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Prevention of Parent to Child Transmission of HIV - New National Guidelines

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Government of India is committed to work towards achievement of the global target of "elimination of new HIV infections among children" by 2015. Based on the new guidelines from WHO (June 2013), Department of AIDS Control has decided to provide life-long ART (triple drug regimen) for all pregnant and breast feeding women living with HIV, in which all pregnant women living with HIV receive a triple drug ART regimen regardless of CD4 count or WHO clinical stage, both for their own health and to prevent vertical HIV transmission from mother-to-child. This would also help in maximizing coverage for those needing treatment for keeping them alive and for their own health, avoiding stopping and starting drugs with repeat pregnancies, provide early protection against mother-to-child transmission in future pregnancies and avoiding drug resistance. These recommendations have the potential to reduce the risk of mother-to-child-transmission to less than 5 per cent in breastfeeding populations.

Mother-to-child-transmission of HIV is a major route of HIV infection in children. However, out of an estimated 27 million pregnancies in a year, only about 52.7% attend health services for skilled care during child birth in India. Of those who availed health services, 8.83 million ANCs received HIV counselling and testing (March 2013) out of which 12,551 pregnant women were detected to be HIV positive. To enhance this coverage, a joint directive from the National AIDS Control Programme (NACP) and the National Rural Health Mission (NRHM) regarding convergence of the two programme components was issued in July 2010, explicitly stating that universal HIV screening should be included as an integral component of routine ANC check-up. The objective was to ensure that pregnant women who are diagnosed with HIV would be linked to HIV services for their own health as well as to ensure prevention of HIV transmission to newborn babies under the Prevention of Parent to Child Transmission (PPTCT) programme.

In the absence of any intervention, a substantial proportion of children born to women living with HIV, acquire HIV infection from their mothers either during pregnancy, labour/delivery or during breastfeeding. *Without any intervention*, the risk of transmission of HIV from infected pregnant women to her children is estimated to be around 20-45%. Use of ART and single dose NVP/Syrup NVP to mother-baby pairs has shown to be quite effective in reducing this transmission as low as 10 per cent. Use of single dose Nevirapine (sd-NVP) at the onset of labour significantly reduces pre-partum HIV transmission[(A)]. However, it is less effective than other available ARV prophylaxis and it does not cover the risk of HIV transmission during the antenatal or breastfeeding periods. Further, it also adds to the risk of acquiring drug resistance to nevirapine (NVP) as well as cross resistance to Efavirenz.[1]

Let us know the basic statistics that there are an estimated 2.1 million (2011) People Living with HIV (PLHIV) in India, with National adult HIV prevalence of 0.27% (2011). Of these, women constitute 39% of all PLHIV while children less than 15 years of age constitute 7% of all infections. As on March 2013, 0.1 million HIV positive children had been registered under the antiretroviral

therapy (ART) programme and 38,579 are receiving free ART. There has been a significant scale-up of HIV counselling & testing, Prevention of Parent-to-Child Transmission (PPTCT) and ART services across the country over last five years. Between 2004 and 2013, the number of pregnant women tested annually under the Prevention of Parent-To-Child –Transmission (PPTCT) programme increased from 0.8 million to 8.83 million and reach of the services has expanded to the rural areas to a large extent. Concurrently, there has also been a significant decentralisation and scale-up of the ART services, with 7.34 Lakhs PLHIV receiving free ART across the country through 409 ART centres and 860 Link-ART centres (LAC). WHO in 2010 had recommended two more efficacious regimen, option A & option B, to further reduce the chances of HIV transmission from mother-to-child. Further in 2013, consolidated ART guideline, WHO has recommended moving away from the previous terms "Options A, B and B+". Instead, the WHO new guidelines (June 2013) recommend two options:

1. Providing lifelong ART to all the pregnant and breastfeeding women[(B)] living with HIV regardless of CD4 count or clinical stage [(C)] OR
2. Providing ART (ARV drugs) for pregnant and breastfeeding women with HIV during the mother-to-child transmission risk period and then continuing life-long ART for those women eligible for treatment for their own health.

There are certain salient points which have been summarized below:

a. Good antenatal care ensures that pregnancy and delivery:

- Is a safe experience for the mother.
- Builds the foundation for the delivery of a healthy baby (minimal risk of HIV transmission to the baby)

b. ART Eligibility in Pregnant Women:

- Initiate lifelong ART in all pregnant women with confirmed HIV infection regardless of WHO clinical stage or CD4 cell count. TDF + 3TC + EFV is recommended as first-line ART in pregnant and breastfeeding women, (including pregnant women in the first trimester of pregnancy and women of childbearing age)
- ART shall be initiated only at ART centre

c. Starting Co-trimoxazole in Pregnancy

- Co-trimoxazole should be started if CD4 count is d" 250 cells / mm3 and continued through pregnancy, delivery and breastfeeding as per national guidelines (Dose: Double strength tablet – 1 tab daily).
- Ensure that pregnant women take their folate supplements regularly

d. All HIV infected pregnant women should be seen on a priority in the ART Centre.

e. The recommended first-line regimen for HIV infected Pregnant Women is Tenofovir (TDF) (300 mg) + Lamuvidine (3TC) (300 mg) + Efavirenz (EFV) (600)

f. Women who are screened and found HIV Infected during labour or just after delivery should be given a Top Priority for Clinical Management and CD4 Assessment in the ART Centre.

g. 5 Do's for infants at 6 weeks

It is important to do the following for infants at 6 weeks:

- Do re-inforcement for Exclusive Breastfeeding for the first 6 months (Continuation of breastfeeds with introduction of complementary feeds thereafter)
- Do EID testing
- Do Immunization
- Do CPT initiation and continue until baby is 18 months old or longer if baby is confirmed positive
- Do stop NVP Prophylaxis for baby at

6 weeks (maternal ART is not of adequate duration)

h. If a pregnant woman is detected to have both HIV-1 and HIV-2 infections, she should receive standard first ART Regimen (TDF+3TC+EFV) recommended for women with HIV-1 infection

i. Provision of treatment for Hepatitis B & C for HIV co-infected pregnant women (with Hepatitis B or C) will be the responsibility of the general health systems.

j. Caesarean sections in HIV positive pregnant women should be performed for Obstetric indications only.

k. Condom should be consistently used by all HIV infected males despite following any other Family Planning Method (Dual Protection)

l. 5 Do's for infants at 6 weeks

For infants at 6 weeks, it is important to do the following:

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- Do EID testing
- Do Immunization
- Do CPT initiation and continue until baby is 18 months/continue if baby is tested positive
- Do stop NVP Prophylaxis for b a b y after 6 weeks (may need extension to 12 weeks if mother has been initiated late on ART)
- Do re-inforcement for Exclusive Breastfeeds for the first 6 monthsfor (Continuation of breastfeeds with introduction of complementary feeds thereafter)

n. Recommendations for infant feeding in HIV exposed and infected infants < 6 months of age

The 2011 National Guidelines on Feeding for HIV-exposed and infected infants < 6 months old recommends:

Exclusive breastfeeding for at least 6 months

- Only in situations where breastfeeding cannot be done (maternal death, severe maternal illness) or individual mother's choice (at her own risk), then exclusive replacement feeding may be considered.

o. AFASS criteria for Exclusive Replacement Feeding

Mothers known to be HIV-infected, if insist on opting for exclusive replacement feeding which is contrary to the WHO/NACO's guidelines of giving exclusive breastfeeds for first 6 months, are doing so at their own risk. They should be counselled not to give any breast feeds during the first six months. Mixed feeding should not be done during the first 6 months. *(Feeding a baby with both breast feeds and replacement feeds in the first 6 months is known as mixed feeding which leads to mucosal abrasions in the gut of the baby facilitating HIV virus entry through these abrasions)*

When opting for Exclusive Replacement Feeding, they should fulfil the AFASS criteria given below:

1. *Safe* water and sanitation are assured at the household level and in the community, and can prepare clean feeds.
2. The mother or other caregiver can reliably *afford* to provide sufficient replacement feeding (milk), to support normal growth and development of the infant, and can *sustain* it un-interruptedly for first 6 months at least.
3. The mother or caregiver can prepare it frequently enough in a clean manner so that it is safe and carries a low risk of diarrhoea and malnutrition.
4. The mother or caregiver can, in the first six months exclusively give replacement feeding, and is *feasible.*
5. The family is supportive of this practice, and *accepts* it without forcing her to breastfeed during the first 6 months.

p. All babies detected positive <2years of age are given Paediatric ART irrespective of CD4 %

q. *Intra-Uterine Contraceptive Device (IUCD)* is a good contraceptive method for HIV infected pregnant women. IUCD Copper T 380A is recommended by MoHFW as a long term reversible method of contraception up to 10 years. PP IUD (Cu-'T' A-380) to be inserted within 48 hrs of delivery.[2]

Finally, we conclude that National Guidelines for Prevention of Parent-to-Child Transmission of HIV have been implemented across the country from 1st January 2014.

(C)WHO Clinical Staging for Adults and Adolescents

Clinical Stage 1

Asymptomatic Persistent generalized lymphadenopathy

Clinical Stage 2

Moderate unexplaineda weight loss (under 10% presumed or measured body weight) (b) Recurrent respiratory tract infection (sinusitis, tonsillitis, otitis media, pharyngitis) Herpes zoster, Angular cheilitis, Recurrent oral ulceration, Papular pruitic eruptions Seborrhoeic dermatitis, Fungal nail infections.

Clinical Stage 3

Unexplained (a) severe weight loss (over 10% of presumed or measured body weight) (b)

Unexplained(a) chronic diarrhoea for longer than one month

Unexplained(a) persistent fever (intermittent or constant for longer than one month) Persistent oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis

Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

(A) Infant NVP Prophylaxis Dosing:

Birth Weight	NVP daily dose (in mg)	NVP daily dose (in ml)**	Duration
Birth to 6 weeks: *			
Infants with birth weight < 2000 gm	2 mg/kg once daily. In consultation with a pediatrician trained in HIV care.	0.2 ml/kg once daily	Up to 6 weeks irrespective of whether exclusively breastfed or exclusive replacement fed.
Birth weight 2000 – 2500 gm	10 mg once daily	1 ml once a day	
Birth weight more than 2500 gm	15 mg once daily	1.5 ml once a day	

**considering the content of 10 mg Nevirapine in 1ml. suspension based on WHO Guidelines.
*infants with birth weight < 2000 gm should receive dose of 2 mg/kg once daily. Consult expert HIV paediatrician in these cases.
Source: WHO Guidelines

(B)Dosing Schedules for ART for Pregnant Women

Clinical Scenario	ARV Prophylaxis and dosing	Antepartum	Intrapartum	Postpartum
Pregnant Women requiring ART	TDF 300mg once daily 3TC 300 mg once daily EFV 600mg once daily	Start ART as soon as possible (first trimester)	Continue ART	Continue ART life-long

Unexplaineda anaemia (below 8 g/dl), neutropenia (below 0.5 x 100/1) and/or chronic thrombocytopenia (below 50 x 100 / 1)

Clinical Stage 4C

HIV wasting syndrome

Pneumocystis jeroveci pneumonia (PCP)

Recurrent severe bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)

Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)

Extrapulmonary tuberculosis

Kaposi sarcoma

Cytomegalovirus infection (retinitis or infection of other organs) Central nervous system toxoplasmosis

HIV encephalopathy

Extrapulmonary cryptococcosis including meningitis Disseminated non-tuberculous mycobacteria infection Progressive

multifocal leukoencephalopthy

Chronic cryptosporidiosis

Chronic isosporiasis

Disseminated mycosis (extrapulmonary histoplasmosis, coccidiomycosis) Recurrent septicaemia (including non-typhoidal Salmonella)

Lymphoma (cerebral or B cell non-Hodgkin) Invasive cervical carcinoma

Atypical disseminated leishmaniasis

Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

a Unexplained refers to where the condition is not explained by other conditions.

b Assessment of body weight among pregnant women needs to consider the expected weight gain of pregnancy.

c Some additional specific conditions can also be included in regional classifications, such as the reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in the WHO Region of the Americas and penicilliosis in Asia.

References

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