**Revised National PPTCT Guidelines-2014**

Opportunity to eliminate Paediatric HIV in India

Prevention of Parent to Child Transmission of HIV - Services and Updated guidelines

Early Infant Diagnosis Algorithm A

Early Infant Diagnosis Algorithm B

Karnataka State AIDS Prevention Society

Based on Updated Guidelines for Prevention of Parent to Child Transmission (PPTCT) of HIV- December 2013

Ministry of Health & Family Welfare, Department of AIDS Control
### Prevention of Parent To Child Transmission of HIV (PPTCT)

**Services and Updated Guidelines**

#### Four prongs of PPTCT:
- Primary prevention of HIV, especially among women of young and child-bearing ages
- Preventing unintended pregnancies among women living with HIV through meeting family planning needs of HIV positive women
- Prevention of mother to child (vertical) transmission, through a complete cascade of PPTCT services to HIV positive pregnant women
- Assuring linkages of HIV positive mother and infants to care, support and treatment services and prevent maternal and infant deaths related to HIV

The PPTCT cascade of services flow chart (Page No: 2 or 3) describes the essential PPTCT services related to third and fourth prongs.

Based on the analysis from new evidences on ART and ARV prophylaxis regimens to prevent HIV transmission from mother-to-child, WHO 2013 guidelines recommends:

- All babies detected positive <2years of age are given Paediatric ART irrespective of CD4 %/count
- HIV-exposed children should be immunized according to the routine national immunization schedule, unless the child is severely symptomatic where live vaccines are not indicated

#### Goal of PPTCT program: Elimination of new HIV infection in infants and young children by 2015

- Avoiding stopping and starting drugs with repeat pregnancies
- Providing early protection against mother-to-child transmission in future pregnancies
- Avoiding drug resistance

The PPTCT interventions in India over the past few years have transitioned from the use of Single Dose Nevirapine (SD NVP) through triple drug ARV prophylaxis to lifelong ART, to efficiently bring down the rate of mother to child transmission of HIV from around 30% to less than 5% in breast feeding populations in India.

The guiding principles developed by Department of AIDS Control, Government of India for the use of ART to prevent HIV transmission from mother-to-child are:

- All pregnant and breast feeding women living with HIV receive lifelong triple-drug ART regimen regardless of CD4 count or WHO clinical stage
- Postpartum ART initiation to mother and ARV (Nevirapine) Prophylaxis to child are aimed at improving HIV-free child survival by reducing HIV transmission through breastfeeding.
- HIV exposed infants should be followed-up and managed as per the National Guidelines on “Care of HIV exposed infants and children”

#### Infant feeding:
- Exclusive breast feeding to all HIV exposed infants for a minimum period of 6 months and continuation of breast feeding along with complementary feeding (Gradual weaning) till one year in EID negative babies.
- In EID positive babies, breast feeding can be continued up to 2 years along with early initiation of paediatric ART.
- No MIXED FEEDING (No mixing of breast feeding and other alternate feeding like milk powder/cow’s milk during the first 6 months) under any circumstances.

#### Drugs Dosage and Side effects

<table>
<thead>
<tr>
<th>Name of ARV drug</th>
<th>Dose Schedule</th>
<th>Side-Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Tenofovir (TDF)</td>
<td>300mg OD</td>
<td>Nephrotoxicity, hypophosphatemia</td>
</tr>
<tr>
<td>2 Lamivudine (3TC)</td>
<td>300mg OD</td>
<td>Rare pancreatitis</td>
</tr>
<tr>
<td>3 Efavirenz (EFV)</td>
<td>600 mg BS</td>
<td>CNS toxicity, Visual symptoms, dermatitiis, insomnia, dizziness, headache, increased appetite, Metropolitan syndrome, exacerbation of psychotic disorders (usually subsides by 3-6 weeks)</td>
</tr>
<tr>
<td>4 Losartan/Hydrochlorothiazide (SPV)</td>
<td>40/12.5 mg OD</td>
<td>Hypokalemia, Hypoglycemia</td>
</tr>
</tbody>
</table>

*Tenofovir (TDF) 300mg + Lamivudine (3TC) 300mg Fixed Dose Combination (FDC) once daily pill + Efavirenz (EFV) 600mg, once daily pill preferably to be taken at bedtime, EFV has to be preferably taken on an empty stomach and also it is suggested to avoid high fat meal.

Other NACO Approved ART Regimens are: AZT+ 3TC+EFV, AZT+3TC+NVP and TDF+ 3TC+NVP (AZT – Zidovudine, 3TC- Lamivudine, NVP-Nevirapine, TDF- Tenofovir and EFV-Efavirenz)
### Care and Treatment of Positive pregnant women during Labour and Delivery

#### I. Care during Labour and Delivery

<table>
<thead>
<tr>
<th>Do's</th>
<th>Don'ts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One PV exam to assess women</td>
<td>• Isolate the women</td>
</tr>
<tr>
<td>• Monitor contractions and fetal heart sound</td>
<td>• Give an enema</td>
</tr>
<tr>
<td>• Give ART to the mother as prescribed</td>
<td>• Perform frequent PV exams</td>
</tr>
<tr>
<td>• Clean Vagina with 0.25% Chlorhexidine</td>
<td>• Rupture membranes unless indicated</td>
</tr>
<tr>
<td>• Apply pressure in perineum when it is bulging to prevent episiotomy</td>
<td>• Use instrumental techniques unless absolutely necessary</td>
</tr>
<tr>
<td>• Follow Universal Work Precautions for all cases while conducting deliveries</td>
<td>• Perform Invasive techniques like fetal blood sampling, scalp electrodes</td>
</tr>
<tr>
<td>• Caesarean sections in HIV positive pregnant women should be performed for Obstetric indications only</td>
<td></td>
</tr>
</tbody>
</table>

For disposal of tissues, placenta and other medical/infectious waste material from the delivery of HIV-infected deliveries, Standard Hospital Waste Disposal Management guidelines should be followed.

#### II. Family Planning: Ensure family planning counselling and practices during discharge and post natal follow-up visits. Also, ensure condom usage as a safer sex method along with choice of contraceptive method for dual protection against HIV and STIs.

#### Care and Treatment of New Born / HIV Exposed Infant

<table>
<thead>
<tr>
<th>Do's</th>
<th>Don'ts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dry, warmth</td>
<td>• Use mouth-operated suction</td>
</tr>
<tr>
<td>• Clear airway</td>
<td>• Suction newborn with nasogastric tube unless meconium-stained liquor</td>
</tr>
<tr>
<td>• Mouth and nostrils to be wiped as soon as head is delivered</td>
<td></td>
</tr>
<tr>
<td>• Cut cord with new blade, in adequate light</td>
<td></td>
</tr>
<tr>
<td>• Initiate feeding as per mother’s feeding choice</td>
<td></td>
</tr>
<tr>
<td>• ARV (NVP) prophylaxis to the baby as prescribed</td>
<td></td>
</tr>
</tbody>
</table>

**HIV Exposed Infant (HEI) - Definition**: Infants / child born to mothers infected with HIV, until HIV infection can be reliably excluded and the infants and children are not exposed to HIV through breastfeeding. The HIV status can be confirmed only at 18 months, regardless of earlier HIV diagnosis. (Algorithm A & B in page 8)

- Syrup Nevirapine (10mg in 1ml suspension) from birth till 6 weeks
- From 6 weeks to 18 months Cotrimoxazole Prophylaxis for opportunistic infections
- Early infant diagnosis (EID) at 6 weeks (DNA-PCR) of age; repeat testing at 6 months, 12 months (or 6 weeks after cessation of breastfeeds)
- Confirmation of HIV status of all babies at 18 months using Antibody (Rapid) Tests
Five possible PPTCT Case Scenarios for provision of ART to mother and ARV Prophylaxis to Infant

1. Pregnant Women identified as HIV positive - Women identified as HIV positive during ANC check-ups
   - Continue ART through pregnancy, delivery and lifelong
   - Start Lifelong ART irrespective of CD4 count or WHO clinical stage (ART can be initiated even in fist trimester of pregnancy)*
   - TDF + 3TC + Kivex

   **Exclusive Breastfeeding**
   - Mothers: Continue Lifelong ART
   - Infants: Daily NVP from birth for 6 weeks.

   **Exclusive Replacement feeding**
   - Mothers: Continue Lifelong ART
   - Infants: Daily NVP from birth for 6 weeks

   *Women found positive in third trimester even after 36 weeks of gestation has to be linked to ART center and started on Lifelong ART and Infant Nevirapine Prophylaxis to be extended up to 12 weeks

   # Pregnant women who had prior exposure to NNRTI drugs (like Nevirapine), a combination of TDF + 3TC + LPV/r has to be given. LPV/r is given in place of EFV because NNRTI group resistance to NVP and EFV (archived resistance) will make EFV-based regimen just a 2 drug regimen

2. HIV Positive Women already on ART* getting pregnant - Known HIV positive women already on ART getting pregnant
   - Continue same ART regime during pregnancy, labour, and delivery

   **Mothers:** Continue ART Lifelong
   **Infants:** Breastfeeding or Replacement feeding: Daily NVP from birth for 6 weeks

   * NACO Approved ART Regimens :
     - AZT + 3TC + EFV, AZT + 3TC + NVP, TDF + 3TC + EFV and TDF + 3TC + NVP
     - (AZT = Didehydroxyxylulinate, 3TC = Lamivudine, NVP = Nevirapine, EFV = Efavirenz and TDF - Tenovif)

3. Women presenting Directly-in-Labour (Unbooked cases) - Unbooked pregnant women with no HIV test report/HIV test report unavailable and is identified as new HIV positive in labour room/delivery ward or immediately postpartum
   - Detected HIV Positive using Whole Blood Finger Prick testing in labour room / delivery ward/immediate postpartum
   - Collect blood sample (single HIV test Kit sites) and send the sample next day to ICTC for Confirmation / ART centre for CD4 (three HIV test sites kits)
   - Initiate maternal ART (TDF + 3TC + EFV)
   - (ART drugs provided at delivery conducting sites in govt. program)

   **Same/Next day:** Postpartum - Counselling and confirmation of HIV status

   **Breast Feeding**
   - **Mother:** Continues Lifelong ART
   - **Infant:** Extended Nevirapine prophylaxis from birth for 12 weeks

   **Replacement feeding**
   - **Mother:** Refer mother for HIV care and evaluation for treatment
   - **Infant:** Daily Nevirapine from birth for 6 weeks

4. Women found to be HIV Positive after delivery - Women delivered at home or identified HIV positive after delivery (when they bring Infant to hospital after delivery)
   - Breast Feeding
     - **Mother:** Link to ART centre for initiation of Lifelong ART
     - **Infant:** Extended Nevirapine prophylaxis from birth for 12 weeks
   - Replacement feeding
     - **Mother:** Refer mother to ART center for HIV care and evaluation for treatment
     - **Infant:** Daily Nevirapine from birth for 6 weeks

5. Mother on ART but interrupts ART regimen while breast feeding - Breast feeding mother discontinues ART due to toxicity, ART drug stock outs or refusal to continue ART
   - **Mother:** Determine an alternative ART regimen or solution; counsel regarding continuing ART without interruption
   - **Infant:** Nevirapine prophylaxis until 6 weeks after maternal ART is restarted (or) until 1 week after breast feeding has ended

II. Nevirapine Prophylaxis and Dosage: Daily Nevirapine from birth till 6 weeks (10 mg of Nevirapine in 1 ml suspension)

<table>
<thead>
<tr>
<th>Birth Weight (g)</th>
<th>NVP daily dose (mg)</th>
<th>NVP daily dose (ml)</th>
<th>Duration</th>
<th>Side-effects of Nevirapine</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2000 g</td>
<td>2 mg/kg Once daily</td>
<td>2.2 mg/kg Once daily</td>
<td>Up to 6 weeks irrespective of exclusive breast feeding or exclusive replacement feeding may be extended to 12 weeks if mother has not received ART for adequate duration</td>
<td>Common: Nausea and diarrhea, Severe and new: Skin rash, muscle/joint pain, jaundice and liver</td>
</tr>
<tr>
<td>2000 - 2900 g</td>
<td>3 mg/kg Once daily</td>
<td>3.3 mg/kg Once daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3000 - 3900 g</td>
<td>4 mg/kg Once daily</td>
<td>4.4 mg/kg Once daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 3900 g</td>
<td>5 mg/kg Once daily</td>
<td>5.5 mg/kg Once daily</td>
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</tbody>
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