NATIONAL DRUG POLICY ON MALARIA (2010)

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Preamble

Malaria is one of the major public health problems of the country. Around 1.5 million laboratory confirmed cases of malaria are annually reported in India. Around 50% of the total malaria cases reported is due to *P. falciparum*. One of the reasons attributed to rise in proportion of *P. falciparum* cases is resistance to chloroquine, which was used for a long time as the first line of treatment of malaria cases. *P. falciparum* infections are known to lead to severe malaria, if timely treatment with effective drugs is not administered.

The National Drug Policy on Malaria was first formulated in 1982 and has subsequently been reviewed and revised periodically. The present National Drug Policy for Malaria (2010) has been drafted keeping in view the availability of more effective antimalarial drugs and drug resistance status in the country.

Early diagnosis and complete treatment is one of the key strategies of the National Malaria Control Programme. All fever cases clinically suspected of malaria should be investigated for confirmation of malaria by either microscopy or Rapid Diagnostic Test (RDT)\(^1\). As and when the bivalent RDT is introduced, it will be used for diagnosis of malaria cases at the field level in remote areas where microscopy is not available within 24 hrs. of starting of fever.

In high Pf predominant areas where it is not possible to get microscopy results within 24 hours, ASHAs/other community health volunteers/MPWs should be provided with rapid diagnostic kits and anti-malarials (including ACT) for early diagnosis and treatment of *P. falciparum* cases.

Effective treatment of malaria under the National Drug Policy aims at:

- Providing complete cure (clinical and parasitological) of malaria cases
- Prevention of progression of uncomplicated malaria into severe malaria and thereby reduce malaria mortality
- Prevention of relapses by administration of radical treatment
- Interruption of transmission of malaria by use of gametocytocidal drugs
- Preventing development of drug resistance by rational treatment of malaria cases.

\(^1\) At present, only Pf RDTs are being supplied under NVBDCP
Treatment of uncomplicated malaria

1. All fever cases suspected to be malaria should be investigated by microscopy or RDT.

2. *P. vivax* cases should be treated with chloroquine for three days and Primaquine for 14 days. Primaquine is used to prevent relapse but is contraindicated in pregnant women, infants and individuals with G6PD deficiency.

   Note: Patients should be instructed to report back in case of haematuria or high colored urine / cyanosis or blue coloration of lips and Primaquine should be stopped in such cases. Care should be taken in patients with anaemia.

3. *P. falciparum* cases should be treated with ACT (Artesunate 3 days + Sulphadoxine-Pyrimethamine 1 day). This is to be accompanied by single dose primaquine on day 2.

4. Pregnant women with uncomplicated *P. falciparum* should be treated as follows:
   - 1st Trimester: Quinine
   - 2nd & 3rd Trimester: ACT

   Note: Primaquine is contra indicated in pregnant woman

5. In cases where parasitological diagnosis is not possible due to non-availability of either timely microscopy or RDT, suspected malaria cases will be treated with full course of chloroquine, till the results of microscopy are received. Once the parasitological diagnosis is available, appropriate treatment as per the species, is to be administered.

6. Presumptive treatment with chloroquine is no more recommended.

7. Resistance should be suspected if in spite of full treatment with no history of vomiting, diarrhoea, patient does not respond within 72 hours, clinically and parasitologically. Such cases not responding to ACT, should be treated with oral quinine with Tetracycline / Doxycycline. These instances should be reported to concerned District Malaria /State Malaria Officer/ROHFW for initiation of therapeutic efficacy studies.
DRUG SCHEDULE FOR TREATMENT OF MALARIA UNDER NVBDCP

Treatment of P.vivax cases

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

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

Age-wise dosage schedule for treatment of P.vivax cases

<table>
<thead>
<tr>
<th>Age (in years)</th>
<th>Tablet Chloroquine (150 mg base)</th>
<th>Tablet Primaquine* (2.5 mg base)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day – 1</td>
<td>Day – 2</td>
</tr>
<tr>
<td>&lt; 1</td>
<td>½</td>
<td>½</td>
</tr>
<tr>
<td>1 – 4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5 – 8</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>9 -14</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>15 &amp; above</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

* Primaquine is contraindicated in infants, pregnant women and individuals with G6PD deficiency. 14 day regimen of Primaquine should be given under supervision.

Treatment of uncomplicated P.falciparum cases

1. Artemisinin based Combination Therapy (ACT)*
   - Artesunate 4 mg/kg body weight daily for 3 days
   - Sulfadoxine (25 mg/kg body weight) – Pyrimethamine (1.25 mg/kg body weight) on first day
   - Primaquine 0.75 mg/Kg body weight on Day 2

   * Caution: 1. ACT is not to be given in 1st trimester of pregnancy.
               2. SP is not to be given to child of age under 5 month and s/he should be treated with Alternate ACT
The Programme has introduced five different age-group specific Combi Blister packs for SP-ACT. The age group wise dose schedule for the same and the colour of each combipack is given as follows:

**Age-wise dosage schedule for treatment of *P.falciparum* cases**

<table>
<thead>
<tr>
<th>Age Group (Years)</th>
<th>1st day</th>
<th>2nd day</th>
<th>3rd day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AS</td>
<td>SP</td>
<td>AS</td>
</tr>
<tr>
<td>0-1 Pink Blister</td>
<td>1 (25 mg)</td>
<td>1 (250 mg +12.5 mg)</td>
<td>1 (25 mg)</td>
</tr>
<tr>
<td>1-4 Yellow Blister</td>
<td>1 (50 mg)</td>
<td>1 (500+25 mg each)</td>
<td>1 (50 mg)</td>
</tr>
<tr>
<td>5-8 Green Blister</td>
<td>1 (100 mg)</td>
<td>1 (750+37.5 mg each)</td>
<td>1 (100 mg)</td>
</tr>
<tr>
<td>9-14 Red Blister</td>
<td>1 (150 mg)</td>
<td>2 (500+25 mg each)</td>
<td>1 (150 mg)</td>
</tr>
<tr>
<td>15 &amp; Above White Blister</td>
<td>1 (200 mg)</td>
<td>2 (750+37.5 mg each)</td>
<td>1 (200 mg)</td>
</tr>
</tbody>
</table>

* Caution: 1. ACT is not to be given in 1st trimester of pregnancy.
  2. SP is not to be given to child of age under 5 month and s/he should be treated with Alternate ACT.
Treatment of uncomplicated *P.falciparum* cases in pregnancy

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

Note: 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: ACT as per dosage given above.

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.

Treatment of severe malaria cases

Severe malaria is an emergency and treatment should be given as per severity and associated complications which can best be decided by the treating physician. The guidelines for specific antimalarial therapy is as follows:

- **Artesunate**: 2.4 mg/kg body weight IV or IM given on admission (time = 0 h); then at 12 h and 24 h and then once a day.  
  (or)
- **Artemether**: 3.2 mg/kg body weight IM given on admission and then 1.6 mg/kg body weight per day.  
  (or)
- **Arteether**: 150 mg IM daily for 3 days in adults only (not recommended for children).  
  (or)
- **Quinine**: 20 mg/kg* body weight on admission (IV infusion or divided IM injection) followed by maintenance dose of 10 mg/kg body weight 8 hourly. The infusion rate should not exceed 5 mg salt/kg body weight per hour.  
  (*loading dose of Quinine i.e. 20mg /kg body weight on admission may not be given if the patient has already received quinine or if the clinician feels inappropriate).

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 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)

- ACT as described.

**Chemoprophylaxis**

Chemoprophylaxis should be administered only in selective groups 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 travellers 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 screening before prescription of the drug.