
14. Monitor product quality (visually inspect commodities and check expiry dates) and physical verification of quantities
15. Ensure that fire safety equipment (fire extinguisher) is available and accessible and that personnel are trained to use it.
16. Ensure fire proof electrical fittings and appliances for any fire due to short circuit and keep the stocks away from the electrical sockets

17. Separate damaged and expired stocks from the usable stock and move the expired stock to secure area and dispose of these products without delay as per the established procedure
18. Monitor stock levels, stock quantities and safety stocks and update stock ledger/records regularly and maintain the files safe custody.

Chapter-12

Quality assurance of laboratory diagnosis of malaria by microscopy and Rapid Diagnostic Tests

Introduction

Early laboratory diagnosis of malaria greatly facilitates the management of the disease by confirming the clinical diagnosis. Under the NVBDCP, both microscopy and RDTs are used for diagnosis of malaria. Microscopy is a reasonably affordable, sensitive and specific technique. Microscopic examination of blood smears stained with JSB stain (and /or Giemsa, Leishman), continues to be the method of choice - the .Gold standard., for confirming the clinical diagnosis of malaria. It not only allows the differentiation of *Plasmodium* species but also provides an estimate of the parasite load i.e. number of parasites per microliter of blood. With the advent and spread of antimalarial drug resistance, particularly of multidrug resistant *P. falciparum*, the need and the importance of accurate microscopic diagnosis has been felt more acutely. Though microscopy is the main tool and .a Gold standard. but it has got its limitations.

RDTs have been introduced under NVBDCP in endemic areas which are inaccessible or where microscopic facilities are either poor or lacking (due to operational reasons). These are relatively easy to perform. The detection of parasite.s antigen is an evidence of a current or recent infection. These RDTs provide quick results, require less skilled persons as compared to microscopic diagnosis and do not require electricity or any equipment. RDTs are based on the principle of immunochromatography, require finger prick blood and detect malaria specific antigen. Different RDTs are available commercially, some of them are specific for detecting Pf antigen and the others detect

two or more of the three malaria species prevalent in India. Currently, under the programme only RDTs which can detect Pf only are being used.

Like other diagnostic tests, various conditions of manufacture, transport, storage and the method of use may impair the accuracy of RDTs. Hence, irrespective of the technique employed, establishment and maintenance of a reliable diagnostic service depends on operational feasibility of the test, availability of adequate trained personnel, equipment and laboratory management systems at all levels. Quality Assurance (QA) and adequate monitoring of laboratory services at the peripheral level have been perceived as one of the important components under NVBDCP which needs to be strengthened. Therefore, it is essential to build and incorporate a sustainable QA programme under NVBDCP.

Quality Assurance (QA)

Quality Assurance (QA) is a wide ranging concept covering all components that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the objective to ensure that the product is of the required quality for its intended use. It denotes a system for continuously improving reliability, efficiency and utilization of products and services. The

activities encompass all those factors in any health care organization that are concerned with inputs, processes and outcomes of the health care system. The QA programme deals with the dynamic ongoing process of monitoring the diagnostic laboratory's testing system for reproducibility in order to permit corrective action when established criteria are not met. This includes sampling specifications, testing methods, reporting and documentation for procedures ensuring that the necessary and relevant steps have been taken for quality services.

Objectives. The objectives of QAP are to

- Assess the quality of the specimen/sample collection and processing.
- Document the validity of the test methods
- Monitor reagents, stains, equipment, performance of test procedures and personnel
- Review test results of microscopy
- Provide feedback for corrective action
- This can however be attained only by active participation of everyone working in the system.

Components. The following are the components of a QA programme:

- Adhering to Standard Operating Procedures (SOP).
- Ensuring correct methods of specimen/sample collection
- Ensuring quality of reagents used and calibration of equipment
- Performing the tests with proper precision and accuracy
- Interpreting of the results correctly
- Monitoring and evaluation
- Coordinating and supervising
- Adequate training and re-training (experienced personnel)
- Giving timely feedback
- Detecting errors in the techniques and taking corrective steps
- Documenting procedures, results, etc.

A QA programme has two important parts: Internal quality control (IQC) and External Quality Assessment Scheme (EQAS). The differences between these two are as follows:

Salient points	Internal Quality Control (IQC)	External Quality Assessment Scheme (EQAS)
Nature	Concurrent and continuous	Retrospective /prospective and periodic
Objective	To provide reliable results on day to day basis	To ensure inter-laboratory comparability and assesses proficiency of participating laboratory
Performed by	Laboratory staff	Independent agency

Current status of QA of Microscopy

There has been a well established programme for cross verification of the laboratory results of microscopy under the Directorate of NVBDCP, wherein all the blood smears found positive at the PHCs or other peripheral laboratories are supposed to be cross-checked for parasite species and stage along with 10% of negative blood slides.

The PHC/ malaria clinic LT is supposed to collect all negative slides examined during the previous month with number ending with the code digit and dispatch to the concerned crosschecking laboratory by 10th of every month. All positive blood smears are crosschecked in the ROHFW and state headquarters laboratories. Depending on the workload, it is shared 50:50 between these laboratories. The negative slides are distributed between state/zonal and ROHFW laboratories, at the ratio of 8.5:1.5 between the former and latter. Instructions are issued to the PHC/malaria clinic laboratory to preserve the rest of the slides, until the crosschecking results are received back.

The results of crosschecking are to be sent to the concerned laboratory by the 10th of the succeeding month. In case of high discrepancy rate i.e. 2% or above, the SPO and Regional Director of each ROHFW should take the necessary remedial action like supervision of the concerned laboratory reporting high discrepancy rate.

Current status of QA programme for RDTs

During the past one decade a number of RDTs for malaria diagnosis have been developed, evaluated and validated for improved sensitivity and specificity. These RDTs are based on the principle of immunochromatography, require finger prick blood and detect malaria specific antigen. They can detect malaria parasite antigens in lysed blood by absorbent using monoclonal antibodies.

RDTs are relatively easy to perform. The detection of parasite.s antigen is an evidence of a current or recent infection. There is therefore, a distinct advantage in using a technique which determines whether antigens are present in a person.s blood or not. RDTs have been introduced under NVBDCP in endemic areas which are inaccessible or where microscopic facilities are either poor or lacking (due to operational reasons) and grass roots level workers are expected to perform these tests.

Need for strengthening the QA programme

Over the years, the QA of malaria microscopy in the form of regular cross-checking of examined blood smears could not be sustained upto the desired extent due to various operational and technical reasons. One of the main reasons was/is vacant posts of LTs at each level, i.e. at PHCs,malaria clinics, at state/zone and ROHFW. Besides, the quantity of the negative slides (10%) is too high.

As mentioned above, RDTs are mostly used by semi-skilled persons in the peripheral areas. Sometimes, they may not be exactly following the guidelines for storage of the kits. Moreover, the climatic conditions like temperature may also play a vital role in deterioration of the RDT quality in the field. Besides, sensitivity of malaria RDTs is dependent on several factors, including the rate of

flow of blood upto the nitrocellulose strip, the adherence of antibody (Ab) to the strip, ability of the Ab to bind antigen (Ag) and the integrity of the Ab-dye conjugate. All these factors are subject to deterioration in adverse transport and storage conditions.

Large numbers of RDTs are procured every year for use in the remote and inaccessible endemic areas where microscopy is unavailable and the quantity is increasing every year.

Moreover, published trials and experience in various countries have demonstrated a wide variability in the sensitivity of malaria RDTs, both within and between product trials. Sensitivity is particularly variable at lower parasite densities.

In view of the above, as well as due to increasing trend of *P. falciparum* cases, emergence of newer foci of drug resistance and high mortality due to malaria, an urgent need has been felt to revitalize the QA component of the laboratory services provided by microscopy and also to develop, implement and establish a QA programme for RDTs as an integrated part of malaria control under NVBDCP.

Proposed QA programme under NVBDCP

As a first step to achieve this goal, the development of SOPs was felt imperative and two SOPs have been developed. For a sustainable and foolproof implementation of QA programme, the NVBDCP has networked the laboratories involving apex institutes, medical colleges, regional and state referral laboratories (SRL), ROHFW and ZMOs. NVBDCP will act as the nodal agency and has identified the NIMR as National Reference Laboratory (NRL) for QA of malaria diagnosis both by microscopy and RDT. The following SOPs and manuals have since been developed:

- Manual on Quality Assurance of Laboratory Diagnosis of Malaria by Microscopy – Guidelines for Standard Operating Procedures
- Manual on Quality Assurance of Laboratory Diagnosis of Malaria by Rapid Diagnostic Tests - Guidelines for Standard Operating Procedures
- Manual on Quality Assurance of Laboratory Diagnosis of Malaria : Networking of Laboratories
- Laboratory Diagnosis of Malaria: Operational Guidelines for Laboratory Technicians.

The SOPs have already been field tested and approved by DGHS for implementation at the periphery.

SOPs

The SOP is the most important document in a laboratory. It describes in detail the complete procedure for performing tests and ensures that consistent and reproducible results are generated. The instructions given in a SOP must be strictly adhered to by all those who are concerned with the functioning of the laboratory.

QA programme of malaria microscopy

Microscopy is the most widely used diagnostic test in India, since the inception of a structured malaria control programme in our country. It is till today the .Gold Standard. for laboratory diagnosis, yet it does have some disadvantages, the most important being the subjectivity in interpretation of the result by the examiner. Human factors as well as reagents and equipment affect the sensitivity and specificity of malaria microscopy. The new QAP includes both internal quality control and external quality assurance.

Internal Quality Control (IQC). It describes all the activities to be taken by a laboratory to monitor each stage of a test procedure to ensure that microscopic examinations are performed correctly that is accurately and precisely which are as follows:

- All testing laboratories adhere to IQC procedures with strict control of techniques (slide preparation, staining, examination etc) and equipment (microscope, micro-slides, pricking needles etc) as per the SOP to ensure reproducibility and sensitivity of detection.
- Periodic training and retraining of microscopists/laboratory staff are ensured.
- Availability of equipment in functioning state and good quality stains/kits are ensured.
- The quality of each prepared slide is assessed at the time of microscopic examination. Whenever possible, any slide that is inadequately spread should be prepared again until a slide of an acceptable standard is produced.
- With a multitude of steps involved in processing of a specimen, errors can occur at any stage. Laboratory management needs to be aware of where errors can happen so as to reduce the possibility of their occurrence and monitoring all stages from the preparation through the examination up to the results. Reference slides and coloured charts supplied by Directorate of NVBDCP should be followed.
- Frequency and magnitude of incorrect results may be determined by independent crosschecking of the results of a proportion of the routine slides by some senior staff in the laboratory, if present.
- Troubleshooting guides for equipment, reagents and methods would be useful additions to the more isolated laboratories where instant help is not available.
- Workstation should be clean and with sufficient light. Ensure availability of water.
- Proper and correct documentation, timely report.
- The Coordinator of each malaria reference laboratory at national/ regional/state level must ensure systematic compliance with the norms for IQC. In peripheral laboratories (PHC/CHC), the MO in charge and LT must assume this responsibility.

External Quality Assurance Schemes (EQAS).

It involves specimens, of known but undisclosed content being introduced into the laboratory by designated .Apex/Reference. laboratory and examined by the staff of participating laboratory/ies using the same procedures as used for routine/normal specimens of the same type. This method checks the accuracy of the test results produced by the participating laboratories.

In the present QA programme, EQAS includes crosschecking of the examined slides and performance evaluation (proficiency testing) of the laboratory technicians working in the peripheral laboratories by coded panel slides.

EQAS of the slides examined in the field

The crosschecking of slides would now be carried out by NIMR and its field stations, ROHFWs and crosschecking laboratories of respective states. States where ZMOs are functional will carry out the crosschecking activity as per the new guidelines.

To assure the quality of microscopy, the DMOs will collect all positive and 5% negative slides from PHCs/CHCs and send them to the SRLs. To get 5% negative slides, a random number will be given every month, and every twentieth slide will be sent. In case a positive slide falls among these numbers, next slide would be sent. This exercise would be done every three months.

The SRLs would in turn send 20% of the referred positive and 5% of the referred negative slides to NIMR. The feedback of results would be sent promptly to the linked laboratory in order to take corrective action.

Proficiency testing

This will be carried out through analysis of known but coded panel slides (high quality stained blood slides), representing all the species present in the region, different parasite densities, mixed infections and also negative slides. The NRL will prepare these according to standardized procedures and will send them for a fixed number of times per year, (not less than twice a year), to each participating laboratory where microscopists are to be assessed. These slides are examined by the same staff using the same procedures as normal specimens of the same type. The results of these tests will be dispatched to the National Reference Centre/ institution concerned, within a specified time, for comparison with the national identities of each slide after decoding. Results from a laboratory might be highly reproducible but consistently incorrect. This method checks the accuracy of the test results. Feed back are to be sent promptly to correct the results.

Slide banks of unimpeachable quality with their content validated at NIMR would be utilized for training as well as for support assessment of microscopists. Such coded slides prepared according to SOPs, would be acquired by NIMR through its field stations, as they have access to the required range of *Plasmodium* species. NIMR should also be capable of providing coded and matching negative slides to make standardized and high-quality slide sets that can be used for EQAS. These slides must be cross-checked to ensure the accuracy of the original diagnosis. It should contain the slides of all the three human species of malaria parasites *P. falciparum*, *P. vivax*, *P. malariae* (prevalent in India) in thick and thin smears with different parasitemia level, including rare forms of *P. falciparum*, mixed infections and negative slides as well.

Proposed QA programme for RDT

The RDTs are mostly used by semiskilled persons in the peripheral areas who, sometimes, may not be exactly following the guidelines for storage of the kits. Moreover, the climatic conditions like temperature may also play a vital role in deterioration of the RDT quality in the field.

The target for a reasonable RDT performance is 95% sensitivity at a parasite density of 200 parasites / μ l. Therefore, it is important to determine the sensitivity and specificity under field conditions and to monitor any deterioration over time. On the other hand for procurement of new RDTs for use in the programme it is of paramount importance to assess the post dispatch (post purchase) quality. Normally pre-purchase QA is mandatory for procurement of RDT under NVBDCP.

Post dispatch QA will be carried out after the RDTs are received at the district by the DMO. Before dispatching the RDTs to the periphery, samples will be taken out randomly, and sent to the designated SRL / RRL. Thereafter, 7 RDTs will be collected randomly at an interval of 3 months till the date of expiry. Like microscopy, the QA of RDT also includes both internal quality control and external quality assurance.

IQC

The IQC starts with proper shipment and storage of the kits/samples. The DMOs should ensure that the consignee lists are prepared before shipment. The principle of FEFO should be followed in utilizing the kits. RDTs supplied by NVBDCP, though stable at temperatures up to 40°C, should however be kept in a cool, dry place away from direct sunlight. Care should be taken to ensure that the kits are at a considerable height from the ground away from dampness. The storehouse should be protected from rodents, fire, water and high temperature. IQC should be a part of training of ASHAs, MPWs and its adherence should be ensured by supervisory visits of health supervisors, MTS and DMO.

EQAS

An important component of the EQAS is the development and use of Quality Control (QC) panels to test the threshold sensitivity of RDTs to determine if any deterioration of RDTs has occurred. The method followed to develop the QC panel is preparation of antigen-based or parasite-based samples. Samples with parasite density sufficiently high are used for preparation of QC panel for testing malaria RDTs. Malaria RDTs are designed for use with fresh human blood. QC samples should therefore mimic fresh blood infected with wild parasites as closely as possible.

QA programme for RDTs also aims to ensure high accuracy of tests in the hands of endusers. Besides quality, this programme also aims to monitor technical standards of the RDTs and processes to minimize environmental impact.

Lot/batch testing of RDT kits using QC samples

The sensitivity of malaria RDTs is dependent on several factors and these factors are subject to deterioration in adverse transport and storage conditions. The rates of deterioration and their effect can vary between products. Hence, it is essential to assess the quality of the RDTs at periodical intervals with known low and high positive samples. This would be achieved by lot and batch testing of the procured kits.

From each RDT lot, 13 kits would be drawn and tested using positive (low and high parasitaemias) and negative controls for immediate QC. For long term quality assurance, 28 kits would be drawn in four lots depending on the expiry date of the kit (e.g. if expiry date is around one year, seven kits would be drawn every 3 months). For this, the .Manual for Quality Assurance of Malaria Diagnostic Tests. By the NVBDCP would be strictly followed. The tests would be carried out at the in the designated laboratories. At the periphery, DMOs would collect and send 13 randomly selected kits to the linked SRLs for QA testing.

EQAS of RDTs used by health workers at periphery

Once RDTs are supplied to the states, samples would be drawn and tested for their quality from various levels. The DMOs would collect RDT samples from the periphery and send the same to the SRL. Some kits would also undergo a temperature sensitivity test.

The DMO would monitor the process of QA at peripheral levels i.e. at the lever of ASHA and health workers apart from PHCs/CHCs to determine any deterioration in the kit. Both immediate and long term QA will be performed with the RDT kits supplied to the periphery. It will be the responsibility of the DMO to pick up 2 samples from different sources to check the sensitivity and specificity of RDTs on quarterly basis by selecting the villages randomly.

The DMO would collect information on lot number and batch number of the consignment at the time of distribution. He would retain randomly 14 kits out of the entire lot to send seven of them to the SRL. After 3 months randomly he would select some PHCs, out of which from one subcenter he would pick up one RDT. The process would be repeated to collect total seven RDTs from different subcenters after every three months. The next batch of seven RDTs would be collected from different centers at an interval of 3 months. The process of QA will be continued till the expiry period as mentioned on the kits by the manufacturer. (e.g. if expiry date is 12 months from the date of manufacturing and consignment is received after 3 months, then on receipt the 1st round of QA, thereafter 2nd, 3rd and 4th round should be carried out. The DVBC consultants and MTSs will also be actively engaged in the QA programme.

ASHAs and other end-users of RDT shall be making blood smears of all samples whether RDT is positive for *P.falciparum* or not. The negative smears are to be sent to the laboratory for confirmation of other than falciparum infection (*P. vivax*). After the tests used RDT (positive or negative) and the blood slide of the RDT positive should be marked and stored for QA. The slides of

all positive and 5% negative samples by RDT would also be collected and sent to the DMO, who in turn would send them to designated laboratory SRL for crosschecking.

EQAS in referral laboratories by coded QC samples

Coded panel samples will be sent to all the RRLs and SRLs for testing twice every year. International shipping norms would be followed while shipping the samples for testing. The linked laboratories will be required to send back the results within one month of receiving the sample. The results will be matched at the referral laboratory and corrective measures adopted. Proper documentation of the test results will be ensured.

Results

- The results of cross-checking by the reference laboratories in the prescribed format should be sent to the concerned DMOs by the 15th of the succeeding month with a copy to the state and Directorate of NVBDCP. The NVBDCP envisages use of NAMMIS for transmission of data on crosschecking of results as well.
- The district would pass on the results to the PHCs during the monthly review meeting which is held in each district every month.
- The states would compile the data of each district and send to the Directorate of NVBDCP.
- In case of high discrepancy rate i.e. 2% or above, the crosschecking laboratories would take the necessary remedial action as per SOP.
- There will be supervision of the concerned laboratory to find the condition of the microscope and to provide hands on training to the concerned LT(s).
- Results of QA of will also follow the similar route.
- Remedial actions would be taken in consultation with the SPO.

Reporting

The Directorate of NVBDCP envisages that all the documents of QA testing would be completed within the same day and the report sent to the NVBDCP and NIMR within 48 hours of the test. The data and documents are to be maintained preferably in the electronic format.

Supervision

NVBDCP would actively monitor and supervise the activities in the field and the laboratory. Officers and staff from the headquarters would visit the field areas for training and supervision. Officers from NIMR and ROHFWs also make supervisory visit and undertake necessary corrective measures. SPOs, DMOs, VBD consultants, MTSs would also be actively involved in the activity and will serve as a link between NRL, concerned SRL and periphery.

Biosafety aspects

Biosafety is a key component of total QC programme. There is definitely a potential risk of infection to Health care workers (HCWs), who provide direct or indirect health care to people or handle samples (blood) and thus continuously come in contact with pathogenic organisms, The HCWs handle infected waste and transport potentially infected specimens. Therefore, all biosafety measures should be ensured as per guidelines and HCWs must take all precautionary measures to protect themselves from accidental injury, while handling the blood (standard work precautions) and patients must also be protected from infection. RDTs are biological components and need special disposal. The guidelines for segregation and disposal of wastes would be followed.

Training

Training will be provided to the officials of the districts, states and ROHFWs involved in malaria programme and also to the identified laboratory personnel involved under QA network. Training will include both IQC and EQAS including programme implementation, supervision and monitoring. Emphasis would be given on good clinical and laboratory practices, hospital / laboratory waste management, universal safety precautions, and various aspects of QA of RDTs. For LTs, special trainings for orientation on QA procedures and remedial trainings are designed. The NVBDCP manuals will be followed and distributed for this purpose so as to maintain uniformity.

Roles and responsibilities

The Directorate of NVBDCP would be the nodal agency for the QA programme on laboratory diagnosis of malaria. It would be the focal point for national and international contacts regarding any issue related to the National malaria QA programme. Initially the QA programme would be implemented in the endemic areas by NIMR which will then be handed over to the states to carry out as an integral component of malaria control. The NIMR would act as the NRL and provide technical support to the national QA programme, as per the criteria laid down by the Directorate of NVBDCP. For details of the responsibilities of programme managers at regional, state and district levels, refer the SOPs. The whole concept of QA is a team work and if one member of the team does not adhere to the SOPs, the entire system may collapse. Therefore, it is essential that Regional Directors, SPOs, ZMOs, DMOs, VBD Consultants and MTSs are well conversed with the procedures and NVBDCP guidelines on QA.

Chapter-13

Calculation of requirements of antimalarials and RDTs

Norms for calculation of Anti-malarials

The norms for calculation of antimalarial drugs to avoid stock-outs even in circumstances like unforeseen outbreaks and procurement delays are as follows:

The data of positive malaria cases of the last completed year is taken as basis for calculation. 25% additional quantity is taken as buffer on the technical requirement. However, in view of cyclic trends of malaria outbreaks occurring, the possible requirements may be up to the maximum number of cases reported in any of the years during the decade. Therefore, this figure is also considered while calculating the requirements of antimalarial drugs, e.g. for calculating the requirements for the year 2006, the maximum number of cases reported in a year in the preceding decade, i.e. in 1997 were taken, which was 40% cases more than 2006. This factor is also important particularly when under-reporting is known.

Chloroquine

The practice of presumptive treatment of fever cases with 4 tablets of chloroquine has been stopped. However, the requirement for treatment of suspected malaria cases as clinical malaria with the full dose may remain up to 50% of blood slides collected due to delay in obtaining microscopy results. The average requirement per patient is worked out as 6 tablets considering the different dosages for various age groups. Thus, the requirement of number of tablets of Chloroquine is worked out on the following norm:

Requirement of the Chloroquine tablets (in No.) = No. of blood Slides collected × 62

This amount is also expected to take care of confirmed *P. vivax* cases and in remote and inaccessible areas where treatment after diagnosis is not possible within prescribed time. The requirement of Chloroquine for treatment of clinical malaria is expected to be reduced to less than 25 % of blood slides collected, when bivalent RDTs (which can detect both *P. vivax* and *P. falciparum*) are introduced in the programme. After a few years, when the case detection facilities are enhanced including both RDTs and microscopy, then just the technical requirements and buffer stocks will suffice for the need.

Primaquine

As per the national drug policy for treatment of malaria cases, *P. vivax* cases should be given radical treatment with primaquine. Primaquine is contraindicated in infants and pregnant women. For easy dose adjustments 2.5 mg tablets of Primaquine are used for pediatric *P. vivax* cases. 7.5 mg strength tablets of Primaquine are used for all *P. falciparum* cases and adult cases of *P. vivax*. The dose for *P. vivax* case is 0.25 mg per kg body weight for 14 days and for *P. falciparum* cases it is a single dose of 0.75 mg per kg body weight.

Primaquine (2.5 mg) tablets

Children (1-14 year old) are estimated to constitute 40% of *P. falciparum* / *P. vivax* cases. The average number of 2.5 mg tablets of Primaquine required per day per child is estimated to be 4 tablets. Therefore, the requirement of Primaquine tablets (2.5 mg) is calculated as = (Total number of *P. vivax* cases x 40% x 4 x 14) with an additional 25% as buffer stocks.

Primaquine (7.5 mg) tablets

Primaquine (7.5 mg) tablets are required for the following:

(a) Adults constitute 60% of *P. vivax* cases and require 15 mg Primaquine (2 tablets of 7.5 mg each) for 14 days. Therefore, the requirement = (No. of *P. vivax* cases x 60% x 2 x 14) + 25% buffer.

(b) Adults constitute 60% of *P. falciparum* cases and require 45 mg Primaquine (6 tablets of 7.5 mg) as a single dose. Therefore the requirement of Primaquine (7.5 mg) tablets = (Total No. of *P. falciparum* cases x 60% x 6) + 25% buffer.

(c) Children constitute 40% of *P. falciparum* cases and require 30 mg Primaquine at an average when different age groups of children are considered. Therefore, the requirement of Primaquine (7.5 mg) tablets = (Total No. of *P. falciparum* case cases x 40% x 4) + 25% buffer The total requirement of Primaquine (7.5 mg) tablets is the sum of requirements calculated in (a),(b) and (c) above.

Artemisinin based Combination Therapy (ACT)

As per the National Drug Policy 2008, ACT is rolled out in entire areas of 117 identified districts and in addition, 258 PHCs which have either chloroquine resistance or surrounding resistant cluster block PHCs. ACT-SP is the combination of ACT which is approved for use under the NVBDCP. At present, ACT-SP combiblisters are available for adults only; for children, ACT is provided by loose tablets of artesunate and SP. Efforts have been taken for introduction of ACT-SP combiblisters for various age groups of children.

ACT combiblisters for adult patients

It is estimated that 60% of *P. falciparum* cases are adults. One blister pack containing 3 tablets of Sulpha Pyremethamine (SP) and 12 tablets of Artesunate (50 mg) is required for treatment of one adult case. The pack is to be given to the confirmed *P. falciparum* cases, especially in high Pf and chloroquine resistance areas and therefore:

Technical requirement of ACT blister packs for treating *P. falciparum* cases = (No. of *P. falciparum* cases x 60% x 1) + 25% buffer.

Net total requirement will be technical requirement plus deployment reserve as mentioned above.

ACT combiblister pack for pediatric patients

It is expected that by 2010, ACT-SP combiblister packs will be available for different pediatric age groups for treatment of confirmed cases of *P. falciparum* malaria. Thereafter, no loose tablets of artesunate and SP will be procured. The distribution of cases will be as follows:

- Adults - 60% of total
- Pediatric age group - 40% of total; among pediatric age group, further:
 - Under 1 year - 10%
 - 1 to 4 years - 22%
 - 5 to 8 years - 30% and
 - 9 to 14 years - 38%

The technical requirement of ACT combiblister packs for each age group will thus be as under:

- For children under 1 year of age = (No. of Pf Cases x 0.4 x 0.1)
- For children in 1-4 year age group = (No. of Pf Cases x 0.4 x 0.22)
- For children in 5-8 year age group = (No. of Pf Cases x 0.4 x 0.3)
- For children in 9-14 years age group = (No. of Pf Cases x 0.4 x 0.38)

25% buffer will be kept in addition for each of the age groups.

There are various no / types of outlets for treatment which includes ASHA at village level, Subcentre, PHCs, CHC and hospital. To ensure no stock out of this important drug, deployment reserves are essential and the estimated norms of deployment reserve to be kept at each level are:

- ASHA - 2 courses for each age group.
- Subcentre - 3 courses for each pediatric age group and 6 courses for adults.
- PHC - 10 courses for each pediatric age group and 25 courses for adults.
- CHC - 15 courses for each pediatric age group and 50 courses for adults.
- At the district and state levels, stock for replenishing will be kept on the basis of total Pf cases expected to be treated in a year which will include blisters of all age group in the following proportion:

25% is additionally kept as buffer for each of the age group to meet the requirement for exigencies and requirement for other Chloroquine resistant areas.

Net requirement for each of the age group will be technical requirement plus deployment reserves. The deployment reserves will be almost same for each of the age group. To ensure no stock-outs at each level the expiry of ACT at various levels may be inevitable as the shelf life of ACT is only 2 years and effective shelf life after reaching periphery may be 1½ year only.

Quinine and Arte-ether injections

These injections are required for treatment of severe and complicated Pf cases. Adults are treated with Arte-ether Injection while children and pregnant women are treated with Quinine injections. The proportion of cases in adults and children is taken as 60% and 40% respectively. It is assumed that in the prevailing infrastructure in high malaria endemic areas, upto 10% of Pf cases may develop severity and complications. An average 3 injections of Arte-ether / 10 injections of quinine are required per patient. The requirement of Arte-ether and Quinine injections are as follows:

Arte-ether injections = (No. of Pf cases x 60% x 10% x 3) + 25% buffer

Quinine injections = (No. of Pf cases x 40% x 10% x 10) + 25% buffer

Generally, treatment with Quinine injection is required to be given for 3 days or till patient is able to take oral treatment. An average of 30 Quinine Sulphate tablets is required per patient during the remaining 7 days.

The requirement of Quinine Sulphate tablets are = (No. of Pf cases x 40% x 10% x 30) + 25% buffer

Requirement of RDT kits

RDT kits are to be used in remote / hard to reach Pf predominant areas where microscopy results cannot be obtained within 24 hours of the case reporting to a health worker/volunteer/facility. At present, around 100 million blood slides are collected in the country of which 40% are from high Pf endemic areas. Out of it around 40% are estimated to be from remote / hard to reach areas.

The programme is endeavoring to train ASHAs in the use of RD Kits and administration of malaria drugs. RDK use is to be scaled up along with the training of ASHAs. Once the trained ASHAs are deployed in these areas, around 16 million RD Kits would be required for the country. When multivalent RDTs are introduced in the programme, then this requirement may go up to 40 million and microscopy will be reduced by similar numbers which will enable in improving quality of slide examination.

At present the states may follow the steps given below for working out the RDT requirements for *P. falciparum* case detection:

40% of total blood slide collection from PHCs with > 3 API and >30% Pf will be from remote / hard to reach areas where blood slide results are not available within 24 hours. An additional 25% RDTs will be required as buffer stocks.

Chapter-14

Detailed planning for epidemic containment measures

Mass Survey

Manpower Requirements

It is expected that a two member team can collect 100 blood smears and administer treatment in a day. The number of persons required for blood smear collection and administration of treatment $= (\text{Total population} \times 2) / (100 \times 7)$

If the mass survey cannot be completed in seven days, it can be extended by another three days. Any further delay will result in extension of the epidemic zone and deaths.

Requirements of materials

It is assumed that in any epidemic at the most 40% population would be affected. Out of those affected, around 60% will be adults and 40% children (based on demography of the country). ACT-SP used under the programme is available at present as blister packs for adults and loose tablets of artesunate and SP for children. The requirements of various drugs and other commodities are as follows:

1. No. of blister packs of ACT for adults - Total population \times 0.6 (adults) \times 0.4 (affected)
 2. No. of artesunate tablets for children - Total population \times 0.4 (children) \times 0.4 (affected) \times 8 (No. of artesunate tablets required per child)
 3. No. of SP tablets for children - Total population \times 0.4 (children) \times 0.4 (affected) \times 2 (No. of SP tablets required per child)
- (Once, ACT blister packs are available for all age groups, the calculations will be done according to the demographic profile of the population)
4. No. of chloroquine tablets - Total population \times 0.4 (affected) \times 6 (No. of tablets required per case)
 5. No. of primaquine (7.5 mg base) tablets - Total population \times 0.4 (affected) \times 6 (No. of tablets required per case)
 6. No. of microscopy slides / RDTs - Total population \times 0.4 (affected) \times 1 (RDT would be 40% of number of slides)
 7. No. of microscopists - Total population / 50 \times 7
 8. No. of microscopes - One per microscopist
 9. Injection Arteether - Total population \times 0.6 (adults) \times 0.4 (affected) \times 0.1 (10% may develop severe malaria) \times 3 (No. of ampoules per case)
 10. Injection Quinine - Total population \times 0.4 (children) \times 0.4 (affected) \times 0.1 (10% may develop severe malaria) \times 10 (No. of ampoules per case) - for use in children and pregnant women.
 11. JSB Stain, cotton-wool, alcohol/savlon, slide boxes, lancets, material for cleaning and packing of slides, stationery, etc. to be procured on ad-hoc basis.
 12. Accordingly other supportive materials like IV set, IV fluids etc should be provisioned.

Proformae for epidemic management

Epidemic Control Proforma - I: List of villages within the Malaria Epidemic Zone

PHC_____

Subcentre_____

Epidemic Control Proforma - II: Proforma for field recording of survey data

The M-1 format will be utilized for the purpose of recording survey data. This information will also be reflected in the fortnightly case surveillance report in M-4.

After completion of rapid fever survey or mass survey, the field data of Proforma-II are tabulated in Proforma-III given below for epidemiological evaluation and analysis of the pattern and course of epidemic

Epidemic Control Proforma - III: Results of mass survey In epidemic area

S. No	Name of village	Population					
		<1 year	1-4 years	5-8 years	9-14 years	15 years & above	Total
1	2	3	4	5	6	7	8

Population tested (blood slides / RDT)						Drugs consumed			
< 1 year	1-4 years	5-8 years	9-14 years	15 years & above	Total	Chloroquine	ACT	Primaquine	Paracetamol
9	10	11	12	13	14	15	16	17	18

Positives detected						% of blood smears collected / RDTs done	Positives				Remarks
< 1 year	1-4 years	5-8 years	9-14 years	15 years & above	Total		Pv	Pf	Mixed	Total	
19	20	21	22	23	24	25	26	27	28	29	30

Anti-vector Measures

Indoor space Spray should be started as soon as survey results of a village are available. Do not wait for completion of survey in the entire area. Other villages are included as soon as the survey results are available.

Formulation	Dilute 1 litre of 2% Pyrethrum extract with 19 litres of kerosene oil to make 0.1% solution, ready for spray
Dosage	15 to 30 cc to be sprayed in 30 cubic metres of space
Equipment	Hand operated micro-discharge fogging machine/hand operated atomizers (Flit pump)
Timing	Preferably evening hours or early morning
Precaution	Close all doors/windows and other openings before space spray

(Commercial ready to use formulations such as .Finit., .Hexit. or .Baygon., etc. may be used for space spray)

IRS Operations - Manpower and equipment required for 10 days operation:

No. of spray squads required to cover the area

No. of squads required in plain areas

No. of human dwellings and mixed dwellings in the targeted villages/600

No. of houses sprayed per pump per day - 30 in plain areas

No. of houses sprayed per squad - 60 (2 stirrup pumps in each squad) No. of houses sprayed by one squad in 10 days – 600

No. of squads required in hilly areas

No. of human dwellings and mixed dwellings in the targeted villages/500

No. of houses sprayed per pump per day - 25 in plain areas

No. of houses sprayed per squad - 50 (2 stirrup pumps in each squad) No. of houses sprayed by one squad in 10 days – 500

Depending upon terrain and the number of squads, the following is the requirement:

- Field Workers
- Superior Field Workers
- Stirrup Pumps reserve
- Bucket 3 gallon capacity
- Bucket 2 gallon capacity
 - 5 per squad
 - 1 per squad
 - 2 per squad (with 1 additional pump per 2 squads)
 - 4 per squad
 - 1 per squad

- Soap, straining cloth, nozzle tips, measuring jug, rope, pump repair kit, asbestos thread, washers and plastic sheets Insecticide required should be calculated proportionately for the population affected by epidemic for one round of spray

● DDT 50% wp	@ 75 MT per million population
● Malathion 25% wp	@ 300 MT per million population
● Deltamethrin 2.5% wp	@ 30 MT per million population
● Cyfluthrin 10% wp	@ 9.38 MT per million population
● Lambdacyhalothrin 10% wp	@ 9.38 MT per million population

The spray operations are planned village-wise. A ten day advance spray programme covering all villages in the epidemic zone is chalked out in the proforma.

The MPW/Superior Field Worker of the mobile epidemic team will supervise spray operations and maintain the diary to record daily achievement of spray coverage of human dwellings, mixed dwellings and rooms in the villages sprayed. On completion of IRS and space spray operations, the completion report is prepared for both operations and sent to appropriate authorities. The MOPHC along with MTS will supervise these operations during their entire course.

Chapter-15

Malaria Surveillance, Monitoring and Evaluation

Introduction

Ever since the inception of the National Malaria Control Programme in 1953, the programme has regularly collected epidemiological data and compiled indicators, which have been the basis of impact assessment and future planning. The programme has over the years adapted to the ever changing needs on Monitoring & Evaluation, which today is one of the most important aspect of programme implementation and management. The concept of programme monitoring has now evolved from mere monitoring of impact and disease burden to close follow up of processes, outputs and outcomes.

Traditionally the programme has compiled epidemiological data through a system of sixteen manual reporting formats which are exhaustive in reporting. In the past few years the anti-malaria programme has undergone significant policy changes. Newer diagnostics like RDTs have been introduced, at the peripheral level and bednets have been distributed which will be scaled up rapidly in the coming years. In view of this, mechanisms to generate accountability for these expensive resources have to be developed. Until now MPWs were involved in active case detection by house to house visit. Over the years shortage of these MPWs has led to poor surveillance activity in the programme. The integration with NRHM and induction of the ASHA as the first point of contact with the health care delivery, has called for further modifications in reporting requirements.

There is a need for strengthening the monitoring of programme management in NVBDCP. Programme monitoring enables continuous follow up of processes and outputs to identify problems at local level and help decision making where it is most needed. New cadre of M&E staff in the form of Malaria Technical Supervisor (MTS) is being appointed at sub-district level. It becomes imperative to utilize these personnel not only in routine monitoring of activities but also in assessment of quality of service delivery and for obtaining reliable data on programme management to assist in programme planning. The NVBDCP envisages to implement Lot Quality Assurance Sampling (LQAS) based system of annual/ biannual/ quarterly surveys to obtain quality data on availability of diagnosis and treatment within 24 hours, on utilization of bed-nets and quality of IRS coverage and reasons for non-acceptance. This data will be reported through Programme Management Monitoring Reports (PMMRs) which will also report trainings, field visits, logistics etc.

A system also needs to be developed to continuously report in patients with severe malaria and deaths on account of malaria. For this purpose a network of sentinel sites is required to provide data on trends of severe malaria and deaths due to malaria. NVBDCP now foresees establishing 1-2 sentinel sites in each high endemic district being covered under World Bank Project to begin with, for effective system of computerized data entry for the speedy transmission and analysis of this data.

Cash grants are being released to the states for various activities, which necessitates stringent monitoring of finances in the programme. This component is being strengthened for more effective use of resources.

In-depth reviews are conducted by involving various institutions and agencies which have contributed to assessment of programme implementation as well as its impact. It is now planned to conduct surveys at more regular intervals to obtain information on utilization of services by beneficiaries and behavioral aspects related to malaria, prevention and control for formulating area-specific control strategies.

Terminology

1. Surveillance

Surveillance has been defined as a continuous scrutiny of the factors that determine the occurrence and distribution of disease. Surveillance is essential for effective control and prevention, and includes the collection, analysis, interpretation and dissemination of relevant information for action. In the programme active case detection is carried out by MPWs through domiciliary visits while passive case detection is done by facilities like ASHAs, subcentres, PHCs, malaria clinics etc. where the patient comes for diagnosis and treatment.

Not all aspects of the disease can be captured through a case management based system alone. Related indicators, such as drug resistance and insecticide resistance are tracked in a few carefully chosen sites spread across the country, called .sentinel surveillance. sites. Similarly, a few carefully chosen hospitals will serve as sentinel sites for tracking incidence and outcomes of severe malaria.

2. Monitoring

Monitoring encompasses on-going follow-up of the planned program activities / processes to examine whether the program is being implemented as planned and whether it is on track to reach stated goals. Planning, implementation and monitoring can be thought of as a sequence of cyclical processes, where monitoring provides the information and feedback needed to plan corrective action as and where necessary.

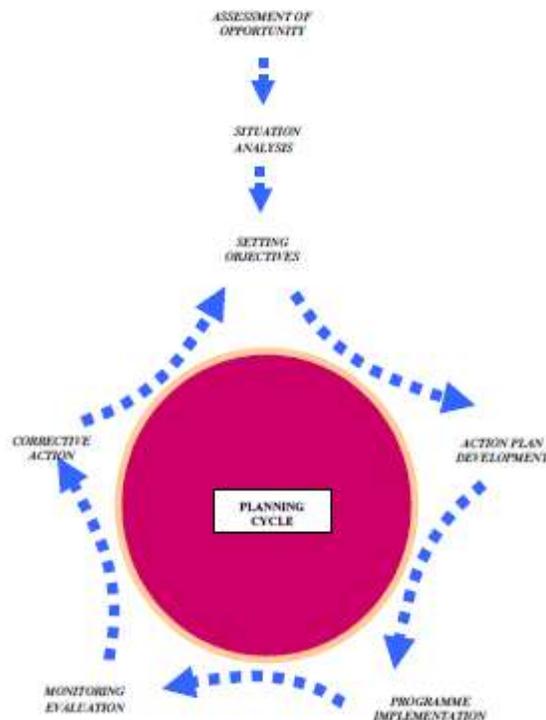
3. Evaluation

Evaluation tells the program whether it has achieved the stated goals in defined time-periods, and why it may have succeeded or failed. Evaluations are expected to lead to modification of program design and policies. The performance of the program is evaluated by independently conducted periodic surveys and qualitative assessments which provide measurements of a set of predetermined indicators. These include indicators like proportion of cases receiving timely case management, the correct use of bed nets, IRS, incidence of severe malaria and malaria mortality.

4. Planning

Planning means the rational use of relevant epidemiological data to make the most effective possible utilization of program resources, based on the best understanding of cause-effect relationships, leading to the achievement of program goals. Planning is a necessary element of program management.

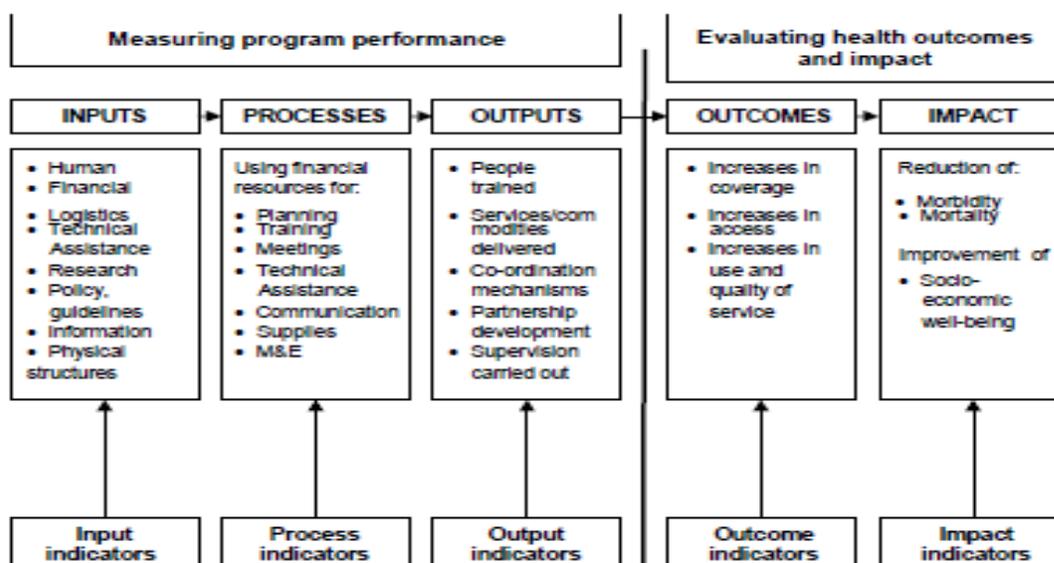
Planning is a cyclical process which is initiated with the identification of opportunities for change and improvement. This is supported by situation analysis to assess the baseline information on disease burden, epidemiological determinants and behavioral factors influencing prevention and control. Once the disease burden is ascertained the potential for change is estimated and objectives are set. The objectives are set keeping in mind the feasibility aspects. It is therefore always recommended to formulate SMART objectives i.e. specific, measurable, achievable, realistic and time-bound objectives, following which resources are identified and a costed plan is developed for execution to achieve the set objectives. Programme implementation is then begun and is constantly monitored to assess whether activities are progressing as planned. Programme Evaluation is done at periodic intervals and based on the findings, mid-course corrections are made. Final programme evaluations assist in impact assessment and reframing of programme policies. Fig below illustrates the sequence to be followed in a planning cycle



In the malaria program, routine planning is an annual feature at block, district and higher levels, usually undertaken by core malaria program staff. Typically, surveillance and other program monitoring data is used to plan for insecticide spray, identification of areas for distribution of bednets, planning for outbreak preparedness, planning for supplies and trainings related to case detection and management.

5. Types of indicators

Indicators are specific, well-defined parameters, to represent some aspect of the disease or the program. As described later, indicators typically describe inputs, processes, outputs, outcomes or impact of the program in a manner that makes comparisons possible over time or between two or more groups. The indicator helps define and measure distinct elements of the program, for example, Annual Parasite Incidence (API) is an indicator of disease burden and programme impact. Fig 11.2 below illustrates the relationship between different stages of programme implementation and M&E framework.



Requirement of indicators, at each level of health care delivery, is very specific. At the lower levels like PHCs and districts, indicators are utilized for local decision making while at the national level they are more relevant for policy making and assessing the overall progress.

i. Input Indicator

Input indicators tell us what the program is investing. Besides financial resources, the timely procurement of equipment and supplies, recruitments of staff and training provided to all functionaries are program inputs. Input indicators include, for instance, the achievement of targets

for numbers of health workers or volunteers trained, achievement of procurement targets for specified supplies, etc.

a. Process Indicator

Process indicators tell us whether specified program activities are happening as planned, in quantity and quality. Quality of training or the quality of supplies provided are processes that are often measured. Similarly, review and planning meetings held, plans made, supervisory visits made and contracts awarded, are all processes. The quality control of data is itself a process, and whether specified data quality assurance processes have been established is an indicator of the process.

b. Output Indicator

Output indicators tell us what the immediate results of the inputs and processes were. Typically, what health workers do are outputs, which have come about as a result of many inputs and processes. The distribution of bed nets, detection of fever cases, achievement of spray targets are all outputs.

ii. Outcome Indicator

Outcome indicators tell us whether the program interventions are having desired effects. Timely case management, correct use of bed nets and reduction in vector density are all outcomes. These can be thought of as indicators of the status of the immediate causes of disease. From the best available current knowledge of the disease, one would predict that, if these indicators improved, disease burden should decrease.

a. Impact Indicator

Impact indicators tell us whether we have reached our goals. In the context of malaria, these are indicators of the burden of disease: incidence of malaria, incidence of severe malaria and death rates from malaria. The categorization of a given indicator as input or process or output indicator should not be considered rigid, but should be utilized as a convenient framework to facilitate communication and planning within the program.

Definitions

Definitions in malaria control are to be applied to disease management as well as selection criteria of target population for vector control. Standard case definitions are required to bring about uniformity in management of cases as well as their reporting, which enables comparability within the same reporting unit over a period of time and across different reporting units. These case definitions are to be used at all levels in the programme.

1. Case Definitions

Table below provides case definitions for use in conjunction with indicators related to case detection and management.

1. As per the revised Drug Policy (2008) all fever cases suspected as malaria should be investigated by microscopy or RDT. Therefore all efforts should be made to diagnose a suspected case. With the availability of RDTs in remote areas it is possible to confirm diagnosis in the remotest areas. Only in

exceptional circumstances where diagnosis by microscopy or RDK is not possible, cases with fever without any other obvious cause should be considered as clinical malaria and treated.

	Terms	Definitions
1	Suspected Malaria	<p>A patient with fever in endemic* area during transmission season, or who has recently visited an endemic area, without any other obvious cause of fever like:</p> <p>Cough and other signs of respiratory infection Running nose and other signs of cold Diarrhoea Pelvic inflammation indicated by severe low back ache, with or without vaginal discharge and urinary symptoms Skin rash suggestive of eruptive illness Burning micturition Skin infections e.g. boils, abscess, infected wounds Painful swelling of joints Ear discharge</p> <p>However, none of these symptoms exclude malaria with certainty. Only an experienced health functionary can exclude other "obvious causes of fever".</p>

2	Clinical Malaria	<p>A patient with fever in endemic area during transmission season, or who has recently visited an endemic area, without any other obvious cause of fever will be considered as a case of clinical malaria if the diagnosis cannot be established within 24 hours and treated accordingly. For ruling out other causes of fever, the following should be looked for.</p> <ol style="list-style-type: none"> 1. Cough and other signs of respiratory infection 2. Running nose and other signs of cold 3. Diarrhoea 4. Pelvic inflammation indicated by severe low back ache, with or without vaginal discharge and urinary symptoms 5. Skin rash suggestive of eruptive illness 6. Burning micturition 7. Skin infections e.g. boils, abscess, infected wounds 8. Painful swelling of joints 9. Ear discharge <p>However, none of these symptoms exclude malaria with certainty. Only an experienced health functionary can exclude other "obvious causes of fever".</p>
3	Uncomplicated malaria (confirmed)	<p>A patient with fever without any other obvious cause and diagnosis confirmed by microscopy showing asexual malaria parasites in the blood and/or positive rapid diagnostic test (RDT) and not having complications. These cases are recorded as either Pf or Pv; a case of mixed infection is recorded as Pf in the programme.</p>
4	Severe malaria	<p>A patient, who presents with symptoms and/or signs of severe malaria with laboratory confirmation of diagnosis.</p> <p>Severe malaria is clinically characterized by confusion or drowsiness with extreme weakness (prostration). In addition, the following may develop: cerebral malaria; generalized convulsions; pulmonary oedema; severe anaemia; renal failure; hypoglycaemia; metabolic acidosis; circulatory collapse/shock; spontaneous bleeding; laboratory evidence of DIC; macroscopic haemoglobinuria; hyperthermia and hyperparasitaemia.</p>
5	Malaria death	<p>Death of a patient with severe malaria, defined according to the above criteria. A death can be medically certified as due to malaria only if blood smear and/or RDT have been positive for <i>P.falciparum</i>.</p>

2.

Recent literature points to the possibility of severe malaria in patients with *Plasmodium vivax*. Although this is very rare, it should be recognized, so cases with only *P.vivax* may also be recorded as severe, if they fulfill the clinical criteria.

3. If the slide is positive for *P.vivax* only, death can only be certified as due to malaria by a tertiary level or higher facility, and a case report must be submitted to the State VBDCP for detailed death investigation. * Endemic area - Constant presence of a disease in a given geographical area without importation from outside i.e presence of local transmission.

2. Integrated Vector Management

As per the modified Plan of Operation (MPO) areas recording more than 2 API taking sub-centre as unit are eligible for IRS with the appropriate insecticide. The Expert Committee (1995) further devised high risk criteria taking village as unit for identification of areas to be sprayed. However, for judicious use of resources and focused intervention the Technical Advisory Committee (2002) on Malaria has rationalized the criteria for selection of villages for undertaking IRS indicated in the table below.

Vector Control Method	Target Population
IRS	<p>Areas with API more than 2 are classified as high risk. The Technical Advisory Committee on Malaria in its meeting held on 30.05.2002 has rationalized the criteria for undertaking indoor residual spraying. These criteria are as follows:</p> <ul style="list-style-type: none"> • To spray on priority basis all areas, taking village/ sub-centre as a unit, with more than 5 API with suitable insecticides, where ABER is 10% or more. • To spray on priority basis with suitable insecticide all areas reporting more than 5% SPR (based on passive collection of blood slides), if the ABER is below 10% • Due priority be accorded for spray if Pf proportion is more than 50%. • To accord priority for IRS in areas with less than API 5 and SPR 5% in case of drug resistant foci, project areas with population migration and aggregation or other vulnerable factors including peri-cantonment area. • To make provision for insecticidal spraying in epidemic situations. • Rotation of insecticides may be done so as to prolong their effectiveness. - Other parameters including entomological, ecological parameters etc. may also be considered while prioritizing areas for spraying. <p>The population must be defined in terms of its size, as well as the no of households. It should be estimated annually village wise. It should also be mapped at the beginning of each year.</p>

At present IRS and ITNs/LLINs are the two key vector control interventions used in malaria control. Programme experience, drawn from years of operational problems encountered, has taught that IRS is a cost as well as labour-intensive activity. The In-depth review conducted by NIMR in the year 2006 also indicates the low coverage rates of IRS. Studies conducted across the globe in malaria endemic regions have shown that the average annual cost of bed-nets is much less than the cost of IRS; however, the use of bed nets requires continuous measures to improve community utilization. The NVBDCP has therefore taken the conscious decision to use either IRS or bednets in a given area which means areas chosen for one method will usually not be covered by the second method of vector control. The High risk area requiring vector intervention and difficult for conducting spray operations and supervision of spray activities (remote, inaccessible areas, hilly terrain, forested area etc.) or areas where bednet usage and acceptability is high, would be covered with ITNs/ LLINs. The unit of area for coverage will be village.

Monitoring & Evaluation System

The system for monitoring and evaluation of malaria in the country comprises of

- Routine Health Management Information System (HMIS)
- Supportive supervision and data quality assurance

- Malaria surveillance including sentinel surveillance of severe cases and deaths
- House and health facility surveys
- Evaluations

The above components provide data on case management, vector control, programme Management, coverage and utilization of services. In addition very specific monitoring for *Pf* Resistance, entomological aspects and quality assurance are carried out.

i. Management Information System (MIS)

The MIS is a series of recording and reporting formats to be maintained and transmitted by different tiers of the health care delivery system. The records and reports are to be maintained in such a way that high quality reliable data is generated from them. This data is the treasure house of information from which a series of indicators are derived at different levels.

a. Recording and reporting

Integration of all public health programmes and concerted service delivery under the umbrella of NRHM along with changing data and information needs of NVBDCP have prompted the revision and simplification of the HMIS. New interventions like RDTs, ACT, and ITNs which have been recently introduced, are expensive inputs into the programme and it becomes important to closely monitor their utilization. Reporting on training activities, field visits, logistics and LQAS are to be done as part of programme management monitoring. For the purpose of routine recording and reporting the following M-1 to M-4 formats, VC-1 to VC-12 formats and Programme Management Monitoring Report is used.

Case detection and management

- M-1 : Report of surveillance by ASHA/ MPW/ health facility
- M-2 : Laboratory request for slide examination
- M-3 : Record of slide examination in PHC laboratory
- M-4: Fortnightly report of cases from sub centre/ PHC/ district/ state

Integrated vector Control

- VC-1: Primary record of IRS
- VC-1S: Wall stencil
- VC-2: District IRS output form
- VC-3: Primary record of bed net delivery and impregnation
- VC-4: Bed net delivery and impregnation form
- VC-5: District annual stock report on vector control supplies
- VC- 6. IVM plan - Block level

Programme Management Monitoring Report (PMMR)

An overview of these records and reports is provided below in the table:

Monitoring indicators used in disease surveillance and case detection

S. No.	Area	Indicator	Definition	Frequency	Source
1	Disease burden & impact	Fever Cases Malaria Cases Pf Cases Deaths due to Malaria	Total Fever Cases Total Malaria Cases Total Pf Cases Total deaths due to malaria	Monthly, Cumulative for the year	M-1, M-4- SC, M-4- PHC
2	Surveillance/ case finding	Monthly Blood Examination Rate (MBER) (should be more than 1% of population in the transmission season)	$\{(\text{Number of blood smears examined} + \text{RDTs positive in a Month}) \div \text{Total Population} \} \times 100$	Monthly	M-4-PHC
3	Surveillance/ case finding	Annual Blood Examination Rate (ABER) (expected to be more than 10% of population)	$\{(\text{Number of blood smears examined} + \text{RDTs positive in a year}) \div \text{Total Population} \} \times 100$	Annual	M-4-PHC
4	Disease burden & impact	Annual Parasite Incidence (API)	$\{(\text{Total No. of positive blood smears positive for malaria parasite} + \text{RDTs positive for malaria Parasite in a year}) \div \text{Total Population} \} \times 1000$	Annual	M-4-PHC
5	Disease burden & impact	Annual Falciparum Incidence (Afi)	$\{(\text{Total No. of blood smears positive for Pf malaria parasite} + \text{RDTs positive for Pf malaria Parasite in a year}) \div \text{Total Population} \} \times 1000$	Annual	M-4-PHC
6	Disease burden & impact	Test Positivity rate (TPR) (Test = Slide+RDT) is independent of surveillance activity, therefore a better indicator for impact assessment	$\{(\text{Total No. of blood smears positive for malaria parasite} + \text{RDTs positive for malaria Parasite}) \div (\text{Total No. of blood smears examined} + \text{positive RDTs}) \} \times 100$	Monthly, Cumulative for the year	M-4-PHC
7	Disease burden & impact	Test falciparum Rate (TfR) It is independent of surveillance and indicates Pf preponderance	$\{(\text{Total No. of blood smears positive for Pf malaria parasite} + \text{RDTs found Positive for Pf}) \div (\text{Total No. of blood smears examined} + \text{positive RDTs}) \} \times 100$	Monthly, Cumulative for the year	M-4-PHC
8	Disease burden & impact	Pf percentage (Pf %) indicates trends in proportion of cases due to Pf out of total cases	$\{(\text{Total No. of blood smears positive for Pf malaria parasite} + \text{RDTs found Positive for Pf}) \div (\text{Total No. of positive blood smears} + \text{positive RDTs for malaria parasite}) \} \times 100$	Monthly, Cumulative for the year	M-4-PHC
9	Process	% of Community level facilities equipped with RDT in the last reporting period	$(\text{ASHA/ other community volunteers equipped with RDT} \div \text{Total ASHA/ other community volunteers}) \times 100$	Quarterly, Annual	PMMR
10	Output	Utilization of ACT	No of Pf cases treated with ACT	Monthly, Annual	M-4-PHC
11	Output	Utilization of ACT	No of severe cases treated with inj arte-ether	Monthly, Annual	M-4-PHC

Vector control

The vector control formats are to be utilized for the purpose of reporting of vector control activities undertaken during the transmission season. The indicators used for monitoring integrated vector control are described in the below table. The indicator definition, periodicity of its use and the source format are given in detail.

Monitoring indicators in IVM

S. No.	Area	Indicator	Definition	Frequency	Source
1	Process	% of spray equipment in working condition	(Number of spray equipment in working condition ÷ No. of spray equipment present) X 100	Annual (Pretransmission)	VC-2
2	Process	% of spray squads engaged	(No of spray squads engaged ÷ No. of spray squads required) X 100	Annual (Pre-transmission)	VC-2
3	Output	Bed nets distributed	Number of nets distributed	Quarterly, Annual	VC-4
4	Output	Bed nets treated	Number of nets treated	Quarterly, Annual	VC -4
5	Output	Insecticide use - average insecticide per bednet	Volume of Insecticide used for treatment of Bednets Volume of insecticide used for bednet treatment/ No of bednets treated Volume of insecticide used for IRS	Annual	PMMR
6	Outcome	% of eligible population covered by ITN (Should be 80% or more)	(Number of households with at least 2 effective bed nets ÷ eligible households) X 100	Annual	VC-4 versus Annual Plan
7	Outcome	% of targeted population covered by ITN (Should be 80% or more)	(Number of households with at least 2 effective bed nets ÷ targeted households) X 100	Annual	VC-4
7	Outcome	% of eligible villages with more than 80 % population coverage with ITNs	(Number of eligible villages with more than 80% coverage with ITNs ÷ No. of eligible villages) X 100	Round wise, Annual	VC-4
8	Outcome	IRS coverage - eligible population (%) (Should be 80% or more)	(Population covered with IRS ÷ Total Eligible population) X 100	Round wise during transmission season	VC-2 versus Annual Plan
9	Outcome	IRS coverage - targeted population (%) (Should be 80% or more)	(Population covered with IRS ÷ Total targeted population) X 100	Round wise during transmission season	VC-2
10	Outcome	IRS coverage - targeted Rooms % (Should be 80% or more)	(Rooms sprayed completely in houses covered ÷ Total No. of rooms Targeted) X 100	Round wise during transmission season	VC-2

Programme Management Monitoring Report (PMMR)

This report is to monitor progress made on different programme processes and other management issues. Update on training status of the staff as well as the trainings conducted, field visits and reviews conducted and reviews undertaken as well as situation of logistics and stock-outs are to be provided on a quarterly basis. The report is given in Annexure K-12. It has the following sections:

Part A: Field visits and reviews

Part B: Quality of service delivery

Part C: Training activity

Part D: BCC activity for malaria control

Part E: Status of logistics

In future this report will also contain data collected by MTSs through Lot Quality Assurance Sampling (LQAS) based surveys. The report is generated by the district every quarter and sent to the state by the 15th of the month following the quarter. The quarterly state level report should be compiled and should reach NVBDCP by the 21st of the month following, e.g. for the 1st quarter of 2009 (1st Jan 09 - 31st Mar 09), the district should forward the report to the state by 15th April 09 and the state should send its report to NVBDCP by 21st of April 09.

Monitoring indicators in programme management

Programme management indicators help assess the effectiveness of programme implementation. These indicators usually focus on interim aspects like percentage of staff in position, percentage of staff trained, percentage of facilities reporting stock-outs, number of BCC activities conducted etc. which enable translation of inputs into outcomes and ultimately impact. The programme management indicators to be applied in malaria control are described in the below table:

Monitoring indicators used in programme management

S. No.	Area	Indicator	Definition	Frequency	Source
1	Input	Nos of RDTs & ACTs planned versus received and used	<ul style="list-style-type: none"> Number of RDTs planned to be used Number of RDTs received Number of RDTs used Number of ACTs planned to be used Number of ACTs received Number of ACTs used Number of functional microscopes 	Annual	M-1, M-4-SC, M-4-PHC PMMR
2	Input	% of staff in place (ASHA, MPW, MTS, LT, DVBD Consultant)	(No of staff In place÷ Total No. of staff sanctioned) X 100	Quarterly, Annual	PMMR
3	Process	% of MPW/ASHA/ other volunteers trained for use of RDT / ACT (calculated separately for different staff)	(Total No. of MPW/ ASHA/ other volunteers trained for use of RDT or ACT ÷ Total No of MPW/ ASHA/ other volunteers) X 100	Quarterly, Annual	PMMR
4	Process	% of diagnostic facilities functional with microscopy/RDT in the last reporting period	(Total No. of PHCs/Pvt Sector Centres with functional microscopy ÷ Total No of PHCs/ Pvt sector centres) X 100	Quarterly, Annual	PMMR
5	Process	% of facilities (SC and PHC) / village level functionaries (ASHA, AWW) reporting stock-out of antimalarials during the fortnight	(No. of health facilities reporting stock-outs in the previous fortnight ÷ No of Health facilities) X 100	Fortnightly	M-4-SC, M-4-PHC
6	Process	BCC activities	No of BCC/ IEC activities e.g. meetings, rallies, exhibitions, street plays, miking, posters/ pamphlets, wall paintings, etc.	Quarterly, Annual	PMMR
7	Outcome	% of fever cases with access to complete diagnosis and treatment	(Fever cases who were tested for malaria by microscopy or RDT with a positive test result and were started on treatment no later than the next day with ACT ÷ Total no of fever cases who were tested for malaria by microscopy or RDT with a positive test) X 100	Quarterly/ half yearly	PMMR based on LQAS
8	Outcome	% households adequately protected by personal protection methods	(House holds in which beneficiaries reported having slept under ITNs / LLINs previous night ÷ Total No of houses with bednets surveyed) X 100	Quarterly/ half yearly	PMMR based on LQAS
9	Outcome	% of PHCs with acceptable level of utilization of ITNs/ LLINs	(PHC sampled in which utilization of ITNs/ LLINs was more than 80% ÷ Total No of PHCs sampled for utilization) X100	Quarterly/ half yearly	PMMR based on LQAS

Flow of information

The flow of reports in the HMIS and their feedback paths are given in the Fig 11.3. Various records maintained at different levels are compiled to generate different programme reports. The flow of reports in the system is given below.

Surveillance/ case detection and management. The report of surveillance by ASHA/ MPW/ Health facility (M-1) is maintained at every level diagnosing and treating cases like ASHAs/ AWWs/ CHVs at village level, MPWs at subcentre level and MO-PHCs. The M-1 is submitted to the subcentre fortnightly, where it is compiled village/ health care provider wise into fortnightly report of cases (M-4) by MPW(M) or in his absence by MPW (F). Subcentre M-4 is submitted by MPW to the MO-PHC. At the PHC the report is further compiled for all the subcentres in the PHC area, the PHC data is further added to it. PHC level M-4 is sent to the district where data is entered in the web-based HMIS i.e. NAMMIS and if not possible sent manually to state. Laboratory request form for slide examination (M-2) is sent along with slides transported to lab for examination. All slides sent to lab for examination are entered in the record of slide examination in PHC laboratory (M-3) and result is transmitted back (indicated by dashed line) in the M-2. The feedback pathways are shown by blue dotted arrows.

Vector control. Primary record of IRS (VC-1) and primary record of bed net delivery and impregnation (VC-3) are the village level record of activities conducted. VC-1 is maintained by SFW and submitted to MO-PHC. Similarly VC-3 is filled by MPW with assistance from ASHAs/ AWWs/ CHVs and submitted to MO-PHC. At the PHC, VC-1 is compiled subcentre wise into IRS output form (VC-2) and VC-3 is compiled into VC-4. PHC level output reports are sent to district where they are entered into the web-based system of data entry. In case NAMMIS is not functional the district level report should be sent manually to the state.

Programme Management Monitoring Report. This report is compiled quarterly by the district and sent to the state. When NAMMIS is operational this may be directly entered into the web based system.

Role of health care staff in monitoring and evaluation

Village level (ASHAs/ AWW/ CHV). These peripheral level workers form the first point of contact with fever cases and are the primary source of large proportion of data related to case detection and treatment. Therefore the scope of their work involves the following:

- To maintain the record of all fever cases in M-1 and provide fortnightly report of the same to the MPW by 21st of the month for the 1st fortnight and the 7th of following month for the 2nd fortnight.
- To enter slides of RDT negative cases which are to be sent to lab for examination in M-2 and arrange for their transportation the same day to the lab. On receipt of results in the completed M-2 from lab, to enter the dates and results against respective fever cases in M-1.

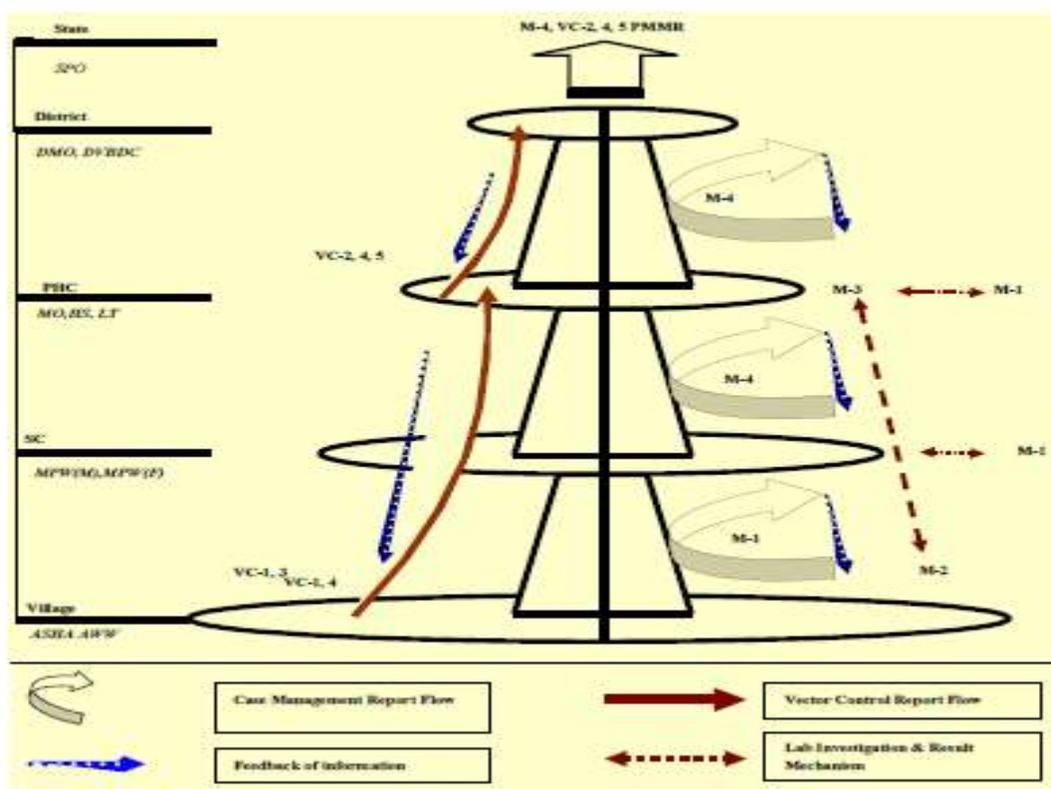
- To determine and analyse simple indicators given in table below. These indicators should be displayed in front of the ASHA.s or AWW.s or CHV.s house/ panchayat ghar. Each month the surveillance / case finding indicators of the current and previous fortnight should be updated. Any significant increase over the previous fortnight should be brought to the notice of the MPW and MO-PHC.
- To assist the MPW (M) in undertaking the annual bednet survey in the village during the pre-transmission season to enumerate bednets available in the households in VC-4. To assist in the impregnation and distribution of bednets and the filling up of VC-4 format.

Role of health care staff in monitoring and evaluation

Village level (ASHAs/ AWW/ CHV). These peripheral level workers form the first point of contact with fever cases and are the primary source of large proportion of data related to case detection and treatment. Therefore the scope of their work involves the following:

- To maintain the record of all fever cases in M-1 and provide fortnightly report of the same to the MPW by 21st of the month for the 1st fortnight and the 7th of following month for the 2nd fortnight.
- To enter slides of RDT negative cases which are to be sent to lab for examination in M-2 and arrange for their transportation the same day to the lab. On receipt of results in the completed M-2 from lab, to enter the dates and results against respective fever cases in M-1.
- To determine and analyse simple indicators given in table below. These indicators should be displayed in front of the ASHA.s or AWW.s or CHV.s house/ panchayat ghar. Each month the surveillance / case finding indicators of the current and previous fortnight should be updated. Any significant increase over the previous fortnight should be brought to the notice of the MPW and MO-PHC.
- To assist the MPW (M) in undertaking the annual bednet survey in the village during the pre-transmission season to enumerate bednets available in the households in VC-4. To assist in the impregnation and distribution of bednets and the filling up of VC-4 format.

Flow of Information in malaria HMIS



Village level indicators

Surveillance/ case finding	<ul style="list-style-type: none"> No of fever cases (M-1) No of total Malaria cases (M-1) No of Pf cases (M-1) No of deaths (M-1)
Integrated Vector control	<ul style="list-style-type: none"> No of houses completely sprayed (VC-1) - No of bednets impregnated (VC-4) No of houses with at least two bednets (VC-4)
Others	<ul style="list-style-type: none"> No of houses assisted in acceptance of spray operations

Sub centre level - MPW (M)

MPW (M) or in his absence MPW (F) is the principle supervisor of the subcentre area and is also the person who would conduct the annual bednet survey with assistance from ASHAs/ AWWs/ CHVs. The following roles are therefore envisaged from them

- Compilation of all M-1 forms received at the end of the fortnight and prepare the subcentre.s fortnightly report of cases in M-4 and submit it to the MO-PHC by the 25th of the month for the first fortnight and 10th of following month for the second fortnight.

- To undertake the annual household bednet surveys in the eligible villages of the subcentre during the pre-transmission season to ascertain the bednet requirement and enumerate bednets available in the households and enter the details in VC-4. Send copy of this form to MO-PHC for use in district level planning.
- To conduct impregnation and distribution of bednets in all the targeted villages and fill the VC-4 format. To submit the VC-4 at the completion of village level activity to MO-PHC.
- To determine and analyse simple indicators given in table below. The surveillance / case finding indicators should be charted every 15 days, village wise, for the current and previous fortnight. Any significant increase over the previous fortnight should be brought to the notice of MO-PHC. The vector control interventions should be charted for each village of the subcentre at the completion of the activities.

Sub centre level indicators

Surveillance/ case finding	<ul style="list-style-type: none"> • No of fever cases (M-4-SC) • No of malaria cases (M-4-SC) • No of Pf cases (M-4-SC) • No of deaths (M-4-SC) • No of RDTs received and used (M-4-SC) • No of ACT blister packs received and used (M-4-SC) •
Integrated Vector Control	<ul style="list-style-type: none"> No of ITNs/ LLINs distributed (VC-4) • Bednets treated (VC-4) • No of houses with at least two bednets (VC-4) • IRS coverage - population (%) (VC-1) • IRS coverage - rooms (%) (VC-1)
Others	<ul style="list-style-type: none"> • Outbreaks reported Yes/ No

PHC Level

MO-PHC. MO-PHC is the person in-charge of all malaria prevention and control activities in the area of PHC. He holds a position of immense responsibility as he is the signing authority for all reports to be furnished by the PHC. He has the following roles in reporting.

- Compilation of all reports received at the end of the fortnight from subcentres and prepare the PHC.s fortnightly report of cases in M-4 and submit it to the DMO by the 28th of the month for the first fortnight and 13th of following month for the second fortnight.
- To compile VC-1 received from the SFWs into the VC-2 and send the IRS output report to DMO within 15 days of completion of all IRS activities in the PHC area.

- The MO-PHC facilitates the conduct of bed net survey by MPWs (M)/ ASHAs for enumeration of bed nets in households in VC-3 during the pre-transmission season. He provides full cooperation to the DMO and furnishes all relevant information to the DMO.
- To compile VC-3 received from the MPWs into the VC-4 and send this bed net output report to DMO within 15 days of completion of all activities.
- The surveillance / case finding indicators should be charted every 15 days, at least sub centre wise and compared with the corresponding fortnight of the previous year. Comparison is made of occurrence of cases in the year with the corresponding period of the previous year. Sub centre wise tabulation of all vector control indicators should done during the transmission season at the completion of the activity. The list of indicators to be applied is given in table below:

PHC LEVEL INDICATORS

Surveillance/ case finding/ Disease Burden	<ul style="list-style-type: none"> • Monthly Blood Examination Rate (MBER) (M-4-PHC) • Annual Blood Examination Rate (ABER) (M-4-PHC) • No of fever cases (M-4-PHC) • No of malaria cases (M-4-PHC) • No of Pf cases (M-4-PHC) • No of deaths due to malaria (M-4-PHC) • Annual Parasite Incidence (API) (M-4-PHC) • Annual falciparum Incidence (AfI) (M-4-PHC) • Test Positivity rate (TPR) (M-4-PHC) • Test falciparum Rate (TfR) (M-4-PHC) • Pf percentage (Pf %) (M-4-PHC)
Integrated Vector Control	<ul style="list-style-type: none"> • Insecticide use (VC-2, VC-5) • No. of ITNs/ LLINs distributed (VC-4) • IRS coverage (eligible) - population (%) (VC-2) • IRS coverage (targeted) - population (%) (VC-2) • IRS coverage - rooms (%) (VC-2) • % of eligible population covered by ITN (VC-4) • % of targeted population covered by ITN (VC-4) • % of eligible villages with more than 80 % population coverage with ITNs- bednets Treated (VC-4) • % of house holds in which beneficiaries reported having slept under ITNs/ LLINs previous night (PMMR) • % of fever cases who were tested for malaria by microscopy/ RDT with a positive test result for RDT and were started on treatment no later than the next day with ACT (PMMR)
Others	<ul style="list-style-type: none"> • No. of RDTs received and used (M-4-PHC) • No. of ACT blister packs received and used (M-4-PHC) • Outbreaks reported (M-4-PHC) Yes/ No • % of MPW/ASHA/other volunteers trained for use of RDT / ACT (PMMR) • % of diagnostic facilities functional with microscopy/RDT in the last reporting period (PMMR) • No. of BCC activities (PMMR)

Health supervisor/ Malaria inspector

Health supervisor/ Malaria inspector assists the MO-PHC in all malaria control activities. He therefore is the second in guard in the PHC area and is responsible in assisting in all the following reporting responsibilities

- To assist in the compilation of all reports received at the end of the fortnight from sub centres and prepare the PHC.s fortnightly report of cases in M-4.
- To assist in the compilation of VC-1 received from the SFWs into the VC-2.
- To assist in the compilation of all VC-3 received from the MPWs into the VC-4.
- To assist in the analysis of reports generated.

Lab technician

Lab technician is responsible for malaria microscopy and its reporting at the PHC Laboratory. He has the following roles in malaria diagnosis:

- To receive the M-2 format along with the slides sent for examination by the peripheral workers like ASHAs/ AWWs/ CHVs and also from the PHC OPD.
- To enter all slides received from the periphery or PHC-OPD in M-3.
- To examine all the sides received preferably on the same day. Enter the results in M-3 correctly and arrange for transportation of results back to the fieldworker on the same day or following day for timely initiation of treatment.
- To maintain the M-3 up to date and to prevent back backlog of slides.
- To assist the MO-PHC in the compilation of M-4.

District Level

District Malaria Officer (DMO). DMO is the person in-charge of all malaria prevention and control activities the district. For recording and reporting he has the following responsibilities which he will execute with help from District Vector Borne Disease Consultant (DVBDC) and Assistant Malaria Officer (AMO), if present.

- Compilation of all reports received at the end of the fortnight from PHC.s and preparation of district fortnightly report of cases in M-4 and timely submission to the state by the 30th of the month for the first fortnight and 15th of following month for the second fortnight.
- To compile VC-2 received from PHCs into a district level IRS output report and send it to state within 30 days of completion of all IRS activities in the PHC area.
- The DMO should coordinate with MO-PHC to ensure undertaking of bednet survey by MPW (M)/ ASHAs for enumeration of bednets in households in VC-3 during the pre-transmission season. He should also ensure that this information is duly collected from the MO-PHC so that it is available for the development of Annual district action plans.

- To compile VC-4 received from the PHCs into district level bednet output report and send it to the state within 15 days of completion of all activities.
- The DMO should compile district annual stock report on Insecticides in VC-5 based on PHC stock registers within 15 days of completion of the reporting year and send to the state.
- The DMO should oversee the maintenance of a yearly log of LLINs distributed in VC-6.
- The PMMR is compiled at the end of each quarter and sent to the state no later than the 15th day of the following month.
- To analyze and tabulate preferably sub centre wise fortnightly surveillance/ case finding indicators and compare with the corresponding fortnight of the previous year as well as comparison of occurrence of cases in the year with the previous year. Vector control indicators should be charted during the transmission season at the completion of the activity for all sub centres. The following indicators should be used for analysis.

District level indicators

Surveillance/ case finding/ Disease Burden	<ul style="list-style-type: none"> • Monthly Blood Examination Rate (MBER) (M-3) • Annual Blood Examination Rate (ABER) (M-3) • No of fever cases (M-4) • No of malaria cases (M-4) • No of Pf cases (M-4) • No of deaths due to malaria (M-4) • Annual Parasite Incidence (API) (M-4) • Annual falciparum Incidence (Afi) (M-4) • Test Positivity rate (TPR) (M-4) • Test falciparum Rate (TfR) (M-4) • Pf Percentage (Pf %) (M-4) • % of fever cases who were tested for malaria by microscopy/ RDT with a positive test result for RDT and were started on treatment no later than the next day with ACT (PMMR)
Integrated Vector Control	<ul style="list-style-type: none"> • % of spray equipment in working condition (VC-2) • % of spray workers trained (VC-2) • Insecticide use (VC-2, VC-6) • No of ITNs/ LLINs distributed (VC-4) • IRS coverage (eligible) - population (%) (VC-2) • IRS coverage (targeted) - population (%) (VC-2) • IRS coverage - rooms (%) (VC-2) • % of eligible population covered by ITN (VC-4) • % of targeted population covered by ITN (VC-4) • - % of eligible villages with more than 80 % population coverage with ITNs- bednets treated (VC-4) • % of house holds in which beneficiaries reported having slept under ITNs/ LLINs previous night (PMMR) • % of PHC sampled in which utilization of ITNs/ LLINs was more than 80% (PMMR)
Others	<ul style="list-style-type: none"> • Full Time DVBDCCO/ DMO Yes/ No • No of RDTs planned versus received and used (M-4) • Outbreaks reported Yes/ No • No of ACT blister packs planned versus received and used (M-4) • % of facilities (SC and PHC) / village level functionaries (ASHA, AWW) reporting stock-out of antimalarials lasting more than 15 days during the quarter (PMMR) • % of staff in place (ASHA, MPW, MTS, LT, DVBD Consultant) (PMMR) • % of MPW/ASHA/other volunteers trained for use of RDT / ACT (PMMR) • % of diagnostic facilities functional with microscopy/RDT in the last reporting period (PMMR) • No of BCC activities (PMMR)

State level

State Programme Officer (SPO). At the state level the SPO is responsible for all reporting requirements to be furnished to the Directorate of NVBDCP.

- Compilation of all district fortnightly report of cases in M-4 received from districts and preparation of state level report and timely submission to the Dte. of NVBDCP by the 5th of the following month for the first fortnight and 20th of following month for the second fortnight.

- To compile district level VC-2 received, into state IRS output report and send it to the Dte. of NVBDCP within 45 days of completion of all IRS activities in the districts.
- To compile district bednet output reports (VC-4) received, into state level bednet output report and send it to the Dte. of NVBDCP within 15 days of completion of all activities.
- The state should compile district annual stock report on insecticides (VC-5) and send it to the centre no later than 30 days of completion of the reporting year.
- The district the PMMRs received by the state is compiled at the end of each quarter and sent to the centre no later than the 21st day of the following month.
- To analyze and tabulate at least district wise fortnightly surveillance/ case finding indicators and compare with the corresponding fortnight of the previous year. Comparison of cumulative occurrence of cases in the year with the previous year should be done. Vector control indicators should be charted during the transmission season at the completion of all activities. The following indicators should be used for analysis at the state level.

State level indicators

Surveillance/ case finding/ Disease Burden	<ul style="list-style-type: none"> • Annual Blood Examination Rate (ABER) (M-3) • No. of fever cases (M-4) • No. of malaria cases (M-4) • No. of Pf cases (M-4) • No. of deaths due to Malaria (M-4) • Annual Parasite Incidence (API) (M-4) • Annual falciparum Incidence (Afi) (M-4) • Test Positivity rate (TPR) (M-4) • Test falciparum Rate (TfR) (M-4) • Pf percentage (Pf %) (M-4) • % of fever cases who were tested for malaria by microscopy/ RDT with a positive test result for RDT and were started on treatment no later than the next day with ACT (PMMR)
Integrated Vector Control	<ul style="list-style-type: none"> • % of spray equipment in working condition (VC-2) • % of spray workers trained (VC-3) • Insecticide use (VC-2, VC-6) • No of ITNs/ LLINs distributed (VC-4) • IRS coverage (eligible) - population (%) (VC-2) • IRS coverage (targeted) - population (%) (VC-2) • IRS coverage - rooms (%) (VC-2) • % of eligible population covered by ITN (VC-4) • % of targeted population covered by ITN (VC-4)

	<ul style="list-style-type: none"> • % of eligible villages with more than 80 % population coverage with ITNs- bednets treated (VC-4) • % of house holds in which beneficiaries reported having slept under ITNs/ LLINs previous night (PMMR) • % of PHC sampled in which utilization of ITNs/ LLINs was more than 80% (PMMR)
Others	<ul style="list-style-type: none"> • Full time SPO Yes/ No • No of RDTs planned versus received and used (M-4) • No of ACT blister packs planned versus received and used (M-4) • Outbreaks reported Yes/ No • % of facilities (SC and PHC) / village level functionaries (ASHA, AWW) reporting stock-out of antimalarials lasting more than 15 days during the quarter (PMMR) • % of staff in place (ASHA, MPW, MTS, LT, DVBD Consultant) (PMMR) • % of MPW/ASHA/other volunteers trained for use of RDT / ACT (PMMR) • % of diagnostic facilities functional with microscopy/RDT in the last reporting period (PMMR) • No of BCC activities (PMMR)

National level

NVBDCP, Delhi has the overall responsibility of compilation of all state level reports on case management, integrated vector control and programme management. The national level is required to analyze this data and provide feedback to states on key observations. The following indicators are required to be determined at the national level.

National level indicators

Policy and strategy development	<ul style="list-style-type: none"> • Sites to monitor post-purchase quality of RDTs, drugs and insecticides recommended for use by national policy • Each of the established drug resistance monitoring sites completes at least one successful study every second year • Independent external evaluations carried out at least twice during project implementation • All endemic districts have quality-controlled data on incidence of vector-borne diseases segregated by age-group and gender
Surveillance/ case finding/ Disease Burden	<ul style="list-style-type: none"> • Annual Blood Examination Rate (ABER) (M-3) • No of fever cases (M-4) • No of malaria cases (M-4) • No of Pf cases (M-4) • No of deaths due to malaria (M-4) • Annual Parasite Incidence (API) (M-4) • Annual Falciparum Incidence (AFI) (M-4) • Test Positivity rate (TPR) (M-4) • Test falciparum Rate (TfR) (M-4) • Pf percentage (Pf %) (M-4) • % of fever cases who were tested for malaria by microscopy/ RDT with a positive test result for RDT and were started on treatment no later than the next day with ACT (PMMR)

Integrated Vector Control	<ul style="list-style-type: none"> • % of spray equipment in working condition (VC-2) • % of spray workers trained (VC-3) • Insecticide use (VC-2, VC-6) • No of ITNs/ LLINs distributed (VC-4) • IRS coverage (eligible) - population (%) (VC-2) • IRS coverage (targeted) - population (%) (VC-2) • IRS coverage - rooms (%) (VC-2) • % of eligible population covered by ITN (VC-4) • % of targeted population covered by ITN (VC-4) • % of eligible villages with more than 80 % population coverage with ITNs- bednets treated (VC-4) • % of house holds in which beneficiaries reported having slept under ITNs/ LLINs previous night (PMMR) • % of PHC sampled in which utilization of ITNs/ LLINs was more than 80% (PMMR)
Others	<ul style="list-style-type: none"> • No of full time SPO • Full time DVBD/CO/ DMO Yes/ No • No of RDTs planned versus received and used (M-4) • No of ACT blister packs planned versus received and used (M-4) • Outbreaks reported Yes/ No • % of facilities (SC and PHC) / village level functionaries (ASHA, AWW) reporting stock-out of antimalarials lasting more than 15 days during the quarter (PMMR) • % of staff in place (ASHA, MPW, MTS, LT, DVBD Consultant) (PMMR) • % of MPW/ASHA/other volunteers trained for use of RDT / ACT (PMMR) • % of diagnostic facilities functional with microscopy/RDT in the last reporting period (PMMR) • No of BCC activities (PMMR)

Supportive Supervision

Supportive supervision is a continuous process which aims to increase the knowledge, develop the skills, improve the attitude and enhance the motivation of the health care functionaries. Supportive supervision is not an instrument for fault finding but aids in identification of problems, solving them and improving performance. It provides an opportunity to the supervisor and health workers to identify and address weaknesses together, thus preventing poor practices from becoming routine. It is also an effective tool for checking and maintaining quality of data at the peripheral level by regular onsite visits. Progression from traditional to supportive supervision may require changes in attitudes, practices and perceptions on the part of supervisors.

The protocol of supervision for each level of staff is given in below table:-

Supervisory protocol for staff under NVBDCP

Level	Staff	Frequency
Sub Centre	MPW (M); MPW(F)	<ul style="list-style-type: none"> • Visit 1 ASHA per village during their visit and 2 patients treated by her in the last one month (checked from her record) • Supervise IRS rounds in their villages as per supervisory schedule for IRS

Level	Staff	Frequency
PHC	MPHS (F); MPHS(M)	<ul style="list-style-type: none"> As per their supervisory schedule visit all subcentres in the PHC During visit to subcentres, try to visit remote villages and interview ASHA and 2 patients treated by ASHA in the last one month (checked from her records) Supervise IRS rounds in their villages as per supervisory schedule for IRS
	MO	<ul style="list-style-type: none"> Visit all subcentres in the PHC once a month During visit to subcentres, try to visit remote villages and interview ASHA and 2 patients treated by ASHA in the last one month (checked from her records) Supervise IRS rounds in their villages as per supervisory schedule for IRS
Block PHC CHC/FRU/Sub Dist. Hosp.	MPHS (F); MPHS (M); MO	<ul style="list-style-type: none"> As described above
	MO	<ul style="list-style-type: none"> Visit all PHCs and microscopy centres in the area of Block BHC once a month Monitor sentinel sites once a month Visit all subcentres once in 2-3 months During visit to subcentres, try to visit remote villages and interview the ASHA and 2 patients treated by ASHA in the last one month (checked from her records) Supervision of IRS rounds in the area of Block PHC
	Malaria Technical Supervisor (where deployed)	<ul style="list-style-type: none"> Visit all PHCs and microscopy centres in the Malaria Unit (MU) once a month Visit all sentinel sites in the MU once a month Visit all subcentres once in 2 months; visit all villages once in 6 months During visit to subcentres, try to visit remote villages and interview the ASHA and 2 patients treated by ASHA in the last one month (checked from her records) Supervise IRS rounds in the area of MU, especially the remote and operationally difficult areas
District	District Malaria officer	<ul style="list-style-type: none"> Visit all PHCs and microscopy centres in the district once in 2-3 months. During each such visit, 2-3 subcentres are to be visited in each PHC area. Visit all sentinel sites in the district once a month. Check laboratory function in each visit of microscopy centre and sentinel site. During visit to subcentres, try to visit remote villages and interview the ASHA and 2 patients treated by ASHA in the last one month (checked from her records) Supervise IRS rounds in the district, especially the remote and operationally difficult areas
	VBD consultant	<ul style="list-style-type: none"> Visit all PHCs and microscopy centres in the district once in 2-3 months Visit all sentinel sites in the district once a month Visit all subcentres once in 6 months
		<ul style="list-style-type: none"> During visit to subcentres, try to visit remote villages and interview the ASHA and 2 patients treated by ASHA in the last one month (checked from her records) To cover all PHCs of the district during spray inspection/supervision in each round of spray. To visit and observe at least 5 to 10 villages every week to check the quality of spray.
State	SPO/ Officer from SPO Office	<ul style="list-style-type: none"> 1 - 3 districts to be visited every month. All districts to be covered once in a year.
Regional Offices	RD/ Officer from RD Office	<ul style="list-style-type: none"> 1 district to be visited every month.

Establish supportive supervision

A. Improve performance

- Use a protocol/standard operating procedure including a supervisory checklist for each type of unit supervised. (e.g. Checklist of MTS at Annexure K 20)
- Conduct supportive supervisory visits also within health care facilities you are in charge of.
- Provide staff with updates on policies or new recommended practices. Undertake on-the job training supported by guidelines, manuals and visual aids.
- Plan supervision schedule in advance and communicate it to all those, who need to know. Lesser performing health facilities should receive extra or lengthier visits, so make sure that the initially planned schedule has time for this.
- Plan these visits as much as possible, when it is possible to observe the staff and interview patients. Talk to patients about the quality of services, preferably away from the health facility.
- Plan to spend sufficient time (from several hours, to a full day or more) to conduct the
- supervisory visit for each unit. Rushed visits with no time for dialogue are inefficient.
- Follow up on recommendations made during previous visits. Discuss progress with the health facility
- Check the stocks and the condition of equipment. Compare stocks with records. Are storage conditions correct? If not, help find solutions. Carry materials, and supplies for the health facility according to requests made or needs identified at previous visit.
- Review health facility records and provide feedback to the staff as well as MO in charge.
- Check the various records like M-1 of ASHAs, M-3 of Lab and reports like M-4 for completeness, consistency, and accuracy. Mark columns which were expected to be entered but have not been filled. Try to compare case detection with the use of logistics, e.g. the numbers of fever cases in which RDTs were used for diagnosis (column 12) of M-1 with the utilization in the lower part of the record in the same month.
- Analyze programme indicators for the health facility to make the performance objective and measurable.
- Involve the community in the evaluation process. Ask community members how they are treated when they visit the facility. Talk to community leaders during the visit to get their feedback and identify jointly, what the community can do.

- Find out, if the relationship between community and health workers is good; if not, find out what is wrong and remedy the situation.
- Discuss strengths and weaknesses, and actions to be taken (by whom and by when). Identify gaps and solve problems in positive ways
- Praise health workers in public for good performance and for practices that meet quality. Correct the performance through person-to-person contacts.
- Work with other health programmes to coordinate supervisory activities in a spirit of mutual support.
- Schedule a return visit before leaving the site.

B. Maintain and enhance motivation

- Give praise and recognition to health workers for what they are doing right.
- Involve health workers in planning and encourage health facility supervisors to work together with their staff.
- Take part in staff meetings if possible. Talk to staff about their work situation, needs and ambitions.
- Act on feedback from the health workers. Health workers will feel valued that they have an impact. Show that you trust them (as much as you actually do)
- Establish monthly meetings with all health facilities within a district. This provides an opportunity for health workers to learn new approaches and strategies used in different
- health facilities and to receive continuing education. It can also be a forum to acknowledge their achievements.

C. Build sustainability

- Collect data on positive results gained from supportive supervision, such as improved performance of health workers, improved coverage of IRS, better treatment etc.
- Develop a team approach to increase supportive supervision at the health facility and make it a routine procedure, with or without frequent visits from the central/ state/ district level.
- Health facility staff can develop supervision plans that fit their structures and conduct regular self-assessments to monitor their performance.

Data quality

It is important to ensure that the data collected through reports is complete, accurate and consistent. This is possible only when records are maintained immaculately on a regular basis and a system of verification of reports exists. Therefore, the quality of data is the responsibility of the supervisory staff and the Officer Incharge/ signing authority of the reports. It is necessary to verify data during onsite visits of villages, subcentres and districts. During field visits the supervisory staff like MTS, DVBCD consultants, DMO and other PHC/ district /state/ centre level personnel should make an effort to crosscheck M-1 for the individual patient records and visit patients diagnosed and treated in the previous month. Similarly a sample of reports should also be reworked from the records to check for their validity e.g. the BMO should recheck the compilation of M-4 of all Subcentres into M-4 at PHC each month. The reports should also be tracked for timeliness and completeness each time they are received. The time schedule for each report is mentioned in table below.

S. No.	Report	Time Schedule
1	Fortnightly report by ASHA/CHV/ MPW/ PHC (M-1)	Ist Fortnight- 21 st of the month IInd Fortnight- 7 th of following month
2	Fortnightly report of cases (M-4-SC)	Ist Fortnight- 25 th of the month IInd Fortnight- 10 th of following month
3	Fortnightly report of cases (M-4 PHC)	Ist Fortnight- 28 th of the month IInd Fortnight- 13 th of following month
4	Fortnightly report of cases (District)	Ist Fortnight- 30 th of the months IInd Fortnight- 15 th of following month
5	Fortnightly report of cases (State)	Ist Fortnight- 5 th of the following month IInd Fortnight- 20 th of following month
6	IRS output (VC-2) - round wise	PHC - 15 days of completion of Spray District - 30 days of completion of spray State - 45 days of completion of Spray
7	Bednet delivery and impregnation form (VC-4)	PHC - 15 days of completion of activity District - 30 days of completion of activity State - 45 days of completion of activity
8	District PMMR	15 th day of the following quarter
9	State PMMR	21 st day of the following quarter

Feedback mechanisms, data sharing and transparency

There should be a two way flow of information in any system of data management. Therefore, a system of preliminary tracking of reports for data timeliness, completeness and consistency should be in place and a system for prompt feedback on such discrepancies observed should be established

at all levels. Beside this there should be a timely review of all reports received on epidemiological and programme management aspects. Any unusual deviation in various monitoring parameters should be communicated to the reporting units. The centre/ state/ district /PHC should establish this system through regular letters and e-mails, with their respective reporting units to notify the observations made. The reporting unit should respond within one week to such correspondence with required clarifications.

The centre/ district / state should also come up with annual reports for the reporting units which should be widely disseminated.

Programme review

Regular review of the program by authorities is a way of taking stock of programme progress as well as it provides opportunity of interacting with the implementing partners to address administrative issues. It is imperative that such reviews are organized at regular interval which reflects commitment of the highest order. The norms for such reviews are as follows

S.No	Level	Type of review
1	Centre	Biannual review of States by Centre
2	State	Quarterly review of District by State (in First month of the following quarter)
3	District	Monthly review of NVBDCP under chairmanship of District collector
4	District	Monthly review of NVBDCP by DMO/ DVBDPO with his staff

The participation of highest level administrative officials should be ensured in programme monitoring. Wherever possible the health secretary should be involved in such programme reviews at state level. The district collector should also review the programme as per the prescribed norm especially in the transmission season. Microplanning of IRS as well as continuous monitoring of its implementation should be a district collector driven initiative. The checklists to be used by health secretary and district collector in such reviews are given in Annexures K-13 and K-14 respectively.

Surveillance in malaria

Surveillance is defined as the ongoing and systematic collection, analysis, interpretation, and dissemination of data about cases of a disease and is used as a basis for planning, implementing, and evaluating disease prevention and control activities.

Malaria surveillance in India was traditionally a system based mainly on slide results, which has been refined over many years. It relied on surveillance of fever cases in the community by means of active fortnightly case detection conducted mainly by the MPW (M). Active case detection implies that the MPW (M) would visit all villages within the subcentre area once every fortnight and look for occurrence of fever cases between the current and previous visit. Slides of such fever cases were collected and sent to laboratory for examination along with administration of fever presumptive treatment with chloroquine. A target of Annual Blood Examination Rate (ABER) of 10% of population was kept in order to adequately find fever cases. Active case detection by MPW (M) formed the backbone for all the disease burden indicators. With over half a century of programme implementation it has been realized that shortage of MPWs resulted in decline in this activity. Poor surveillance resulted in inability of the system to generate timely information on fever alerts and response.

The programme now envisages a change in programme strategy from active to passive case detection. It will be conducted through the agency of ASHAs/ CHVs/ AWWs at village level. For the purpose of strengthening village level passive case detection these functionaries are to be equipped with RDTs in areas with poor access to malaria microscopy. Passive case detection will thus be the crux of routine surveillance activities in the programme and active case detection through visits by MPW (M) will be restricted for use in areas where such functionaries are not present. Fortnightly reports of case detection generated in M-1 formats and consolidated in M-4 format will provide the necessary data for continuous surveillance of disease situation.

a. Interpretation of indicators

The main disease incidence indicators listed in Table 3 can be calculated from the data available from M-4 for virtually any level, from village to national level. All suspected cases of malaria in the country (or district or village) are captured in M-1 and consolidated correctly into M-4; the resultant indicator values for API, TPR etc. are then calculated based on the formula described. All surveillance and disease burden indicators should be assessed for an increase or decrease from the corresponding period of the previous year. API of more than 5%, TPR of more than 5%, Pf% more than 50% should always raise an alarm. These indicators are also used to identify high risk areas and identify areas to be focused on priority. Sudden increase of fever incidence in community, OPD fever rate and malaria incidence along with rise in TPR above 5% may indicate an impending outbreak. When assessing IRS or ITN for universal coverage, 100% coverage is considered optimal and at least 80 % utilization by targeted population should be the acceptable cut off. Service delivery or utilization below this should be considered inadequate.

b. Sentinel surveillance for malaria

Malaria surveillance conducted through routine MIS provides reliable data on trends of cases and deaths reported in the public health care system, but do not provide relevant information on severe and uncomplicated malaria. A large number of patients seek health care from the private sector and is also not counted in the programme statistics. The data made available from the routine HMIS therefore is to be seconded by a more exhaustive but high quality information system to be provided by sentinel surveillance that acts as a close watch dog on disease severity, delay in referral and mortality rates.

i. Purpose of sentinel surveillance for malaria control

Very little data is available on severe cases of malaria, their management and on malaria deaths in India. Timely referral of cases to PHCs/ district hospitals/ tertiary centers and their proper management in these centers limits mortality associated with malaria. Therefore, to monitor case referral and practices in in-patient case management it is important that this data is collected, compiled and analyzed. Furthermore, improvements in malaria case management (especially RDTs and ACT) for falciparum malaria, which will be introduced in India on a large scale, may well lead to short-term increases in the API because more patients may be attracted to primary level services. However, these improvements should lead to a decrease in the incidence of severe malaria and malaria deaths. Thus, monitoring of these latter events becomes essential for assessing impact. Aside from this, high or increasing numbers of in-patients from specific peripheral areas in a district may be a warning sign of a deficiency of primary level services or impending outbreaks.

Analysis of data on such cases can provide important additional information, for example: If severe malaria is very frequent in pregnant women, additional efforts must be made to prevent malaria in this particular group. Age trends may be informative; if for example, a large proportion of cases occur in young children, transmission is probably taking place in these areas, but if most cases are in young men, it probably does not. If people of a certain tribe are often hospitalized with malaria, they must be at high risk; if they never get hospitalized for malaria, there may be some kind of barrier.

Since the health infrastructure in the country has limited capacity to manage voluminous data, it is not feasible, at least at this point in time, to collect detailed information on in-patients from all PHCs. To obtain reliable, representative information on severe cases of malaria, Sentinel Sites will be selected in each district. These sites will be providing detailed information on indoor patient admissions. This data when analyzed over a period of time would thus represent the trends in malaria related mortality and incidence of severe malaria.

ii. Norms for establishing sentinel sites

A minimum of two sentinel sites will be established in each district. As this is a new activity and quality is paramount, districts should normally start with only two sites and consider expansion later. Hospitals with large OPDs and inpatient case loads should be chosen. Therefore, the district hospital will automatically qualify as one such site. Other sites are selected amongst the PHCs/ CHCs /private/faith-based hospitals. It is desirable to have sentinel sites in the private/faith-based sector as many patients seek care there and this data is most often not reflected in the HMIS. Districts which have medical colleges should establish a site in these tertiary care centers, if they habitually admit many malaria cases.

The sentinel sites should be adequately staffed and medical officers and LTs should be trained. A sentinel site Medical Officer (SSMO) should be in charge of all activities regarding malaria in the sentinel sites. There should be a laboratory with a qualified LT in charge, where malaria microscopy is quality controlled according to new NVBDCP standards. At each sentinel site, the LT (SSLT) working under the supervision of the SSMO will be responsible for the quality of the malaria laboratory results and for data compilation. A central register for fever cases without any other obvious cause (suspected malaria) should be maintained at each Sentinel Site called Sentinel Site Malaria Register (SSMR) (Annexure K-15). Each day the SSLT will record information of all suspected malaria cases from the lab register of the Sentinel Site into the SSMR. Information of all fever cases from different OPDs and on in-patients is entered on the same form to avoid double-counting and difficulties in patient identification. After entering the data, SSLT notes elements, which need to be re-checked and obtains necessary clarifications on the same day from the OPDs. The record for inpatients is completed from the respective case sheets and the final outcome cured and discharged/ died/ referred / left without discharge is carefully recorded. Every SSMR, which has not been completed with in-patient information, is taken to the relevant in-patient department weekly until it has been completed. The paper based SSMR are filed in the health facility, where they have been generated. At the end of each fortnight the sentinel site report is generated from the SSMR by the SSLT.

iii. Main indicators

The data from sentinel sites will give information on age specific morbidity and mortality due to malaria, especially under 5 morbidity and proportional mortality rate due to malaria. The following indicators are to be derived from the data obtained from M5.

Interpretation of Indicators

S. No.	Indicator	Description	Breakdown (with percentages)
1	Number of out-patient cases of malaria	Self-evident	Clinical/confirmed, under 5/ 5yrs and above, M/F, Pw/Pf, sub-centre area
2	Number of in-patient cases of malaria	As above	As above
3	Number of cases of severe malaria	As above	Clinical/confirmed, under 5/ 5yrs and above, M/F, sub-centre area
4	Number of malaria deaths	As above	Clinical/confirmed, under 5/ 5yrs and above, M/F, sub-centre area
5	% OPD cases attributed to malaria	Total no. of cases of OPD malaria/ Total OPD X 100	Under 5/ 5yrs and above
6	% in-patient cases attributed to malaria	Total no. of cases of in-patient malaria/Total inpatients X 100	
7	Proportional mortality due to malaria	Total no. of deaths due to malaria in hospital admissions / Total no of deaths in hospital admissions X 100	
8	Case fatality rate of falciparum malaria	Total no. of confirmed malaria deaths/total no. of falciparum malaria cases X 100	
9	Case fatality rate of confirmed severe malaria	Total no. of confirmed malaria deaths/total no. of confirmed severe malaria cases X100	

iv. Recording, reporting and use

➤ Data entry

A standard database with a data entry portal corresponding to the SSMR will be entered in NAMMIS and the entry portal will include a check on errors. At the end of each fortnight, the line list of suspected malaria cases will be entered into NAMMIS. After becoming proficient in this, SSLT may delegate this work to a clerk. In addition, SSLT collects data at the end of each month on total number of out-patients, total number of in-patients and total number of in-patient deaths, all separated by gender and below 5 years/ 5 years and above. These data are entered in a relational database, so that they can be used as denominator.

➤ At each sentinel site

Every Fortnight: Fortnightly output of the indicators with their breakdowns. Graph showing fortnightly trend over current calendar year of indicators 1-4 (without breakdown). Every month: Corresponding monthly output. SSMO is responsible for scrutinizing weekly and monthly outputs and

to alert BMO to any finding, which requires urgent attention. The fortnightly and monthly outputs are submitted to Block Medical Officer (BMO).

➤ **Block Medical Officer (BMO)**

Monthly output is submitted by BMO with narrative interpretation and comments to DVBDSCO, in particular on findings which require attention or action. Initiates relevant action, if any data suggest an emergency problem. Every year: Corresponding annual output, and additional computer analyses as requested by SSMO/BMO/DVBDCO

➤ **DVBDCO**

Annual outputs from all sentinel sites are sent by DVBDSCO with narrative interpretation and comments to state NVBDSCO as part of the annual malaria report. An annual summary is prepared by state NVBDSCO as part of annual malaria report. The routine outputs are generated by NAMMIS. This means that once the data have been entered, the routine outputs are generated by a few clicks by the SSLTs. SSLTs and district data managers will be trained to generate additional analyses requested.

Special surveys

The surveillance and program monitoring on the basis of data reported through the routine system and sentinel sites provides a fairly comprehensive picture of the progress of the program towards its objectives. However, this is not sufficiently objective, because it consists of data or reports generated within the program. Any shortcomings inherent to the system are therefore inadvertently incorporated into the picture drawn by them. This system also does not cover the patients seeking care from the private sector (other than a few sentinel sites). The programme indicators thus obtained from the routine and sentinel surveillance system are not true estimates, therefore, to plug such gaps, and to lend more objectivity to program monitoring and evaluation, assessments independent of the HMIS will be periodically carried out.

Two types of surveys are to be conducted in the programme:

A. Lot Quality Assurance Sampling (LQAS) surveys

Lot Quality Assurance Sampling (LQAS) is a survey method which was originally used in the early twentieth century by industries to test quality of batches of products in an assembly line.

The requirement in that context was a sample just sufficient to determine if there was more than a certain acceptable proportion of faulty products per batch. Using binomial probabilities, it was demonstrated that a small sample was sufficient to .pass. or .fail. a given batch or lot of the product in question. This principle has been put to use in public health program settings, particularly for child health but also for a number of other contexts, to provide reasonable results for more than twenty years globally. This method has not yet been used widely in the Indian public health programs, but

holds considerable promise in contexts where it is possible to periodically conduct such small sample surveys.

In essence, the LQAS survey method comprises of collecting data from small but perfectly random samples drawn from a well-defined universe, typically called a supervisory area, such as a sector or block. A commonly used sample size for each such area is 19, such as 19 households or 19 individuals. The survey tools consist of the usual, standard questions used in sample surveys, such as questions related to utilization of bednets or to prompt diagnosis and treatment of fever, but the answers are always coded and analyzed as dichotomous variables (each question has two possible answers: .yes. or .no.). While this sample of 19 cannot provide a reliable point estimate for an indicator, it can reliably tell whether the sampled area has exceeded a .target. prevalence for the indicator. For instance, if the question is whether or not 80% of individuals in a block PHC area sleep under bednets, a random sample of 19 individuals from this universe can reliably tell whether this is true. In this case, a statistically computed cut-off of 13 is used: if in the survey, 13 or more out of 19 individuals say they slept under the bednet on the night before the survey, one may say with 92% confidence that 80% or more people in the block sleep under bednets. The sample size of 19 is the smallest that can give results with acceptable reliability, and therefore is commonly used. Increasing the sample size does not significantly increase the reliability in making such a decision.

In the malaria control program, it has been proposed that the LQAS method will be used for generating information about the coverage of important process and outcome indicators at the sub district (block PHC) levels. The MTS will be trained to collect and tabulate data from a sample of 19 households or individuals in each block PHC that they cover. Each round of data collection will yield a result for each block - whether or not the block has exceeded a certain pre-determined target coverage. Only a small number of questions will be used, to maintain feasibility of data collection within program settings. Several rounds of data collection can take place during a year, depending upon the need and feasibility, and will provide a sense of how each block is progressing. For each round of data, district level coverage of the indicators will be computed by cumulating the samples of 19 from all the blocks, and adjusting for relative population size. Similar weighted estimates for the state level will be generated by pooling data from all districts. The use of periodic small surveys in this manner is expected to provide valuable information to help program monitoring, planning and implementation at all levels - to MO-PHC, DMO, the state and the Directorate of NVBDCP.

The sample of 19 in a block is typically spread over 19 villages. Thus, one household or individual each is sampled from 19 villages. Such a widely spread sample is expensive for a survey investigator to collect, but surveys using LQAS cost very little because the data is collected as a part of the routine field visits of supervisors. It is expected that the MTS will visit up to 2-3 villages a day on his/her motorcycle, and collect this data in prescribed forms along with conducting the rest of his/her supervisory duties in the village, such as interacting with the ASHA, examining records and stocks, meeting people, etc. This will make the use of this method feasible. It should also be noted that the questions required to elicit information to generate estimates of key indicators are also the same questions that the MTS must ask to perform the supervisory role. In this sense, the data collection effort is not an addition to the envisaged job of the MTS.

The number of rounds of data collection per year and the number of blocks covered in each round will depend on the need and feasibility, and if all blocks cannot be covered in each round, a statistical sample of blocks will need to be drawn, repeating some blocks in each subsequent round. This method, also called Large Country LQAS may have to be applied in some settings.

Since this is the first time this method is being used in the Indian health program context, the experience will be reviewed periodically and refined until it is well established. It has been suggested that, in the Indian context LQAS may be renamed as Local Quality Assurance Surveys., to emphasize the role of a program monitoring tool.

B. Large scale surveys

The surveys are designed to capture the main outcome indicators of the programme and other data. Such household level surveys are conducted every 2-3 years by an Independent agency. Expertise of WHO and NIMR is also sought to support the planning and implementation of these surveys and to participate in the evaluation exercise together with selected Indian institutions. The methodologies of these surveys are developed in consultations held with the independent agency hired for the purpose.

The programme also undertakes in-depth review of programme implementation through Joint Monitoring Missions (JMM) organized together with its partners in malaria control like NIMR,WHO and World Bank. Such reviews bring to light programme shortcomings in the area of policy and implementation and enable improvements in programme design.

Evaluation

Periodic large scale evaluations of programme are carried out by independent observers. NVBDCP may call for an independent agency to undertake such reviews which comprise of an in-depth assessment of all programme aspects like case diagnosis and management, treatment seeking behavior of the community, coverage of vector control interventions and community acceptance, impact of BCC activities on community awareness and practices. NVBDCP also undertakes special JMMs along with its partners in malaria control like WHO and World Bank. These large scale evaluations are conducted usually at 5 yearly intervals, to allow for passage of sufficient time for impact to become evident.

Besides this the programme undertakes annual evaluation of programme implementation in high risk areas. This activity is outlined in the following paragraphs.

i. Central evaluation

Central level evaluation is now routinely conducted each year, twice during the transmission season, coinciding with the two rounds of spray. During this period teams are sent to the selected highest

endemic districts of the country comprising of members from Dte NVBDCP, ICMR/ NIMR institutes, regional offices, state offices and districts.

A. Objectives

The objectives of the Evaluation are as follows:

- To evaluate the preparatory activities for IRS in the selected districts and estimate IRS coverage
- To assess the status of programme implementation in the district with particular focus on activities of ASHAs and utilization of RDTs
- To assess distribution of bednets and estimate utilization of bednets by beneficiaries

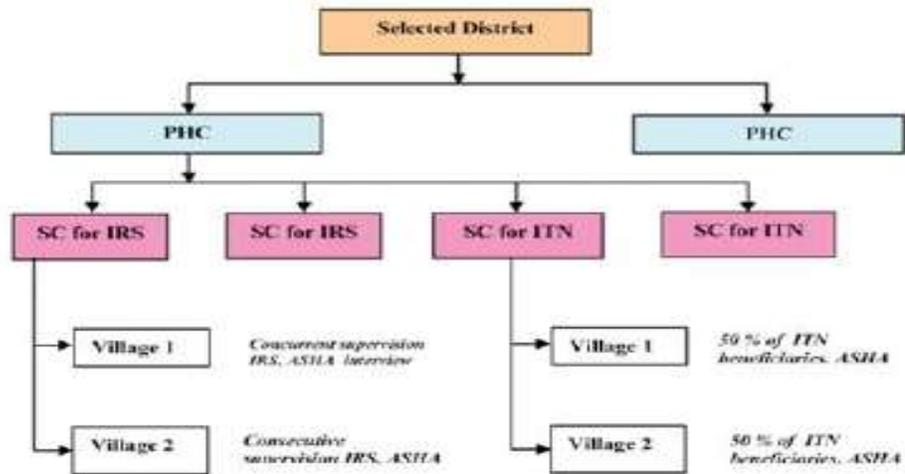
B. Methodology

At the beginning of the transmission season the centre selects the highest endemic districts of the country on the basis of ABER, API and Pf % of the previous year. Central teams visit these districts twice during the transmission season, once in each round of IRS. In the selected high endemic districts two high burden PHCs are selected based on ABER, API and Pf%. In each PHC area 2 subcentres are to be selected for evaluation of IRS, followed by selection of 2 villages in each Subcentre area. Selection of villages is done in such a manner so that in one village concurrent evaluation of IRS is possible on the day of visit; the selection of the 2nd village is done such that IRS is completed and consecutive evaluation is possible. The ASHAs of each selected village are also interviewed.

In each of the selected PHCs, 2 more sub centers are selected in which maximum numbers of bed nets were distributed in the season. If bed nets were not distributed in the selected areas, other PHCs may be selected for the purpose. In each sub centre, villages in which most number of bed nets was distributed in the season are selected. In each of these villages 50% of beneficiaries are selected on a random basis from the records and assessed for utilization of bed nets. The ASHAs of each selected village are also interviewed.

The evaluation is conducted with the aid of prescribed checklists and indicators as determined. The diagrammatic representation of the methodology is given in the figure given below. The reports of the teams are submitted to NVBDCP, where compilation and review of programme implementation is done. The states may devise similar system of evaluation of their own to strengthen the system of regular monitoring.

Methodology of conducting annual central evaluation



Chapter-16
Reporting Formats