

Updated Guidelines for

# Prevention of Parent to Child Transmission (PPTCT) of HIV using Multi Drug Anti-retroviral Regimen in India

December, 2013



Government of India  
Ministry of Health & Family Welfare

**Department of AIDS Control**  
**Basic Services Division**

Chandralok Building, Janpath  
New Delhi - 110001



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लव वर्मा  
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Secretary



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### Foreword

The National AIDS Control Programme (NACP) **launched** Prevention of Parent to Child Transmission (PPTCT) of HIV in the year 2001-02. This provided access to HIV testing services to all pregnant women enrolled for Ante-natal Care (ANC) along with provision of ARV prophylaxis with single dose of Nevirapine (SD-NVP) at the time of delivery; and rapidly **scaled-up** this intervention across India during the NACP-III (2007-12).

In September, 2012, NACP as a **policy** adopted the more efficacious multi drug ARV regimen for PPTCT, based on the recommendations of WHO (2010).

Government of India is **committed** to work towards achievement of the global target of "Elimination of new HIV infection among children" by 2015. **Based on the new Guidelines from WHO (June 2013), Department of AIDS Control (DAC) has decided to initiate lifelong ART (triple drug regimen) for all pregnant and breast feeding women living with HIV, regardless of CD4 count or WHO clinical stage, both for their own health and to prevent vertical HIV transmission and with additional HIV prevention benefits.** This would also help in maximum coverage for those needing treatment for their own health, avoid stopping and starting drugs with repeat pregnancies, provide early protection against mother-to child transmission in future pregnancies, reduce the risk of HIV transmission to HIV sero discordant partners and improve maternal health.

Thus these "**National Guidelines for PPTCT (2013)**" have been updated to incorporate global recommendations and also provide Operational Guidelines for nationwide implementation of Multi Drug Regimen for PPTCT with immediate effect.

It is **crucial** that for efficient PPTCT, all the States /UTs strengthen the **convergence** between NACP and National Reproductive & Child Health (RCH) including STI/RTI, to improve access of HIV awareness, counseling and screening/ testing services **to detect HIV infection amongst pregnant women on their very first contact with health system.** This will promote birth of HIV free children and improve longevity with quality life of people living with HIV infection with supportive environment. It is important that synergies with National Health Mission (NHM) and the General Health Care System are sustained for efficient delivery & management of PPTCT services with well functioning referrals and linkages.

The **meticulous efforts** made by the Basic Services Division with support from all concerned stakeholders and partners are **appreciated** for bringing out these "PPTCT Technical Guidelines, 2013", and surely the PPTCT services will rapidly scale up and strive towards **elimination** of mother-to-child transmission of HIV (e-MTCT) in our country.

  
(Lov Verma)

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**Know Your HIV status, go to the nearest Government Hospital for free Voluntary Counselling and Testing**



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### Preface

India had an estimated 2.1 million persons living with HIV in 2011. The **HIV prevalence** among adult population in India has **consistently declined** over the last one decade from 0.4% in 2000 to 0.27% in 2011. This decline is due to reduction in the new HIV infections among adults, from 2.7 lakh in 2000 to 1.17 lakh in 2011, a drop of about 57%. Wider access to ART has resulted in 29% reduction in estimated annual deaths due to AIDS related causes between 2007 and 2011. This decline reflects the impact of scaled up HIV prevention interventions under NACP.

**Mother to child transmission of HIV** is the primary route of transmission for HIV among children. This transmission is known to occur during pregnancy, delivery and breast-feeding period with equal frequency. It is estimated that without any intervention the risk of transmission of HIV from infected mother to her child is between 20 to 45%. Global evidences suggest that although ARV prophylaxis with single dose Nevirapine is useful, it offers only partial protection against the vertical HIV transmission. Therefore more efficacious multiple drug ARV regimens are recommended, to be started early during the pregnancy and continued throughout pregnancy and until cessation of breastfeeding. These regimens have potential to dramatically reduce HIV transmission from mother-to-child to less than 5%.

In India, the **PPTCT** interventions under the NACP **started in 2001- 02** using single dose Nevirapine prophylaxis to HIV (+ve) pregnant women during labor and her new born child immediately after the birth.

The **PPTCT interventions globally**, over the past few years, have **transitioned** from the use of the single dose Nevirapine (administered to HIV positive Ante-natal women and their exposed babies), to the multi-drug Anti Retro Virals (ARVs) to efficiently bring down the rate of transmission of HIV from mother-to-child to the level of less than 5 percent.

With the Department of AIDS Control / GoI adopting "Option B" of the WHO Recommendations (2010), **India has also transitioned from the single dose Nevirapine strategy to that of multi-drug ARV prophylaxis from September 2012**. To begin with, this strategy was executed in the three southern high HIV prevalent states of Andhra Pradesh, Karnataka and Tamilnadu.

The new Guidelines of World Health Organization (June 2013) recommends that instead of previous terms "Options A, B and B+", **only following option(s) be practiced**, viz,

1. Providing lifelong ART to all the pregnant and breastfeeding women living with HIV regardless of CD4 count or clinical stage,

**OR**

2. Providing ART (ARV drugs) for pregnant and breastfeeding women with HIV during the mother to child transmission risk period and then continuing lifelong ART for those women eligible for treatment for their own health.

Based on the suggestions from the Technical Resource Groups during December 2013, the **Department of AIDS Control / GoI decided to implement the latest WHO Guidelines (2013) vide which lifelong ART will be initiated for all pregnant and breastfeeding women with HIV irrespective of CD4 count, in India with immediate effect.**

Thus the present **updated PPTCT Technical Guidelines-2013 are contained in this document for implementation of PPTCT Services in our country.**

(Dr Ashok Kumar)

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# Abbreviations



ANC	Antenatal Care	IUCD	Intra-uterine contraceptive device
AIDS	Acquired Immune Deficiency Syndrome	LPV/r	Lopinavir/ritonavir
ALT	Alanine Aminotransferase	3TC	Lamivudine
ART	Antiretroviral Therapy	MTCT	Mother-to-Child Transmission of HIV
ARV	Antiretroviral	NACO	National AIDS Control Organisation
ARSH	Adolescent Reproductive & Sexual Health	NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
AZT	Zidovudine	NRTI	Nucleoside Reverse Transcriptase Inhibitor
BCC	Behaviour Change Communication	NRHM	National Rural Health Mission
CPT	Cotrimoxazole Prophylactic Therapy	NVP	Nevirapine
CDC	Centers for Disease Control and Prevention	OIs	Opportunistic Infections
DBS	Dried Blood Spot	PEP	Post-Exposure Prophylaxis
DIL	Direct-in-Labour	PCP	Pneumocystis Jiroveci Pneumonia
DNA	Deoxyribonucleic Acid	PCR	Polymerase Chain Reaction
d4t	Stavudine	PPTCT	Prevention-of-Parent-to-Child-Transmission of HIV
EBF	Exclusive Breast Feeding	RCH	Reproductive & Child Health
EID	Early Infant Diagnosis	RPR	Rapid Plasma Reagin
e-MTCT	Elimination of Mother-to-Child Transmission	NVP	Single-Dose Nevirapine
ERF	Exclusive Replacement Feeding	SRH	Sexual and Reproductive Health
EFV	Efavirenz	TB	Tuberculosis
EPI	Expanded Programme of Immunization	TDF	Tenofovir Disoproxil Fumarate
HBV	Hepatitis B Virus	ULN	Upper limit of normal
HCT	HIV Counselling and Testing	UNAIDS	United Nations Programme on HIV/AIDS
HCV	Hepatitis C Virus	UNICEF	United Nation International Childrens Emergency Fund
HEI	HIV Exposed Infant	VCT	Voluntary Counselling and Testing
HIV	Human Immunodeficiency Virus	WBS	Whole Blood Specimen
ICF	Intensified case finding of TB	WHO	World Health Organisation
ICTC	Integrated counselling and Testing Centre	WBFP	Whole Blood Finger Prick Test
IMNCI	Integrated Management of Childhood and Neonatal Illness		



1



Introduction



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).

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 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 sd NVP/Sy 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. 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 (NNRTIs). 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)<sup>1</sup> recommend two options:

1. Providing lifelong ART to all the pregnant and breastfeeding women living with HIV regardless of CD4 count or clinical stage 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.

<sup>1</sup>World Health Organization, Consolidated guidelines on the use of Antiretroviral drugs for treating and preventing HIV infection, Recommendations for a public health approach, June 2013.



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 maximising 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. These guidelines shall be implemented across the country from 1st January 2014.



PPTCT-Policy, Essential Package and Guiding Principles





## 2.1 The Goals of the PPTCT Programme

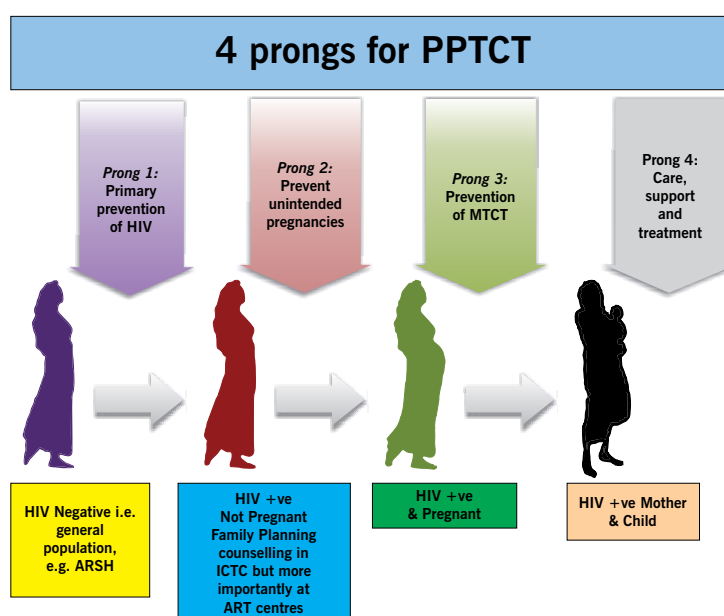
In line with WHO standards for a comprehensive strategy, the National PPTCT programme recognises the four elements integral to preventing HIV transmission among women and children. These are:

**Prong 1:** Primary prevention of HIV, especially among women of child bearing age.

**Prong 2:** Preventing unintended pregnancies among women living with HIV.

**Prong 3:** Prevent HIV transmission from pregnant women infected with HIV to their child.

**Prong 4:** Provide care, support and treatment to women living with HIV, her children and family in women in child bearing age.



The National PPTCT programme adopts a public health approach to provide these services to pregnant women and their children. This approach seeks to ensure equitable access to high-quality PPTCT services at the grass-root level while taking into account what is feasible on a large-scale within available health infrastructure, human and financial resources.

### Goals of National PPTCT Programme in India are:

1. Primary prevention of HIV, especially among women in child-bearing age.
2. Integration of PPTCT interventions with general health services such as basic Ante-natal Care (ANC), Natal and Post –Natal Services, Sexual Reproductive Health and Family Planning, EID, Paediatric ART and Adolescent Reproductive and Sexual Health (ARSH), TB and STI/RTI services.
3. Strengthening post-natal care of the HIV-infected mother and her exposed infant.
4. Provide the essential package of PPTCT services (see Figure 1 on next page).



## 2.2 The Essential Package of Services under the PPTCT Programme

The PPTCT services provide access to all pregnant women for HIV diagnostic, prevention, care and treatment services. As such, the key goal is to ensure the integrated PPTCT services delivery within existing Reproductive & Child Health (RCH) programme.

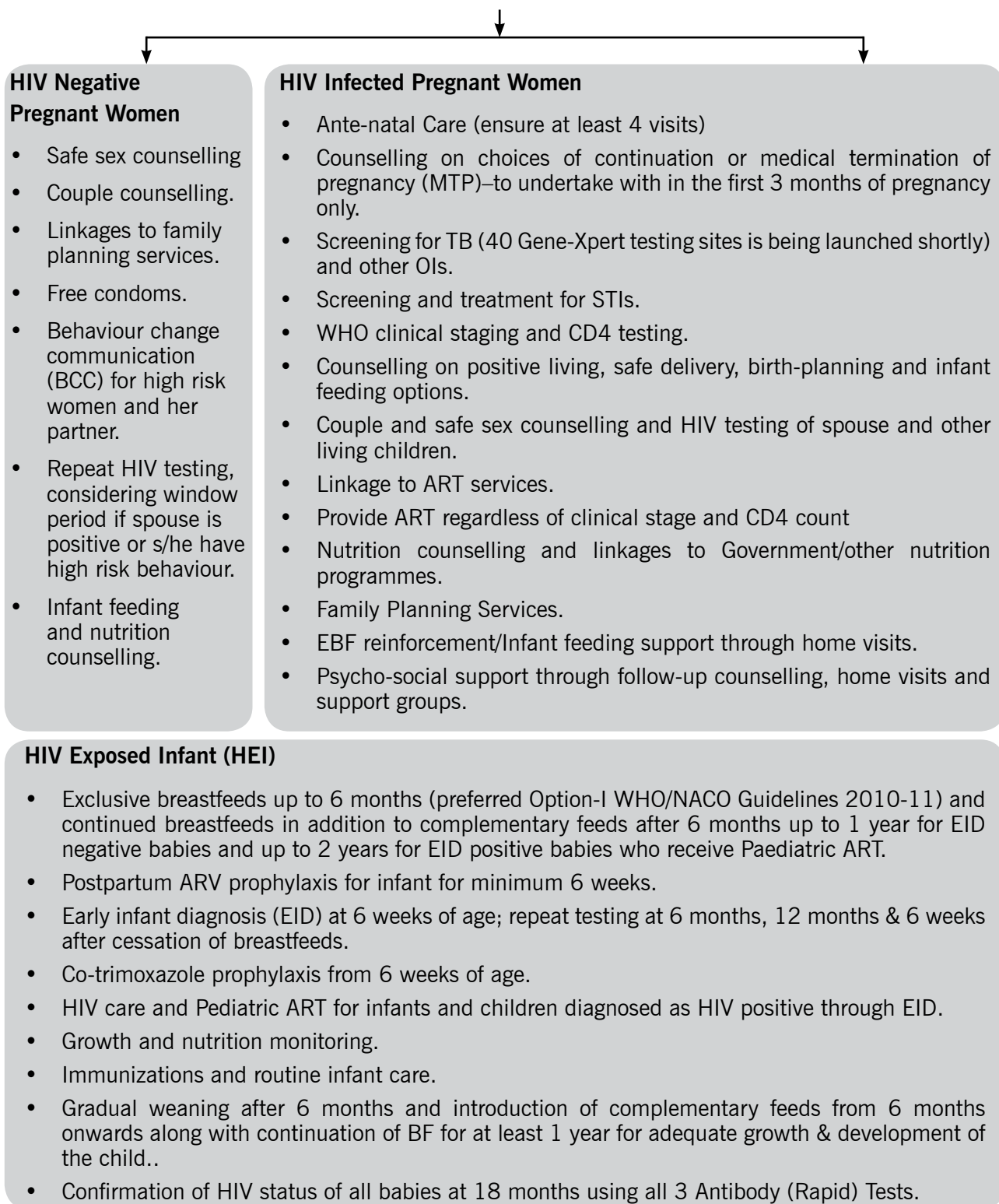
### The Essential Package of PPTCT Services includes:

- Routine offer of HIV counselling (Group/Individual counselling) and testing to all pregnant women attending ante-natal care, with 'opt out' option.
- Ensure involvement of spouse & other family members and move from an "ANC centric" to a "Family centric" approach.
- Provide ART to all HIV infected pregnant women regardless of WHO staging and CD4 count results. Preferred regimen is TDF+3TC+ EFV.
- Promote institutional delivery for all HIV infected pregnant women (ANMs/ASHAs, Community workers to accompany to institutions; reduction of stigma and discrimination amongst health care providers through sensitisation and capacity building).
- Provision of care for associated conditions (STI/RTI, TB & other Opportunistic Infections (OIs).
- Provide nutrition counselling and psychosocial support for HIV infected pregnant women (Linkages with ANM, ASHAs, Community outreach workers, DLNs to advise them on the right foods to take and to go to Anganwadi Centres for nutritional support and to the district level network of Positive People for peer counselling and psycho-social support).
- Provide counselling and support for initiation of exclusive breastfeeds within an hour of delivery as the preferred Option and continue for 6 months. After 6 months, complementary feeding should be given along with breastfeeds. A small number of babies born to HIV infected mothers who have serious illness or have died and a few reluctant mothers (who at their own risk despite counselling) may decide not to breastfeed but adopt exclusive replacement feeding (ERF).
- Provide antiretroviral prophylaxis to infants from birth up to a minimum period of 6 weeks.
- Integrate follow-up of HIV-exposed infants (HEIs) into routine healthcare services including immunization.
- Ensure initiation of Co-trimoxazole Prophylactic Therapy (CPT) and Early Infant Diagnosis (EID) using HIV DNA PCR at 6 weeks of age onwards as per the EID guidelines.
- Strengthen follow-up and outreach through ANMs, ASHAs and District level networks and other outreach workers to support HIV infected pregnant women and their family.

**Figure 1: Essential Package of PPTCT Services**



## Offer of HIV Counselling and Testing Services to all Pregnant Women



**Figure 2: Components of PPTCT Programme**



The first and foremost important step for all pregnant women attending health services is to know their HIV status as part of the routine ante natal screening blood tests. This has been clearly stated a directive jointly issued by both NRHM and NACO<sup>1</sup> (Annexure 1).

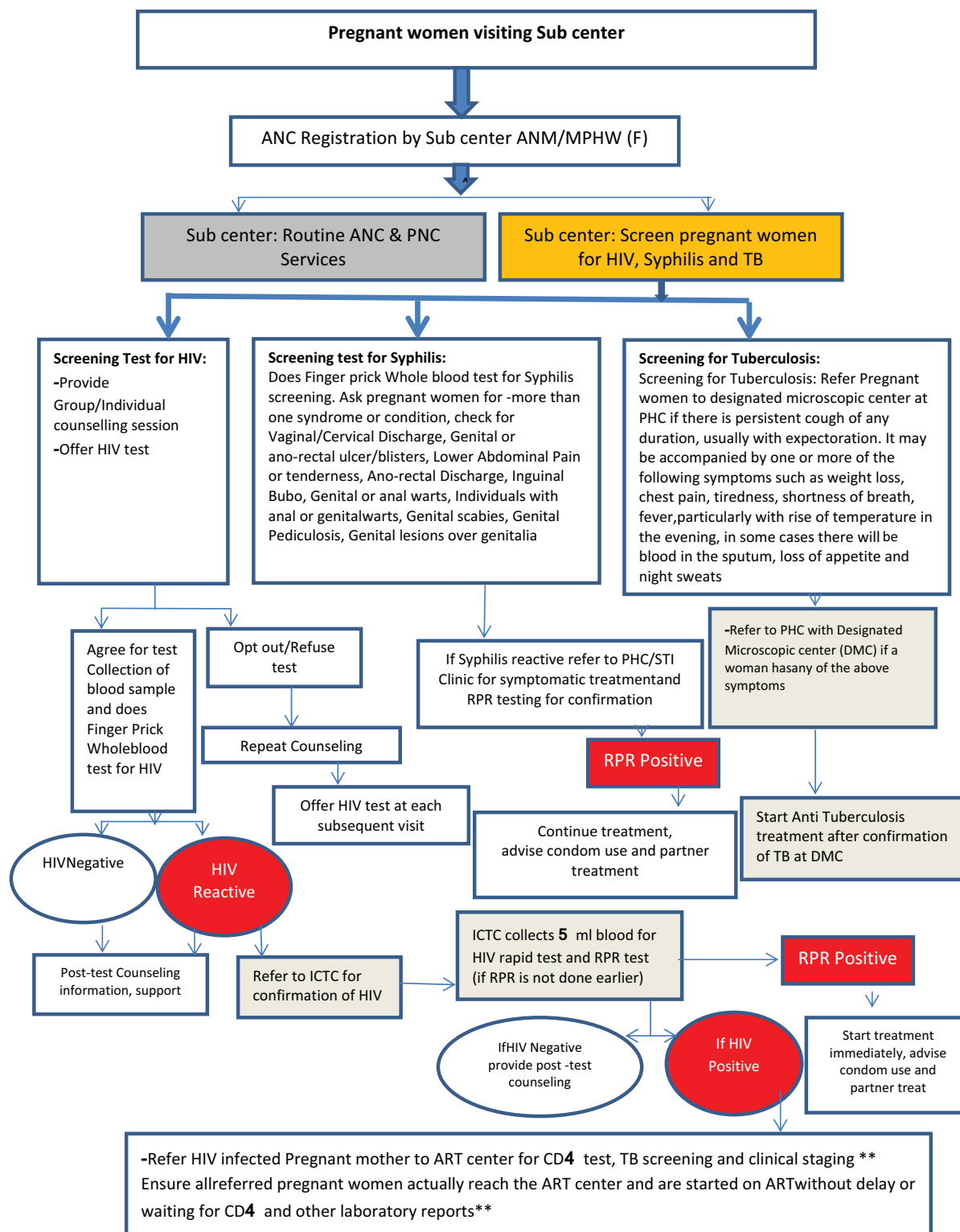
**Four typical scenarios where pregnant women may attend the counselling and testing services include:**

- Women attending ante natal clinics.
- Pregnant spouse of HIV-positive men, or those with high risk behaviour.
- Pregnant women screened at the Sub centre level by ANM/Nurse (whole blood finger prick test) & Confirmation at ICTC.
- Women presenting directly-in-labour (un-booked cases, require a HIV screening test before delivery).

## 2.3 General Principles

- Informed consent as per guidelines to be taken for all ANCs.
- Counselling to inform all pregnant women about the ante natal routine screening tests haemoglobin (Hb %), Urine albumin/sugar, VDRL/RPR, blood grouping & typing and the benefits of testing for HIV.
- Nurse/Counsellors to provide information on the ante natal screening comprehensive package including HIV testing through both individual counselling and group counselling information sessions.
- Pregnant Women who opt-out of HIV testing should be offered repeat counselling to explore the reasons for opting out, address any misunderstandings and encourage her to reconsider her decision. These women should be offered routine HIV testing at each subsequent clinic visit.
- Post-test counselling for all pregnant women is very important so as to educate those with negative tests to remain un-infected; while for those with confirmed HIV positive tests-further counselling, support and referrals to care & treatment services.
- Pregnant women who have been referred by ANMs after whole blood screening tests must undergo pre-test counselling and follow the usual HIV testing protocol similar to the regular ante natal cases at the stand-alone ICTCs for confirmatory tests.
- Disclosure of HIV status is to be done only at stand-alone ICTCs after appropriate confirmatory testing as per laboratory guidelines (post-test counselling) and only by trained health staff (MO, Nurse or Counsellor).
- All pregnant women referred to other HIV services including ART Centre, should be tracked to ensure that they actually reach the services, and have been registered at the respective centres.
- Partner/Spouse and family (other children) testing for HIV to be done as per ICTC guidelines.
- Partner (Husband) involvement during the pregnancy and thereafter. PPTCT interventions and FP methods to be encouraged e.g., couple counselling for mutual psycho-social support, mother to ART and baby to ARV, Family planning counselling etc.

<sup>1</sup>Guidelines for rolling out NACP and NRHM Convergence plan in the state. No X-19020/17/2009-NACP(IEC), 10 August 2010



**Figure 3: Services to Pregnant Women during Antenatal Period**



### 2.3.1 Sexually Transmitted Infections and Reproductive Tract Infections

Sexually transmitted infections and reproductive tract infections (STIs/RTIs) are important public health problems in India. Studies suggest that around 6 per cent of the adult population in India is infected with one or more STIs/RTIs. Individuals with STIs/RTIs have a significantly higher chance of acquiring and transmitting HIV. Moreover, STIs/RTIs are also known to cause infertility and reproductive morbidity. Controlling STIs/RTIs helps decrease HIV infection rates and provides a window of opportunity for counselling about HIV prevention and reproductive health.

The implementation framework of National Rural Health Mission (NRHM) provides the directions for synergizing the strategies for prevention, control and management for STI/ RTI services under Phase II of Reproductive and Child Health Programme (RCH II) and Phase III of National AIDS Control Programme (NACP III). While the RCH programme advocates a strong reference “to include STI/RTI and HIV/AIDS preventions, screening and management in maternal and child health services”, the NACP includes services for management of STIs and ART as a major programme strategy for prevention of HIV.

Syndromic Case Management (SCM) is the cornerstone of STI/RTI management, being a comprehensive approach for STI/RTI control endorsed by the World Health Organization (WHO). This approach classifies STI/RTI into syndromes, which are easily identifiable group of symptoms and signs and provides treatment for the most common organisms causing the syndrome. Treatment has been standardized as given in Table 1. SCM achieves high cure rates because it provides immediate treatment on the first visit at little or no laboratory cost. However, it goes hand-in-hand with other important components like counselling, partner treatment, condom promotion and referral for HIV testing.

**Table 1: Syndromic Management of STI/ RTIs**

Syndrome	Treatment	Colour-coded Kits for STI Treatment
Urethral Discharge (UD), Cervicitis (CD) Ano-rectal discharge (ARD) Painful Scrotal Swelling (PSS) Presumptive Treatment (PT)	Tab. Azithromycin 1 G (1) and Tab. Cefixime 400 mg (1)	Grey
Vaginitis (VD)	Tab. Secnidazole 2 g (1) and Tab. Fluconazole 150 mg (1)	Green
Genital Ulcer Disease- Non Herpetic (GUD-NH)	Inj. Benzathine penicillin 2.4 MU (1) and Tab. Azithromycin 1 G (1) and Disposable syringe 10 ml with 21 gauge needle (1) and Sterile water 10 ml (1)	White
Genital Ulcer Disease- Non Herpetic (GUD-NH)–for patients allergic to penicillin.	Tab. Doxycycline 100 mg (30) and Tab. Azithromycin 1 G (1)	Blue
Genital Ulcer Disease- Herpetic (GUD-H)	Tab. Acyclovir 400 mg (21)	Red
Lower Abdominal Pain (LAP/PID)	Tab. Cefixime 400 mg (1) and Tab. Metronidazole 400 mg (28) and Cap. Doxycycline 100 mg (28)	Yellow
Inguinal Bubo (IB)	Tab. Doxycycline 100 mg (42) and Tab. Azithromycin 1 G	Black



## STI/ RTI Service Package

The syndromic approach is the foundation of STI/RTI services at all facilities. Laboratory tests can be used wherever available. The minimum package of STI/RTI services (Table 2) to be provided at different facilities are tabulated below:

**Table 2: Level of Care Service Provider Modalities Package of Services**

Level of Care	Service Provider	Modalities	Package of Services
Village	ASHA/Link worker/ Health worker (M/F)	Through their outreach meetings and observance of village health and nutrition days	<ul style="list-style-type: none"> <li>Information</li> <li>Condom provision and promotion</li> <li>Screening for STI/RTI</li> <li>Referral for treatment</li> </ul>
Sub-centre	ANM/Health worker	Through ANC clinics, group meetings and household contacts	In addition to above, <ul style="list-style-type: none"> <li>Provide counselling</li> <li>Referral to ICTC</li> </ul>
PHC/Mobile Medical Unit/Dispensary/CHC/ Urban Health post/ Rural Hospital/Sub divisional Hospital	Medical Officer/ Staff Nurse/ LHV/Laboratory Technician	Routine OPDs, ANC Clinics/ Camps	In addition to above, <ul style="list-style-type: none"> <li>STI/RTI treatment through syndromic approach and partner management</li> <li>Simple diagnostic tests (including Syphilis screening)</li> <li>ARSH services</li> <li>Referral to ICTC</li> <li>Reporting to district RCH Officer</li> </ul>
District hospital, Medical College hospitals, select Rural Hospital/Sub divisional Hospital). "SURAKSHA CLINIC"	Medical Officer Staff nurse Counsellor, Laboratory Technician	STI/RTI clinic Gynaecology/ Obstetrics clinics ANC Clinics General OPD	<ul style="list-style-type: none"> <li>Syndromic case management of STI/ RTI (provision of directly observed treatment for single dose regimen)</li> <li>Minimal laboratory testing</li> <li>Counselling</li> <li>Condom Promotion</li> <li>Partner treatment</li> <li>Syphilis screening</li> <li>Referral to ICTC</li> <li>Linkage with other services</li> </ul>

## Pregnant Women and STI/ RTI Services

All pregnant women should be screened for syphilis. Syphilis is one of the easily treatable Sexually Transmitted Infection (STI/RTI) caused by *Treponema pallidum*, which can be transmitted to sexual partners as well as from infected pregnant woman to her new born child. Untreated syphilis is responsible for multisystem complications and other sickness among infected patients and may cause miscarriages, low birth weight and premature delivery in the pregnant woman. Many patients of syphilis



are asymptomatic and do not manifest any symptoms of the disease. The National STI/RTI prevention and control programme mandates a screening test to detect hidden syphilis among all pregnant women attending Antenatal Clinics. The Rapid Plasma Reagin test (RPR Test) or Venereal Diseases Laboratory Test (VDRL Test) are the most commonly used screening tests to detect syphilis. The programme recommends treatment of all RPR reactive patients.

### **Process of Screening ANC Women**

ANM at the village/subcentre level will do screening test for HIV and Syphilis using whole blood finger prick test.

If the Syphilis test is reactive then the pregnant woman would be referred to designated STI/RTI clinics or PHC with RPR testing availability for Syphilis confirmation.

If the HIV test is reactive then the pregnant woman will be referred to stand alone ICTC for confirmation of HIV by rapid tests. The patient then undergoes pre-test counselling at the ICTC by the ICTC counsellor. The ICTC collects 5 ml blood for HIV rapid tests and RPR test.

After HIV and RPR testing, the patient returns to the ICTC counsellor for post test counselling. During post-test counselling the ICTC counsellor provides the HIV and syphilis test report and counsels the patient to go to the STI/RTI clinic for further follow-up and advice from the STI/RTI counsellor and Medical officer for treatment if required.

### **2.3.2 HIV-TB Collaborative Activities**

Tuberculosis (TB) is responsible for about 25% of all deaths among HIV infected individuals. The risk of active TB is approximately 10 times higher in HIV-infected pregnant women compared to HIV uninfected women. Active TB in HIV-infected pregnant women can contribute to increased risk of maternal mortality, and is also associated with prematurity, low birth weight, and perinatal tuberculosis among infants. A recent study in India found that maternal TB increases the risk of HIV transmission from mother -to child by 2.5 times. The key TB prevention interventions recommended by World Health Organization at HIV care settings include airborne infection control at HIV care settings and Isoniazid Preventive Therapy (IPT). NACP is currently implementing airborne infection control measures like fast tracking of cough symptomatic patients, promotion of cough hygiene etc. at ART centres. Further, the National Technical Working Group (NTWG) on TB-HIV collaboration, at NACO endorsed IPT as a strategy and recommended its implementation at all ART centres in the country. This activity is planned for roll-out in 2014-15.

Along with TB prevention, early detection and treatment of HIV-TB are also important for reducing mortality. The NACP and Revised National TB Control Programme (RNTCP) implement various activities jointly to ensure early detection and treatment. These include:





### **Activities for Early Detection of HIV Associated TB**

- HIV testing of presumptive TB cases
- HIV testing of diagnosed TB patients
- Intensified TB case finding (ICF) at ICTC
- ICF at ART centres

### **Activities to Ensure Early Treatment of HIV**

- Linkage of HIV-TB cases to ART
- Initiation of HIV-TB cases on ART

HIV testing of presumptive TB cases: Detection of HIV by offering HIV tests to diagnosed TB patients is being implemented by NACP and RNTCP jointly since

2007-08. NACP and RNTCP decided to offer HIV test upstream during evaluation of patients for TB when they present with TB symptoms. This activity is expected to expedite detection of HIV by 2-4 weeks, leading to early linkage to treatment and hence reduction in mortality.

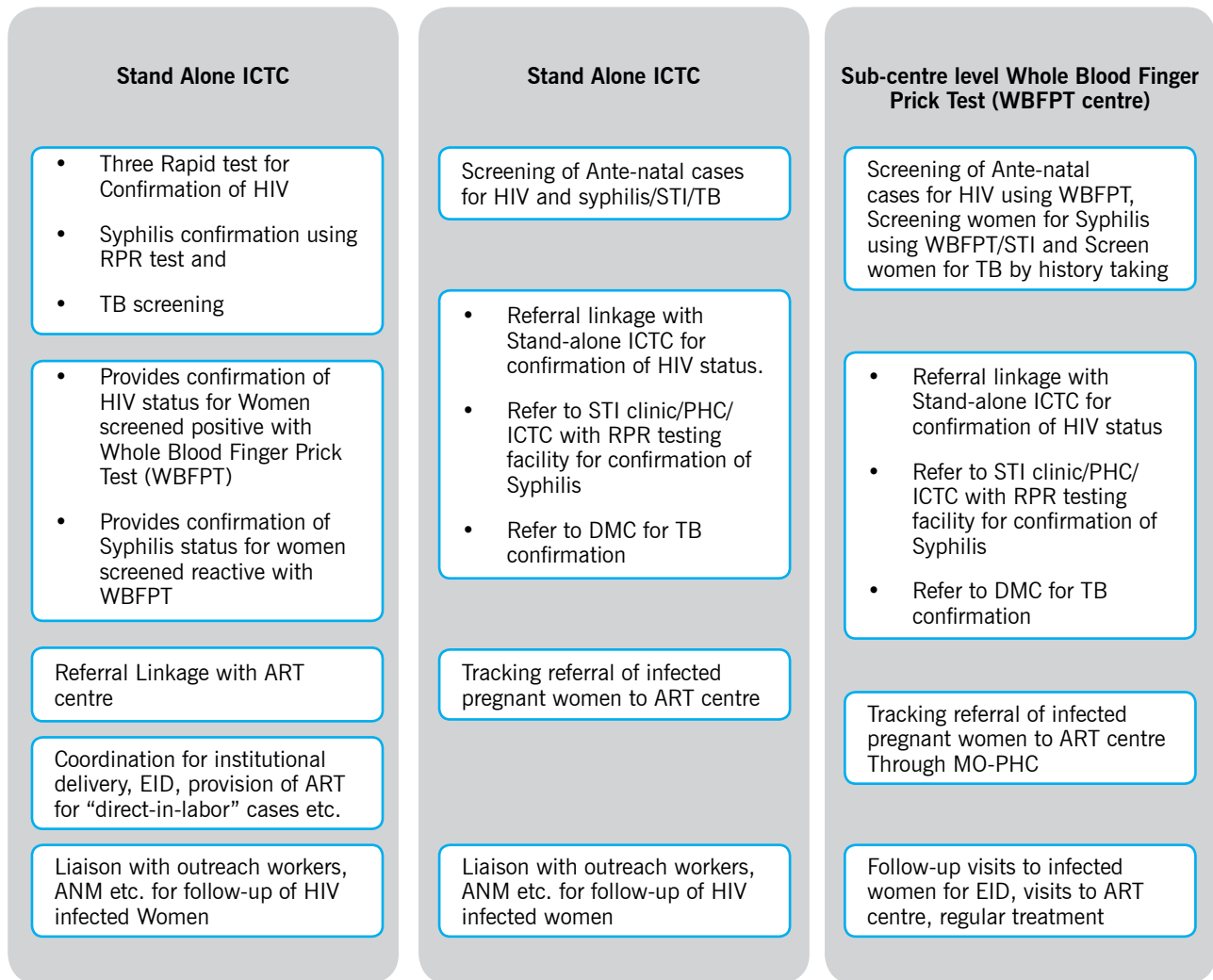
Intensified TB case finding at ART centres: ICF at ART centres is implemented since 2010 and it is now implemented at all ART centres, Link ART centres and Link ART plus centres. Gene-Xpert testing is being proposed by the TB programme in 40 sites soon for early screening and testing for TB.

### **Process of Screening ANC Women**

Women registered for ANC care would be screened for TB along with HIV and Syphilis by ANMs at sub centre level.

ANM checks for TB symptoms (Refer Pregnant women to designated microscopic centre (DMC) at PHC if there is a persistent cough of any duration. It may be accompanied by one or more of the following symptoms such as weight loss, chest pain, tiredness, shortness of breath, fever, particularly rise of temperature in the evening, in some cases there can be blood in the sputum, loss of appetite and night sweats).

Refer all HIV positive pregnant women to RNTCP for TB diagnosis and treatment at the earliest.



**Figure 4: PPTCT Services for Pregnant Women at Different Levels**

## 2.4 Guiding Principles for Use of ART in PPTCT

The guiding principles for the use of ART to prevent HIV transmission from mother-to-child are:

- HIV infected pregnant women, in need of ART for their own health should receive life-long ART
- Postpartum ART initiation to mother and ARV 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”.

In India, the PPTCT programme has been in place for many years, and recommended ARV prophylaxis was sd of Tab Nevirapine (200mg) to mother during labour and single dose of Sy Nevirapine to the infant at birth.

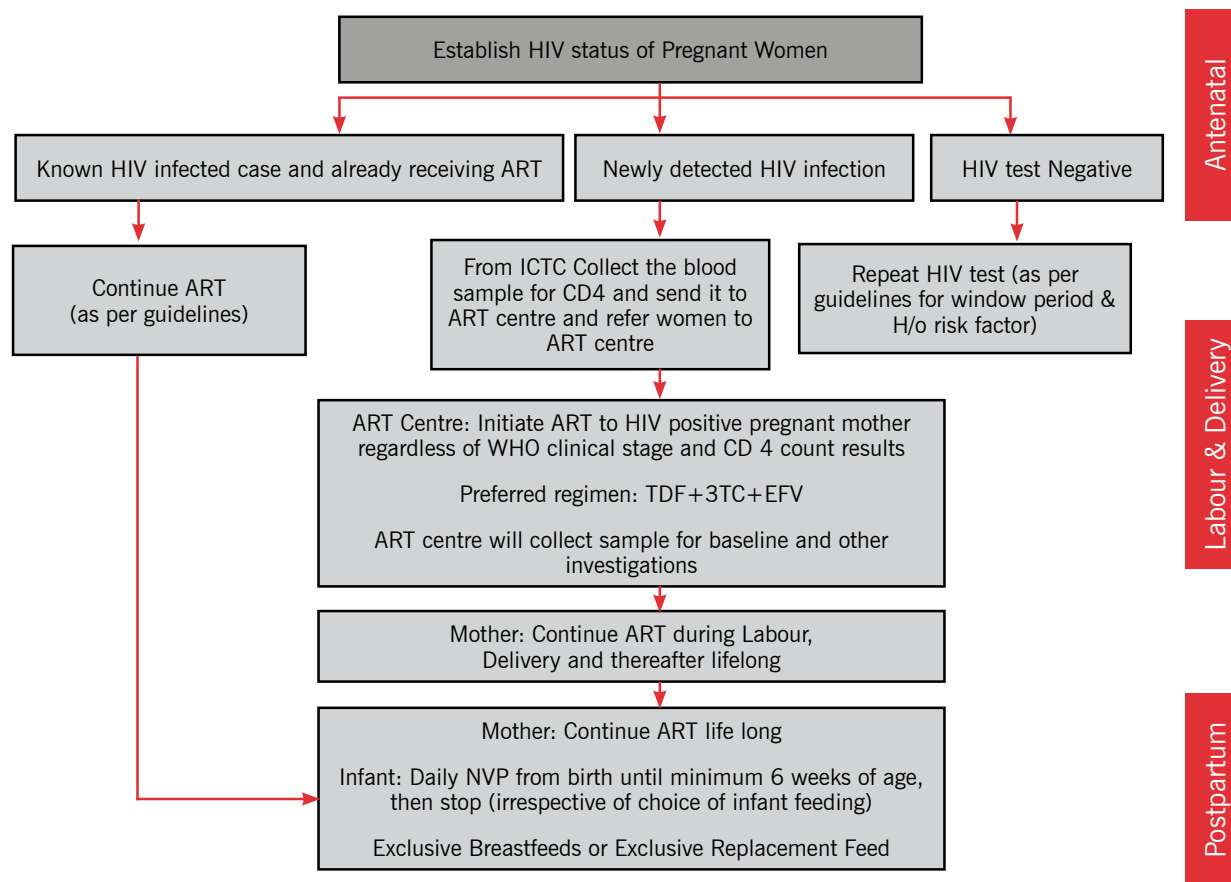


However, with evolving evidence, the National technical guidelines have been revised and, it is recommended that:

1. All HIV infected pregnant women should be initiated on life-long ART (on triple ART) regardless of WHO clinical stage or CD4 cell count.
2. HIV infected pregnant women should preferably be initiated on ART at ART centre and should not be delayed for want of CD4 cell count report.

The summary of the technical guidelines Multi Drug Anti-retroviral Regimen for PPTCT is provided in Figure 5.

Care for the HIV-infected pregnant women begins on the first contact with health services during the ante natal period. Establishing a relationship or a rapport with the HIV infected pregnant woman is fundamental in providing a continuum of care involving prevention, care, support, and treatment for the mother and child. This requires the involvement of the clinical and para-medical team at the health facility – the Obstetricians, Paediatricians, Physicians, Medical Officers, Nurses, ANMs, ASHAs, Lab Technicians, Counsellors and Outreach Workers. District Level Positive Networks, Local Community Based Organizations and Self-Help Groups (SHGs) should help support the HIV infected mother and her family.



**Figure 5: The Summary of the Technical Guidelines and Options for the More Efficacious PPTCT Regimen**



PPTCT Services under NACP



### 3.1 Existing Facilities

Under the National AIDS Control Programme, various HIV related services are provided through public and private health care providers depending on the programme need and the availability of health infrastructure, human resource and their expertise.

**The PPTCT services are provided through the Integrated Counselling and Testing Centres (ICTCs) which are of the following types:**

1. **Stand-Alone ICTCs:** These are HIV counselling and testing facilities supported by NACP in the form of staff (Counsellor & Lab Tech) and necessary logistic support. These centres perform confirmatory tests for HIV. Typically these centres are located in Medical Colleges, District Hospitals, Taluk Hospitals and Community Health Centres.
2. **Facility-Integrated ICTCs (F-ICTCs):** These are facilities where the staff – (Staff Nurses and Lab Technicians) from existing health facilities are trained in counselling and testing, and service delivery is ensured with provision of HIV test kits from the NACP though it would be best to be purchased from NRHM budget. The centres perform only screening tests for HIV using Whole Blood Finger Prick test kits and any client found positive on screening is referred to a stand-alone ICTC for confirmation. Typically, these centres are located at PHCs. The private/NGO facilities also function under this model.
3. **Screening Centres:** These are health facilities where the Auxillary Nurse Midwives (ANMs; now called Jr. Health Assistant (F)) at existing health facilities are trained in counselling and screening for HIV by whole blood finger prick test. These centres perform only screening test for HIV through whole blood finger prick test (WBFPT) and any client found reactive through this screening test is referred to Stand-Alone ICTCs for confirmation. Typically, these centres are located at PHCs and Sub Centres.

The 5 tier structure of public health system and HIV related services at different levels is detailed below in the Table 3:

**Table 3: HIV Services at Different Level of Health Facilities**

Level of Health Infrastructure	Available HIV Facilities	Available HIV Services
Medical College	Stand -Alone ICTC, ART Centre Centre of Excellence (CoE) in HIV care Paediatric Centre of Excellence (pCoE)	ICTC, PPTCT, HIV-TB, ART including Paed. ART, OI, STI, EID
District Hospital	Stand- Alone ICTC, ART Centre Link ART Centre, Blood Bank	ICTC, PPTCT, HIV-TB, ART, OI, STI, EID services, Linkages to DLNs/ DIC for psycho-social support and services
Sub-district/Community Health Centre	Stand- Alone ICTC, Facility-ICTC ART/ Link -ART Centre Blood storage centre	ICTC / HIV Screening, PPTCT, HIV- TB, ART, OI, STI, DIC, EID Services
Primary Health Centres/ 24x7 PHCs	Stand-Alone ICTCs Facility integrated ICTCs	HIV Screening, PPTCT, HIV-TB, STI
Sub-Centres	Screening Centre (Whole Blood Finger Prick Test)	HIV Screening Test

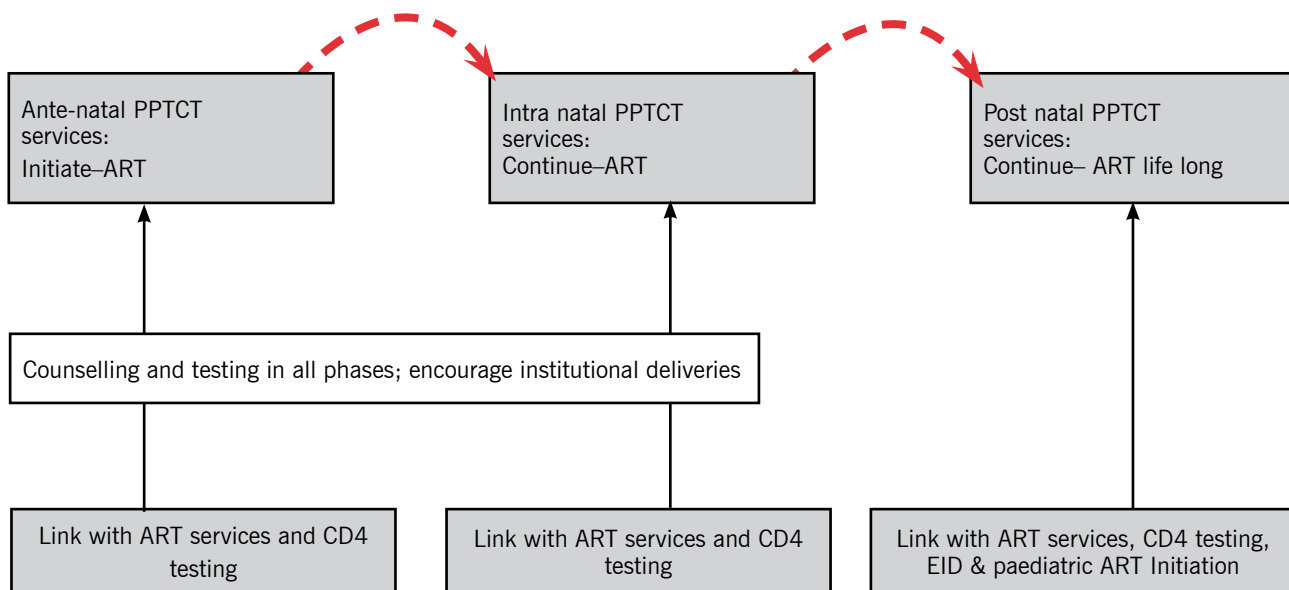


## 3.2. Continuum of care under PPTCT

With the revision of PPTCT guidelines that recommend use of the more efficacious Multi Drug ART regimen, it is important to consider Prong-3 of National PPTCT programme as a continuum of interventions rather than a one-time activity (Fig 6). This requires close coordination between various implementing components for PPTCT-ART linkage, Early Infant Diagnosis (EID), Paediatric ART services etc.

### **The continuum of care involves the following steps:**

1. Increasing uptake of PPTCT services by pregnant women.
2. Counselling and Testing of pregnant women as an integral part of ANC Comprehensive Services package.
3. Detection of HIV infected pregnant women.
4. Linking HIV infected pregnant women to Care, Support and Treatment services.
5. Initiating ART for all HIV infected pregnant women regardless of CD4 count, starting it as soon as diagnosed and continued for life. However, make sure to obtain samples for CD4 cell count and baseline tests at the time of initiating ART or soon after initiating ART.
6. Counselling on birth-planning and institutional deliveries of identified HIV infected pregnant women.
7. Screening emergency labour room deliveries (un-booked cases) for HIV. If HIV positive, providing ART and obtaining sample for CD4 cell count as soon as possible.
8. Linking of HIV infected pregnant women identified through emergency labour-room care services to Care, Support and Treatment services.
9. Provision of Syrup Nevirapine for the new born infant from birth till 6 weeks of age (minimum). At the end of 6 weeks, CPT should be initiated and baby to be linked to the EID programme. CPT continued to baby from 6 weeks up to 18 months or until the confirmatory test of the baby is done using all three Rapid Antibody Tests. If baby is confirmed positive, then CPT will be continued.
10. If the infant is detected positive in EID programme (DBS+WBS tests are positive), then ensure initiation of Pediatric ART for the baby through ART centre as per ART guidelines as soon as possible.
11. Follow-up of HIV infected mother and baby until breastfeeding period is over.
12. At six weeks of age of baby, do DBS test and confirm with WBS test. If the age of baby is more than 6 months, then do antibody (rapid) test first, if found positive then only DBS sample should be sent. If DBS comes positive then do a WBS test. If WBS is positive, start Paediatric ART as soon as possible.
13. Confirmation of diagnosis of child using 3 anti-body tests (Rapid) at ICTCs at 18 months of age.



**Figure 6: PRONG 3: Continuum of Care for HIV Infected Pregnant Women**



Care and Assessment of HIV Infected Pregnant Women





## 4.1 Care during the Antenatal Period

HIV infected pregnant women may present to ICTCs and ART centres at various stages of pregnancy (Refer to Table 4).

- Pregnant Women who are detected to be HIV infected during ante natal care should be initiated on ART (TDF+3TC+EFV) regardless of clinical stage or CD4 count. However, it is important to obtain sample of blood for CD4 count and for baseline tests before initiating ART. The initiation of ART should not be delayed for want of CD4 test results.
- Pregnant women who are detected to be HIV infected by screening test (by one test kit) during active labour should be initiated on ART but should be referred for confirmation of HIV status at the earliest and linked to ART centre, if confirmed positive.
- The table below (Table 4) provides summary of maternal ART (life long) and infant ARV prophylaxis for different clinical scenarios.

**Table 4: Summary of Maternal ART (Life Long) and Infant ARV Prophylaxis for Different Clinical Scenarios**

Scenarios	Different Clinical Scenarios	Maternal ART	Infant ARV prophylaxis	Duration of Infant ARV prophylaxis
Scenario 1	Mother diagnosed with HIV during pregnancy	Initiate maternal ART	NVP	6 weeks
Scenario 2	Mother diagnosed with HIV during labour or immediately postpartum and plans to breastfeed	Initiate maternal ART	NVP	Extending NVP prophylaxis to 12 weeks
Scenario 3	Mother diagnosed with HIV during labour or immediately postpartum and plans Exclusive Replacement feeding(ERF)	Refer mother for HIV care and evaluation for treatment	NVP	6 weeks
Scenario 4	Infant identified as HIV exposed after birth (through infant (at 6 weeks or after) or maternal HIV antibody testing)) and is breastfeeding	Initiate maternal ART	NVP	Perform infant DNA/PCR test if child is 6 weeks old or older Immediately initiate 6 weeks or longer of NVP– strongly consider extending this to 12 weeks
Scenario 5	Infant identified as HIV exposed after birth (through infant or maternal HIV antibody testing) and is not breastfeeding	Refer mother to ART Centre after CD4 tests and baseline test and treatment	No NVP (No drugs)	Do HIV DNA/PCR test in accordance with national recommendations on early infant diagnosis; no infant ARV prophylaxis; initiate treatment if the infant is infected
Scenario 6	Mother receiving ART but interrupts ART regimen while breastfeeding (such as toxicity, stock-outs or refusal to continue)	Determine an alternative ART regimen or solution; counsel regarding continuing ART without interruption	NVP	Until 6 weeks after maternal ART is restarted or until 1 week after breastfeeding has ended



HIV infected pregnant women require joint management from both the HIV care team (for her HIV condition) and the Obstetric team (for successful outcomes of pregnancy). HIV infected pregnant women require all components of good antenatal care, including iron-folate supplementation, anaemia management, baseline CD4 count, screening of TB, prevention and management of OIs, STI treatment, special Obstetric practices especially during labour and delivery, ART initiation and its continuation, counselling for infant feeding options, post natal care, follow-up, family planning and contraception. Postpartum care and follow-up for the well-being of mother and infant, as well as adherence to ART and other care, to prevent HIV transmission during breastfeeding is important.



### Box 1

#### **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)

## 4.2 Initial assessment

**All HIV infected pregnant women should have routine ante natal care for the well-being of her baby including:**

- At least 4 ANC check-ups during pregnancy (registration and 1st check-up within 12 weeks, 2nd between 14-26 weeks, 3rd between 28-32 weeks and 4th between 36-40 weeks) as per RCH/ NACP guidelines.
- History, physical and abdominal examination.
- Antenatal routine blood screening:
  - Hb, blood group & Rh typing, urine routine at 1st visit; including tests for syphilis, Hepatitis 'B' and HIV.
  - Urine routine to be done at all visits, and Hb% to be re-checked at the 3rd visit at 28-32 weeks gestation.
- 2 Doses of Tetanus Toxoid (TT) to prevent maternal and newborn tetanus:
  - First dose: at ANC registration.
  - Second dose: 4-6 weeks after the first dose, preferably at least one month before the expected date of delivery (EDD).
- Antenatal drug supplementation:
  - IFA tablet (100mg iron + 0.5 mg folic acid) daily for 100 days, after 1st trimester to prevent anaemia.
  - Double the dose if anaemia persists.



Counselling on nutrition, rest, warning signs, ART linkages-CD4 testing if HIV positive and ART, birth planning, institutional delivery, exclusive breastfeeding within an hour of delivery, safe sex, HIV-specific advice and contraception.

**From the HIV care aspect for pregnant women, the initial assessment follows standard adult ART guidelines including:**

- WHO clinical staging.
- Clinical screening for TB and STI symptoms: Screen for TB at each visit: Intensified Case Finding (ICF) as per TB-HIV guidelines for screening TB in all HIV-infected individuals.
  - Clinical screening—ask for cough (of any duration), cough with blood in sputum, unexplained fever or weight loss, fatigue, night sweats, loss of appetite, pleuritic chest pain; glands/nodes in neck, armpits/axilla or groin.
  - The normal weight gain in a normal pregnancy is around 11 kg. Most of it occurs in the second and third trimester (approximately 5 kg in each trimester), while the first trimester is usually 1-2 kg. The weight gain patterns should be co-related clinically and other factors like twin pregnancy, hyperemesis gravidarum during the first trimester etc. A failure to gain weight should arouse the suspicion for further evaluation. Weight loss during pregnancy requires detailed assessment, because it can be a sign of underlying Opportunistic Infections (OIs) in HIV infected individuals.
- Screen and treat any STIs: any concurrent STIs may increase the risk of HIV transmission from mother-to-child, and may adversely affect the pregnancy. Treat STIs according to the national guidelines. Baseline laboratory investigations as per national adult guidelines.
- CD4 cell count (baseline):
  - Women who do not return for results should be actively traced back and brought to the continuum of care through the help of grass-root level health functionaries – ANMs/ASHAs/Community health workers.
- Initiate adherence counselling (antiretroviral treatment for mother and ARV prophylaxis for infant) and it is re-emphasized that the initiation of ART for the pregnant women should not be withheld for want of the above laboratory investigations and clinical staging. Initiate Co-trimoxazole Prophylactic Therapy (CPT) if  $CD4 \leq 250$  cells/mm<sup>3</sup>.
- Nutritional counselling for the mother: good food, rest and exercise.
- Adherence to iron-folate and vitamin/mineral supplements.
- Counsel for regular ante natal check-up and institutional delivery.
- Counsel for exclusive breastfeeding within an hour of delivery.
- No MIXED FEEDING (No breast feeding and other milk feeds during the first 6 months) under any circumstances.



### 4.3 Criteria for ART Initiation

Initiation of ART in pregnant women needs to be done at the earliest and after adequate treatment preparedness for adherence to maintain her own health and also to prevent HIV virus transmission to the unborn baby.

**In HIV infected pregnant women the dictum should be “do not delay ART initiation”. The eligibility criteria for initiating ART in HIV positive pregnant women are as below:**



#### Box 2

##### 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

### 4.4 Indications for Co-trimoxazole Prophylactic Therapy (CPT) in Pregnancy

The indications for co-trimoxazole initiation in pregnant women are same as those for other adults ( $CD4 \leq 250$  cells/cmm). Co-trimoxazole prophylaxis is helpful in reducing morbidity and mortality as it prevents Opportunistic Infections (OIs) such as Pneumocystis jiroveci pneumonia (PCP), toxoplasmosis, diarrhoea as well as other bacterial infections.



#### Box 3

##### Starting Co-trimoxazole in pregnancy

- Co-trimoxazole should be started if CD4 count is  $\leq 250$  cells/mm<sup>3</sup> 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.



5



ART for HIV Infected Pregnant Women



All HIV infected pregnant women (irrespective of CD4 count/Clinical stage) should receive lifelong ART.

**This treatment serves two key purposes:**

1. Improves health and prolongs survival of the mother.
2. Reduces the risk of HIV transmission from mother-to-child during pregnancy, labour, delivery, and throughout the breastfeeding period.

## 5.1 HIV Infected Pregnant Women being Newly Initiated on ART

HIV-infected pregnant women who are initiated on ART should be referred for routine baseline clinical and laboratory evaluation as per national guidelines for adults and adolescents. The absence or delay of laboratory investigations should not prevent the initiation of ART.



**Box 4** All HIV infected pregnant women should be seen on a priority in the ART Centre.

## 5.2 Principles of management

### 5.2.1 All HIV-infected Pregnant Women should Start ART

- Start ART as soon as possible and continue ART throughout pregnancy, delivery, breast feeding period and thereafter lifelong.
- Even if the pregnant women presents very late in pregnancy (including those who present after 36 weeks of gestation), ART should be initiated promptly.

### 5.2.2 Choice of ART Regimen for HIV-infected Pregnant Women

There are several regimens recommended for use as first-line ART regimen for adults in India. However, in case of HIV infected pregnant women requiring ART, the recommended first-line regimen is Tenofovir (TDF) (300 mgs) + Lamuvidine (3TC) (300 mg) + Efavirenz (EFV) (600 mg).



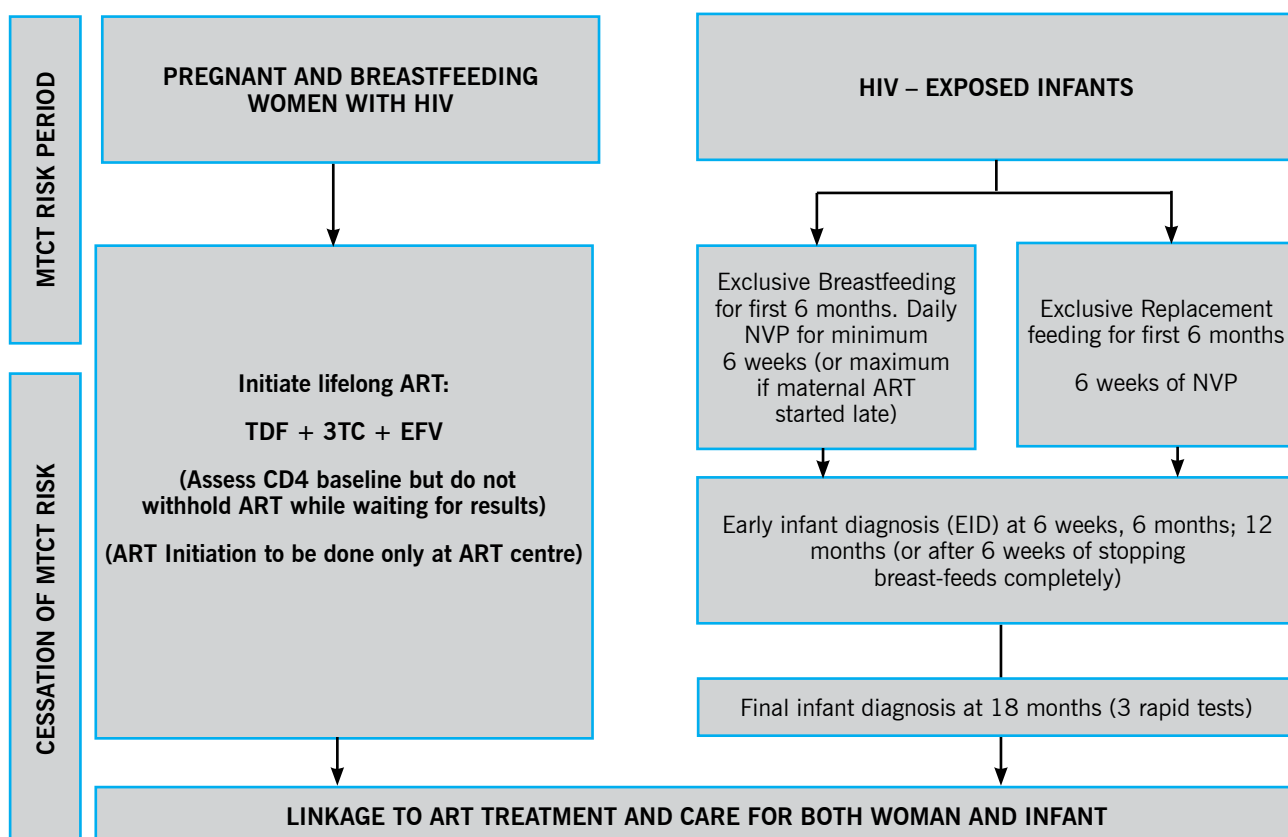
**Box 5** The recommended first-line regimen for HIV infected Pregnant Women is Tenofovir (TDF) (300 mg) + Lamuvidine (3TC) (300 mg) + Efavirenz (EFV) (600 mg) (if there is no prior exposure to NNRTIs (NVP/EFV) at any gestational age



### First line ART for pregnant and breastfeeding women and ARV drugs for their infants

- A once-daily fixed-dose combination of 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.
- Infants of mothers who are receiving ART and are exclusively breastfeeding or doing exclusive replacement feeding should receive atleast six weeks of infant prophylaxis with daily Syp Nevirapine. Infant prophylaxis should begin at birth or when HIV exposure is known.

The recommended first-line regimen for pregnant and breastfeeding women, is available as a fixed dose combination (FDC), is safe for both pregnant and breastfeeding women and their infants, is well tolerated, has low monitoring requirements, is compatible with other drugs used in clinical care, and is harmonised with the new recommendations for non-pregnant women as well as for men. The algorithm for ART for pregnant women and their infants is described in Figure 7 below



**Figure 7: Algorithms for the 2013 Recommendations for Pregnant and Breastfeeding Women Lifelong ART for all Pregnant and Breastfeeding Women with HIV**



The alternate regimen if the pregnant women are unable to tolerate preferred first-line regimen are as below:

First-Line ART for	Preferred First-line Regimen	Alternate First-line Regimens
HIV positive pregnant women	TDF + 3TC+ EFV	AZT+ 3TC+EFV AZT+3TC+NVP TDF+ 3TC+NVP

### 5.2.3 Safety of Efavirenz (EFV) in Pregnant Women

Safety is a critical issue for pregnant and breastfeeding women and infants as well as women who might become pregnant. Although data on EFV and TDF use in pregnant women remain limited, more data have become available since 2010 and provide increased assurance for recommending TDF+3TC+EFV as the first-line ART regimen for pregnant and breastfeeding women (Ford. N *et. al*, 2011, Ekouevi DK *et.al* 2011, Use of Efavirenz during pregnancy: a public health perspective, Technical update on treatment optimisation, Geneva, World Health Organization, 2012). Based on evidence available, EFV has been recommended for use in pregnant women in all trimesters of pregnancy including first trimester.

## 5.3 ART Regimen for Pregnant Women having Prior Exposure to NNRTIs for PPTCT

HIV infected pregnant women who have had previous exposure to Sd NVP (or EFV) for PPTCT prophylaxis in prior pregnancies, an NNRTI-based ART regimen such as TDF+3TC+EFV may not be fully effective due to persistence of archived mutation to NNRTIs. Thus, these women will require a protease-inhibitor based ART regimen viz:

TDF + 3TC + LPV/r (Lopinavir/ritonavir)

The dose will be TDF+3TC (1tabletdaily)+ LPV (200mg)/r (50mg) (2 tablets BD)

## 5.4 Pregnant Women Already Receiving ART

Pregnant women who are already receiving ART for their own health, should continue to receive the same regimen throughout pregnancy, labour, breast-feeding period and thereafter life-long. If a woman is on an EFV based regimen, there is no need to substitute with nevirapine (this was done as per earlier guidelines). She must continue on whatever regimen she is stabilized on and is responding to adequately.





## 5.5 Clinical and Laboratory Monitoring of Pregnant Women Receiving ART

Clinical and laboratory monitoring of HIV infected pregnant women on ART should be done as per national ART guidelines for adults and adolescents.

Key points to be noted in pregnant women in monitoring ART in pregnant women are:

- Look for clinically significant anaemia among HIV-infected pregnant women, since anaemia during pregnancy is common (usually developing around 28-34 weeks of gestation).
- WHO clinical staging will help in monitoring the patient clinically, potential disease progression or treatment failure.
- Weight loss is one of the indicators used to determine deteriorating clinical stage, but this can be difficult to assess during pregnancy. When defining the clinical stage of a pregnant woman, it is necessary to take into consideration her expected weight gain in relation to the gestational age of the pregnancy and her potential weight loss from HIV (see section 5.1).
- ART-related side-effects may overlap with that of common pregnancy conditions eg. nausea and vomiting. Minor symptoms should be controlled symptomatically with medicines. Consult the Obstetrician for drugs that are safe for use in pregnancy.
- Due to pregnancy-related haemo-dilution, absolute CD4 cell count decreases during pregnancy. After delivery, body fluid changes normalise to the non-pregnant state, and CD4 levels may rise by 50-100 cells/ul. Therefore, a decrease in absolute CD4 count in a pregnant woman receiving ART in comparison to CD4 values prior to pregnancy may not necessarily indicate immunologic decline and should be interpreted with caution (ref to SACEP in case of any doubt).

The recommended clinical and laboratory follow-up schedule for pregnant women is similar to that recommended for non-pregnant adults, and is detailed in Table 5. Additional assessments of hemoglobin or Liver Function Tests (LFT), Renal Function Tests (RFT) should be performed when warranted by clinical signs & symptoms.

HIV care and follow-up of pregnant women should be scheduled to coincide with their antenatal visits, as far as possible. Document all investigation results in the RCH/MCH card (Antenatal & Child) also, so that the Obstetric team is aware of test results. Inform patient to ensure that other health care providers in the team eg. Obstetricians & their support staff are updated on the progress of their HIV care.

After 6 months of pregnancy, in case a pregnant woman is unable to go to the ART centre, the ART drugs can be given to an authorised member of her family. The drug dispensing to an authorised member can continue for 2 more months after delivery. ( Refer Annexure-17)



**Table 5: Recommended Clinical and Laboratory Follow-up of Pregnant Women Receiving ART**

Assessment	Baseline	2 Weeks	4 Weeks	8 Weeks	12 Weeks	Every 6 Months	Comment
Clinical evaluation	✓	✓	✓	✓	✓	✓	Every month
Adherence counselling	✓	✓	✓	✓	✓	✓	Every month
Weight	✓	✓	✓	✓	✓	✓	Every month
*Haemoglobin	✓	✓	✓	✓	✓	✓	Re-check at 28-32 weeks
ALT (LFT)	✓	✓	X	X	X	✓	As and when required clinically
Urinalysis*	✓					✓**	**Specifically for TDF-based regimen. Urinalysis dipsticks is routinely done in follow-up
CD 4 count	✓	Thereafter every 6 months as per guidelines					
Blood Urea / Sr. Creatinine	✓					✓	
Blood Grouping and Typing	✓						
HBV, HCV screening	✓						Screening should be performed in States where ANCs are being tested routinely or based on the risk profile (e.g. IDUs, through blood transfusion)
RPR/ VDRL*	✓						
Blood Sugar*	✓						Repeat every 6 months if started on LPV/r based regimen
Lipid profile	✓						

\* Normally part of standard ante-natal routine screening.

A baseline Blood urea and serum creatinine should be undertaken before starting Tenofovir based regimen, wherever available (ART should not be withheld in pregnant women for want of these baseline investigations that could be carried out over time, as soon as possible).

Lipid profile and Blood Sugar at baseline, 6 months and one year, if started on LPV/r based regimen.

**Table 6: Dosage Schedule and Common Side-Effects with ART Drugs**

	Name of ARV	Dose	Major side-effects
1	Tenofovir Disoproxil Fumarate (TDF)	300mg Once Daily	Nephrotoxicity, Hypophosphatemia
2	Lamivudine (3TC)	300mg Once Daily	Very few side effects: Hypersensitivity, rarely Pancreatitis
3	Efavirenz (EFV)	600 mg Once Daily	Neuro-psychiatric symptoms like hallucinations, suicidal ideations, nightmares, vivid dreams etc
4	Lopinavir/Ritonavir (LPV/r)	400/100 mg Twice Daily (Dose of FDC tablet of LPV(200mg)/r (50mg) – 2 tabs BD)	Gastro-intestinal disturbances, glucose intolerance, Lipo-dystrophy and hyperlipidemia



## 5.6 ARV Prophylaxis for Infants Born to Mothers Receiving Life-long ART

Infant ARV prophylaxis is required for all infants born to HIV infected women receiving ART to further reduce pre-partum and postpartum HIV transmission, in addition to the protection received from the mother's ART regimen. Infant ARV prophylaxis provides added protection from early postpartum transmission, particularly in situations where women started ART late in pregnancy, have less than optimal adherence to ART and have not achieved full HIV viral suppression.

The infant ARV prophylaxis where mothers are receiving ART is: Daily NVP for 6 weeks (i.e. till the first immunization visit for the infant), regardless of whether the infant is exclusively breastfed or receives exclusive replacement feeding.

Dose and duration of infant daily NVP prophylaxis is given below in Table 7.

**Table 7: Dose and Duration of Infant Daily NVP Prophylaxis**

*(based on WHO Guidelines)*

Birth Weight	NVP daily dose (in mg)	NVP daily dose (in ml)*	Duration
<b>Birth to 6 weeks:</b>			
Infants with birth weight < 2000 gm	2 mg/kg once daily. In consultation with a paediatrician trained in HIV care.	0.2 ml./kg. once daily	Up to 6 weeks irrespective of whether exclusively breast fed or exclusively replacement fed. (may be extended to 12 weeks, if mother has not received ART for adequate duration i.e atleast 24 weeks
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



# 6



Interventions for Women Diagnosed with HIV  
Infection in Labour and Postpartum



There is a significant percentage of pregnant women with unknown HIV status presenting directly-in-labour for delivery (un-booked cases). Any pregnant woman who presents in active labour with unknown HIV status should be offered the routine screening of HIV, with opt-out option as per National Guidelines. Screening using Whole Blood Finger Prick Test in the delivery/labour ward should be undertaken.

## 6.1 Pregnant Women in Labour Who are Found Positive in HIV-screening Test should be:

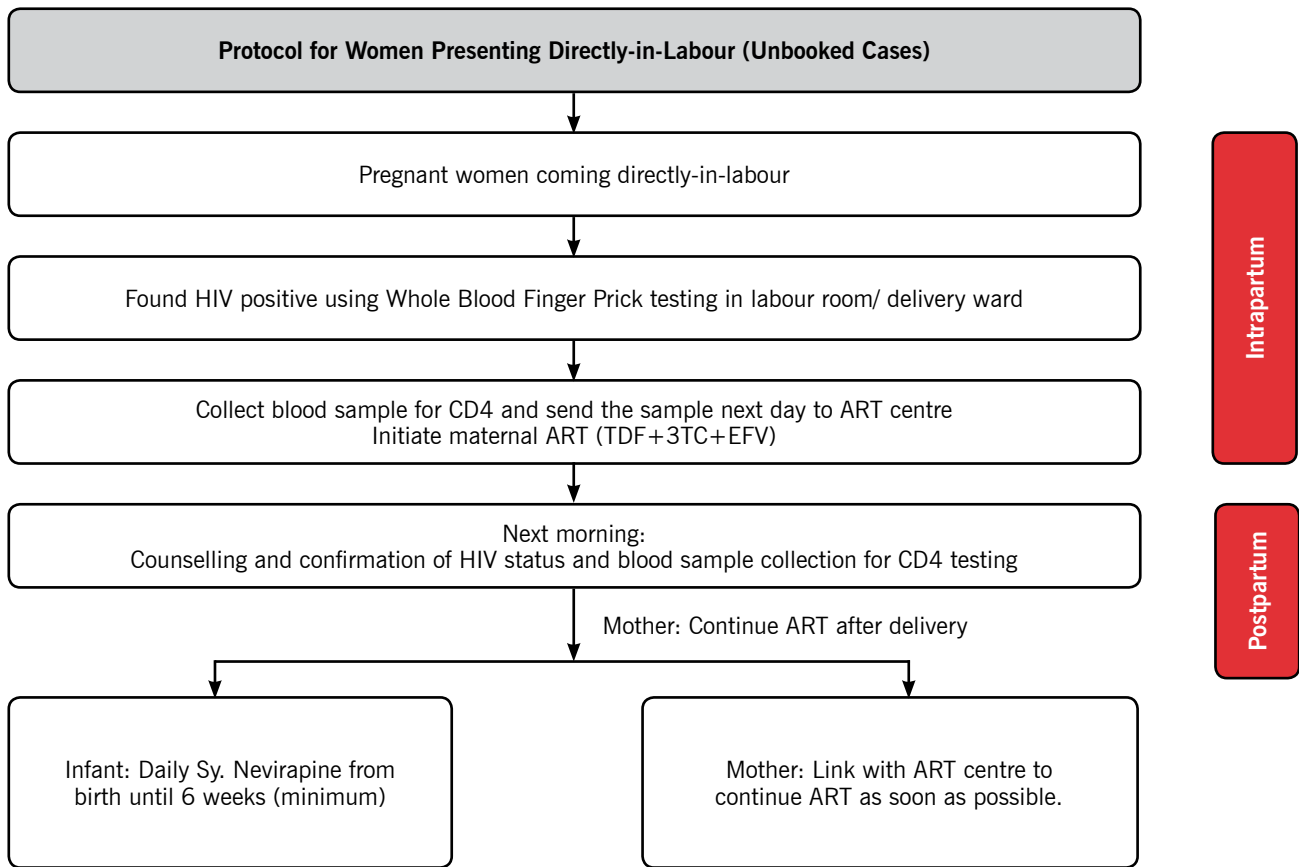
1. Initiated on ART (TDF+3TC+EFV) immediately.
2. The next day the Counsellor should visit the post-natal ward offer pre-test Counselling, counsel and advise for exclusive breast feeding for first 6months, if she has already started breast feeds; *if not* she must be counselled on option for breast vs replacement feeding but must adhere to either exclusive breast feeding or exclusive replacement feeding the first six months. Thereafter, the Lab tech will confirm the HIV status by 3 rapid anti-body tests. Blood sample for CD4 testing shall be drawn of all HIV confirmed cases by Lab tech and S/he will personally carry the sample to CD4 lab and bring the report along with a month's supply of ART taking her spouse or buddy along with her/him under *extreme circumstances* when the post-partum mother is unable to reach the ART Centre within the next 2 days for Pre-ART Registration and Adherence Counselling. However, she should be motivated and followed- up for ensuring she reports to the ART Centre within 30 days. The ICTC Counsellor and Lab Technician after confirming her status the next day will ensure **no interruption** in the continuation ART once the first dose was given to the HIV positive pregnant women in the labour-room and the next day in the post-natal ward.

The broad principle is “as far as possible direct-in-labour women must be seen by ART Medical Officer” at the earliest opportunity but this should not lead to delaying in ART initiation. All efforts should be made that at least she is seen by the facility Medical Officer.



### Box 6

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**.



**Figure 8: Protocol for Women Presenting Directly-in-Labour (Unbooked Cases)**

## 6.2 ARV Prophylaxis for Infants Born to Women Presenting in Active Labour

All infants born to women who present directly-in-labour and receiving intra partum ART and regularly thereafter, should be started on daily NVP prophylaxis at birth and continued for a minimum of 6 weeks. These needs to be extended to 12 weeks as mother has not received adequate duration of ART to suppress viral replication. However, EID should be carried out at 6 weeks as per guidelines.

## 6.3 ARV Prophylaxis for Infants Born to Women who did not Receive Any ART (Home Delivery)

In case of infants who are born to HIV infected mothers who did not receive any antenatal or pre-partum ART, or in cases where maternal HIV infection is detected after the birth of the infant (home delivery):

- Infants should be started on daily Sy NVP prophylaxis at their first contact with health services.



- Daily infant NVP prophylaxis can be started even if more than 72 hours have passed since birth.
- Daily infant NVP prophylaxis should continue for atleast 12 weeks, by which time the mother should be linked to appropriate ART services.

The duration of daily infant NVP prophylaxis will depend on whether the mother is to be initiated on life-long ART and infant feeding practices (see Chapter 12).



## Box 7

### 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)



Special Considerations





## 7.1 Pregnant Women with Active TB

The risk of active TB is approximately 10 times higher in HIV-infected pregnant women compared to HIV uninfected women. Active TB in HIV-infected pregnant women can contribute to increased risk of maternal mortality, and is also associated with prematurity, low birth weight, and perinatal tuberculosis. A recent study in India<sup>2</sup> found that maternal TB increases the risk of HIV transmission from mother-to-child by 2.5 times.

- Intensified Case Finding (ICF) as per national TB-HIV protocols must be instituted for all HIV infected pregnant women.
- All HIV-infected pregnant women presenting with a cough, fever, night sweats and weight loss should be evaluated for TB and started on TB treatment when indicated.
- HIV-infected pregnant women with active tuberculosis should start ART, *irrespective of CD4 cell count*.
- The tuberculosis treatment should be started first, and followed by ART as soon as feasible (usually after 2 weeks)
- Drug interactions between Rifampicin and some of the antiretroviral drugs, including NVP, complicate simultaneous treatment of the two diseases. EFV is the preferred NNRTI for pregnant women which can be used in those with concurrent TB treatment also.
- For those HIV-TB co-infected women not able to tolerate EFV, a NVP-based or a boosted PI regimen can be considered after expert clinical consultation. With the use of a boosted PI regimen, **Rifampicin** should be **substituted** with **Rifabutin**.

## 7.2 Pregnant Women with HIV-2 Infection

Although the great majority of HIV infections in India are due to HIV-1, there are small foci of HIV-2 infection as well, primarily in western India. HIV-2 will also progress to AIDS, although progression is generally much slower. HIV-2 has the same modes of transmission as HIV-1 but has been shown to be much less transmissible from mother-to-child (transmission risk 0-4%).

DETECTION OF HIV-2 INFECTION SHOULD BE DONE ACCORDING TO NACO'S TESTING GUIDELINES for HIV-2

**NNRTI drugs, such as NVP and EFV, are not effective against HIV-2 infection. Therefore, for women who are infected with HIV-2 alone should:**

- Follow standard adult guidelines for HIV-2 treatment which consists of 2NRTIs + LPV/r.
- Prophylaxis NVP with AZT (instead of Symp NVP) to be given to babies in mothers with HIV -2 (Dosage details are given in Table-8)

<sup>2</sup>Maternal Tuberculosis: A Risk Factor for Mother-to-Child-Transmission of Human Immunodeficiency virus. Gupta A, Bhosale R, Kinikar A, et al for the Six

Week Extended-Dose Nevirapine (SWEN) India Study Team. JID 2011:203 (1 February)



**Table 8: Dose of AZT for Infants of Mother with HIV-2 Infection**

Birth Weight	AZT Daily Dosage in mg.	AZT Daily Dosage in ml.	Duration
Infant with birth weight of			
< 2000 gms	5mg/dose twice daily	0.5 ml twice daily	6 weeks
<2500 gms	10mg/dose twice daily	1 ml twice daily	6 weeks
2500 gms and >	15 mgs/dose twice daily	1.5 ml twice daily	6 weeks

Source: WHO Guidelines



**Box 8**

**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**

### 7.3 Pregnant Women with Hepatitis B or Hepatitis C Virus Co-infection

The HIV epidemic in India is driven by injecting drug use in some regions of the Country. Hepatitis B and Hepatitis C may be a concern in these areas.

#### For Women Co-infected with HIV and HBV

- If treatment is required for HBV infection<sup>3</sup>, ART should be started irrespective of the CD4 cell count or the WHO clinical stage:
- The regimen preferred is TDF + 3TC + EFV.
- An elevation in liver enzymes following the initiation of ART may occur in HIV-HBV co-infected women because of an immune-mediated flare in HBV disease secondary to immune reconstitution (IRIS) with therapy, particularly in women with low CD4 cell counts.
- HBV infection may also increase the risk of hepatotoxicity with certain antiretroviral drugs, specifically NVP and protease inhibitors.
- Pregnant women with HIV-HBV co-infection should be counselled about signs and symptoms of liver toxicity.
- For women who do not require HBV treatment, ART general recommendations for HIV-infected pregnant women should be followed.

<sup>3</sup>(Anti-HBV therapy should be considered for all women co infected with HIV and Hepatitis B virus with evidence of severe liver disease)



### **For Women Co-infected with HIV and HCV**

- No specific changes in treatment are recommended in the adult ART treatment guidelines.
- Pregnant women co-infected with HIV and HCV should receive ART according to the general recommendations for HIV-infected pregnant women.
- Those women on ART require careful clinical and laboratory monitoring.

Co-infection with HIV and HBV or HCV is common among Injecting Drug Users (IDUs). Hence, all women living with HIV who are recognized to be IDUs should routinely be offered testing for Hepatitis B and Hepatitis C infections and monitored.



### **Box 9**

**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**



Labour and Delivery in the  
HIV Infected Pregnant Women



## 8.1 Intra-partum Management

The women's sero-status should be recorded in the RCH/MCH Card (Antenatal card) and maternity register. Health care workers should check the woman's HIV status and details of the ART drugs during pregnancy. If her HIV status is unknown and she is in the first stage of labour, offer HIV counselling and testing using Whole Blood Finger Prick Testing. If found positive, she should be administered the first dose of ART and advised for confirmation of tests through ICTC Counsellor and Lab technician the following day. She should be counselled on Exclusive Breast Feeds (EPF) to the baby for the first six months and the baby should be given Sy Niverpine for a minimum of 6 weeks and another 6 weeks continuation if need be.

## 8.2 Intra-partum Anti Retroviral Therapy

Women on life-long ART should continue to receive ART as per the usual schedule including during labour and delivery.

## 8.3 Special Circumstances: Caesarean Section

Caesarean section is not recommended for prevention of mother-to-child-transmission and only if there is an Obstetric indication for the same.

### Use of ARV drugs during Caesarean Sections

- For planned (elective) Caesarean sections, ART should be given prior to the operation.
- Women on life-long ART should continue their standard ART regimen.
- In case of an emergency Caesarean section in pregnant women who are not on ART, ensure that the women receive ART prior to the procedure and continues thereafter.

All HIV-infected women who undergo Caesarean section should receive the standard prophylactic antibiotics. Complications of Caesarean section are higher in women with HIV, with the most frequently reported complication being post-partum fever.



**Box 10** Caesarean sections in HIV positive pregnant women should be performed for Obstetric indications only.

## 8.4 False Labour

In the case of false labour or mistaken ruptured membranes, for women taking ART should continue with normal dosing schedule of the combination regimen.



## 8.5 Safer Delivery Techniques

**Mother-to-child transmission risk is increased by the prolonged rupture of membranes, repeated P/V examinations, assisted instrumental delivery (vacuum or forceps), invasive foetal monitoring procedures (scalp/foetal blood monitoring), episiotomy and prematurity. Thus, when delivering HIV-infected women, observe:**

- Standard/Universal Work Precautions (UWP)
- Do NOT rupture membranes artificially (keep membranes intact for as long as possible).
  - The membranes should be left intact as long as possible and artificial rupture of membrane reserved for cases of foetal distress or delay in progress of labour.
- Minimize vaginal examination and use aseptic techniques.
- Avoid invasive procedures like foetal blood sampling, foetal scalp electrodes.
- Avoid instrumental delivery as much as possible.
  - Unless required in cases of foetal distress or significant maternal fatigue to shorten labour or the duration of ruptured membranes.
  - If indicated, low-cavity outlet forceps is preferable to ventouse, as it is generally associated with lower rates of foetal trauma than ventouse.
- Avoid routine episiotomy as far as possible.
- Suctioning the newborn with a nasogastric tube should be avoided unless there is meconium staining of the liquor.

**Safer surgical techniques are useful in conducting any operative procedures such as the Caesarean section, repairing wounds/lacerations etc.**

Use of 'dry' haemostatic techniques to minimize bleeding; i.e. good observation and following of surgical fascial planes during dissection, judicious use of electro-cautery during Caesarean section etc.

During Caesarean section, wherever possible, the membranes are left intact until the head is delivered through the surgical incision. The cord should be clamped as early as possible after delivery;

- Use of round-tip blunt needles for Caesarean section
- Do not use fingers to hold the needle;
- Use forceps to receive and hold the needle
- Observe good practice when transferring sharps to surgical assistant eg. holding container for sharps.

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



9



Care during the Postnatal Period



## 9.1 The Post-partum Period

- Within an Hour of Delivery
  - Infants born to HIV-infected mothers should receive NVP prophylaxis immediately after birth.
  - Infants after delivery should be put on the mother's abdomen for skin contact to be established which helps in bonding and maintenance of baby's body temperature as well as helps initiation of breast milk within 1 hour of birth.
  - Infants should be given exclusive breastfeeds for the first six months preferably. Exclusive replacement feeding may be done only if the mother has died or has a terminal illness or decides not to breastfeed despite adequate counselling. (See chapter 11 for updated guidelines on infant feeding).
- If the mother has not made a decision about feeding yet, she should be counselled to give exclusive breastfeeds for the first 6 months which is the preferred option, followed by complementary feeds after 6 months. No abrupt weaning to be done after 6 months. The follow up guidance for babies on exclusive breast feeding and exclusive replacement feeding is given in **(Table 9)**.
- Counsel and support parent to give infant NVP prophylaxis using the syringe/dropper provided.
- Emphasize on washing the equipment with clean boiled water after every use.

During the post-delivery period, it is important to continue follow-up and support the postpartum mother, considering the fact that this is a stressful period and she has to assume multiple roles and responsibilities as mother, wife and HIV infected person. Wherever possible, include family counselling (of husband, in-laws, direct family members) to support care of the HIV infected mother and HIV exposed infant. Postpartum depression & psychosis is common in HIV infected women.

- Involvement of men (husband/close male family members) is important so that the family support to the HIV-infected mother and infant is optimal. Husband's support to the mother-baby pair (m-b pair) should be encouraged so as to:
  - To remind the HIV positive mother to take ART regularly
  - Support administration of daily infant NVP prophylaxis medications for 6 weeks to the baby.
  - Be involved in care and follow-up of the infant including clinic visits and immunization follow-up; EID and CPT initiation and continuation up to 18 months at least.
  - Be involved in care of mother for ART centre visits
  - Support exclusive breastfeeding for a minimum period of 6 months and continuation of breastfeeds for 1 year in EID negative babies, and up to 2 years in EID positive babies with initiation of Paediatric ART Weaning foods should be introduced from 6 months onwards in all babies whether breast fed or replacement feeds fed.





- Insertion of Cu-T (temporary contraceptive method) for HIV infected mother at 6 weeks if a post-partum IUD (PP-IUD) has already not been inserted within 48 hours in addition to the use of condoms will prevent unwanted pregnancies (dual protection)
- Encourage male sterilization in father (No Scalpel Vasectomy (NSV) between 18 months to 2 years when baby's survival has been ensured).

**Table 9: Points to be Followed for Babies on EBF OR ERF**

Babies Receiving Exclusive Breastfeeds (EBF) for the First 6 Months	Babies Receiving Exclusive Replacement Feeds (ERF) for the First 6 Months
<b>Mother</b>	<b>Mother</b>
Life-long ART initiated as soon as possible including entire breast feeding period	Life-long ART initiated as soon as possible even though the baby is getting exclusive replacement feeding
<b>Infants</b>	<b>Infants</b>
i) At Birth: Start Sy. NVP Prophylaxis immediately and give until 6 weeks (or more indicated) ii) At 6 weeks: a. Start CPT and continue until baby is 18 months of age b. Immunization: Start 1st dose of DPT/OPV/Hep-B vaccine (2 <sup>nd</sup> dose) c. Early Infant Diagnosis(EID): Do DBS at 6 weeks for all babies; if positive do WBS. If WBS positive, start Paediatric ART irrespective of CD4% for babies less than 2 years. d. NO MIXED FEEDING is to be done during the first 6 months i.e.(not to give along with Breastfeeds any other milk (tinned formula food or cow's milk or dairy milk) liquid, juices or even water	I) At Birth: Start Sy. NVP Prophylaxis from birth until 6 weeks ii) At 6 weeks: a. Start CPT and continue until baby is 18 months of age (and may be thereafter, if babies status is positive in the confirmatory test) b. Immunization: Start 1st dose of DPT/OPV/Hep-B vaccine (2 <sup>nd</sup> dose) c. Early Infant Diagnosis(EID): Do DBS at 6 weeks for all babies; if positive do WBS. If WBS positive, start Paediatric ART irrespective of CD4% for babies less than 2 years. d. NO MIXED FEEDING is to be done during the first 6 months i.e.(not to give Breastfeeds+any other milk (tinned formula food or cow's milk or dairy milk) liquid, juices or even water. No breast feed to be given within first six months

**Post-partum Follow-up and Care Extends Beyond the Six-weeks Postpartum Period and Includes:**

- Assessment of maternal healing after delivery and evaluation for post partum infectious complications.
- Continued counselling and information on fertility choices and effective post partum Contraceptive methods as well as condom promotion and ensuring Cu-T IUD adoption and continued motivation for NSV for males at 18 months Specifically, in HIV infected pregnant women, there should be linking of the baby to the Early Infant Diagnosis (EID) programme and ART programme for mother/child as indicated.



**Box 11** Condom should be consistently used by all HIV infected males despite following any other Family Planning Method (Dual Protection)



## 9.2 Screening for Post-Partum Depression

**Postnatal blues occur in almost 80 per cent of women, most commonly in the first post natal week, and improves afterwards. The “post natal or baby blues” refers to a range of feelings between the third and tenth day after delivery:**

- The feelings include being tearful, irritable, mood changes, fatigue, anxiety and feelings of sadness or loneliness.
- These feelings are thought to be caused by a number of factors, including sudden changes in hormone levels after childbirth, unexpected discomfort from breast engorgement and birth pain, adjustment to parenthood and sleep deprivation.
- These feelings should disappear after a few days and no specific treatment is required, apart from recognition, empathy and support from family and friends.

However, in a group of post partum women, these feelings may persist and become post partum depression. Two prospective studies on pregnant women, in the states of Goa and rural South India, detected depressive disorder in 23 per cent and 16 per cent respectively, with depression persisting six months after child birth in 11-14 per cent of women<sup>6</sup>. In HIV infected women, this may be higher.

**Post partum depression may begin at delivery, or a month later; in some women, it may begin during the first post-natal menstrual period or weaning:**

- The symptoms include crying, irritability, sleep problems (insomnia or sleeping all day), eating problems (no appetite or eating all day), persistent feelings of sadness, lack of desire or inability to care for self or baby, exaggerated concerns about the baby, and memory loss.
- Some women may feel extremely anxious or fearful, sometimes experiencing panic attacks including palpitations, chest pain, dizziness, cold flushes and shaking.

Post partum depression should be detected early so that counselling support and other interventions may be provided. Postpartum depression can interfere with mother-infant bonding, cause problems with spouse and family or other children; and may affect health of the mother. More importantly, **postpartum depression may reduce the adherence to ART** especially the infant NVP prophylaxis for the first 6 weeks of life.

Screening for postpartum depression should be done before the mother goes home after delivery and during follow-up visits. See Annex 7 for the screening tool.



## 9.3 Counsel and Follow-up Mother-baby (m-b) Pairs after Discharge

### Counselling on Issues Related to the Mother:

- Counsel mothers taking ART for her own health for good adherence to life-long ART
- The ART drugs will reduce the risk of HIV transmission through breastmilk during breastfeeding
- Counsel mother who came directly-in-labour about the importance of ART.
- Counsel mother to have adequate rest, nutrition and to take iron-folate during the lactation period, ensure enough proteins and fluids in the diet.
- Family support: involve husband and family members to help out with baby care so that she can rest and recuperate, and to remind her of her ART and infant ARV prophylaxis.
- Counsel mother for her post-natal checkup at 6 weeks to coincide with the infant's first immunization visit.
- Discuss and ensure contraception Copper-T (Cu-T) insertion and condom use as dual protection at subsequent visits.<sup>4</sup>
- Arrange for the mother on ART to be followed with the ART Centre.
- ANMs/ASHAs/Counsellors/ORWs will follow-up the mother and baby within a week of discharge for mother's progress, support infant feeding practice, ensure adherence to infant NVP prophylaxis at home, general counselling advice and infant follow-up.

*Refer to Annex 9: Counselling the HIV infected mother/family for infant feeding options: 0–6 months.*

### Counselling for Issues of Infant to the Parents/ Caregivers:

- Counsel and reinforce decision on infant feeding practice whether exclusive breastfeeding for first 6 months (preferably) or exclusive replacement feeding (for first six months if not willing to breast-feed and resistant to doing so).
- All infants (irrespective of maternal ART in mother) must receive a minimum of 6 weeks of infant NVP prophylaxis daily until the first visit for immunization at 6 weeks of age.
  - If exclusive replacement feeding is being done, then infant NVP prophylaxis may be stopped at 6 weeks of age.
- Infants who are diagnosed DNA/ PCR negative.
  - Should continue breastfeeding and be re-evaluated as per EID protocol.
  - Stop NVP prophylaxis at 6 weeks for babies given exclusive replacement feeding.

<sup>4</sup>*Postpartum psychiatric care in India: the need for integration and innovation. Prabha S Chandra. World Psychiatry. 2004 June; 3(2): 99–100.*



- Infants who are diagnosed DBS positive, are to be referred to the ART Centre for Whole Blood Specimen (WBS) collection. If WBS is also positive, then the infant will be initiated on Paediatric ART, irrespective of CD4 %.
- Final confirmation of the HIV status in the baby should be done at 18 months in ICTC by doing all 3 Rapid Tests even if the first rapid antibody test comes negative.



## Box 12

### 5 Do's for infants at 6 weeks

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

Do re-inforcement for Exclusive Breastfeeds for the first 6 months for (Continuation of breastfeeds with introduction of complementary feeds thereafter)

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 baby after 6 weeks (may need extension to 12 weeks if mother has been initiated late on ART)



10



Infant Feeding Practice



Refer to *National Guidelines for Nutrition of HIV affected and infected infants and children, 2011*.

More than 50 per cent of children under 5 years of age in India have malnutrition. NFHS-3 (2005-06) data show that overall, 57 per cent of women of childbearing age in India (urban and rural) have anaemia with 30 per cent of infants being born underweight. Growth retardation in young children starts during pregnancy and is irreversible by age of two years if not corrected. But especially in rural areas, where women often go back to the fields a few days after giving birth, babies' diets are often supplemented with cow's milk and water, which exposes them to infection.

The infant feeding guidelines for HIV-exposed and infected infants age 0 to 6 months has been updated in 2011. After 6 months of age, complementary foods should be introduced just like for other infants of this age.



### Box 13

#### **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

Exclusive breastfeeding is the preferred feeding option for HIV-exposed infants <6 months of age. However, it is recognized that for some women, breastfeeding may not be possible – for example in situations of maternal death and severe maternal illness in which case Exclusive Replacement Feeding should be done only when AFASS criteria is fulfilled:

A – Affordable F – Feasible A – Acceptable S – Sustainable S – Safe

## 10.1 Principles of Infant Feeding for HIV Infected Pregnant Women

The 10 principles of infant feeding options for HIV infected pregnant women and their infants are:

1. All HIV infected pregnant women should have PPTCT interventions provided early in pregnancy as far as possible.
2. Exclusive breastfeeding is the recommended infant feeding choice in the first 6 months, irrespective of the fact that mother is on ART early or infant is provided with ARV prophylaxis for 6 weeks.
3. MIXED FEEDING SHOULD NOT BE DONE AT ANY COST WITHIN THE FIRST 6 MONTHS (Feeding breast-feeds and replacement feeds simultaneously in the first 6 months).



### 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*)

### Box 14

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.
4. Only in situations where breastfeeding cannot be done or on individual parents' informed decision, then replacement feeding may be considered only if AFASS Criteria for exclusive replacement feeding is fulfilled (Figure 8).
  5. Exclusive breastfeeding should be done for at least 6 months, after which complementary feeding should be introduced gradually, irrespective of whether the infant is diagnosed HIV negative or positive by EID.
  6. Mother should be receiving ART during the whole duration of breastfeeding (remember it is lifelong ART for the mother).



7. For breastfeeding infants diagnosed HIV negative, breastfeeding should be continued until 12 months of age ensuring the mother is on ART as soon as possible.
8. The EID is repeated for the 3<sup>rd</sup> time (when previous 2 EIDs have been negative) after 6 weeks of stopping breast feeds, repeat EID i.e., Rapid test followed by DBS (if Rapid Test turns positive) send DBS test. If DBS is positive, do a WBS test. If WBS test is positive, Paediatric ART should be initiated in ART centre. However, confirmation test for HIV has to be done at 18 months using 3 Rapid Tests for all babies irrespective of the earlier EID status or the fact that Paediatric ART has already been initiated.
9. For breastfeeding infants who have been diagnosed HIV positive, paediatric ART should be started and breastfeeding to be continued ideally until the baby is 2 years old.
10. Breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.
11. **Breast-feeding should NOT be stopped ABRUPTLY.**

Refer to **Annex 9** for flowchart on counselling mothers and families for infant feeding 0-6 months of age.

The summary charts given in the next few pages, gives the various action points in the continuum of the PPTCT activities according to infant feeding practices. Most HIV infected women should breastfeed their infants, unless there are special situations described previously.

To use the summary charts, start from the left side of the chart and continue towards the right side. Advice to the mother/child for ART and for ARV prophylaxis, when to stop or continue infant NVP prophylaxis, when to continue or stop breastfeeding etc. is described on the headings of the charts.



### **Box 15**

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





**Chart 1: Exclusive Breastfeeding (EBF)**

Infant feeding summary charts: Continuum of Prevention of HIV Transmission from Parent-to-Child (PPTCT) through ante natal, labour/delivery, post partum and infant feeding options

HIV positive pregnant woman	ART Eligibility	Mother antiretroviral drug regimen				Infant Feeding Choice
		Mother	Antenatal (AN)	During Labour and Delivery	Postpartum (PP)	
	HIV Positive Pregnant women	ART regimen for mother's own health TDF+3TC+EFV	Initiate mother on lifelong ART, irrespective of pregnancy gestation and Continue ART throughout AN, labour/delivery, PP throughout breastfeeding period and thereafter life-long			EBF

Infant NVP: Give first dose of NVP within 6 to 12 hours of delivery and continue daily NVP for ***	EID* results at 6 weeks	EBF till	Introduce complementary feeding at 6 months of age as usual	Stop BF at (Maximum Time)	Confirmation of HIV status by 3 antibody HIV tests at 18 months of age, irrespective of the results of the earlier EID status	Remarks
6 weeks minimum (consider another 6 weeks when mother has been initiated on ART later in pregnancy or post partum)	EID negative	6 months		12 months		Stopping breastfeeds should be done gradually within 1 month
	EID positive	6 months	24 months	Infants diagnosed EID positive should be on ART as per national paediatric guidelines		

\*EID means DNA /PCR screening at ICTC, and if detected positive, confirmation by Whole Blood Specimen (WBS) at the ART centre.

\*\*Wherever written "HIV positive pregnant women", kindly read it as "HIV infected pregnant women".

\*\*\*6 weeks after cessation of breastfeeds the baby's 3rd EID should be done if earlier EID tests were negative(Rapid Test positive, do DBS; if DBS positive; do WBS; if WBS positive, start Paediatric ART, irrespective of baby's CD4 %.

+ Follow up as usual at ART centre for routine ART monitoring.



**Chart 2: Exclusive Replacement Feeding (ERF)**

Note: HIV infected women who become pregnant while on ART should also follow the charts below

**Infant feeding summary charts: Continuum of Prevention of HIV Transmission from Parent-to-Child (PPTCT) through ante natal, labour/delivery, postpartum and infant feeding options**

HIV positive Pregnant Woman	ART eligibility	Mother	Mother antiretroviral drug regimen	Antenatal (AN) During labour and delivery	Postpartum (PP)	Infant feeding choice
	HIV positive pregnant women	ART regimen for mother's own health TDF+3TC+EFV	Initiate mother on life-long ART, irrespective of pregnancy gestation and continue ART throughout AN, labour/delivery, PP and thereafter life- long →			ERF

Infant NVP: Give first dose of NVP within 6 to 12 hours of delivery and continue daily NVP for....	EID* results at 6 weeks	EBF till	Introduce complementary feeding at 6 months of age as usual and continue BF	Confirmation of HIV status by 3 antibody HIV tests at 18 months of age, irrespective of the results of the EID tests done earlier	Remarks
6 weeks minimum (consider another 6 weeks when mother has been initiated late in pregnancy or post-partum)	EID negative	6 months			Infants diagnosed EID positive should be initiated on ART as per national paediatric guidelines
	EID positive	6 months			

\* EID means DNA/ PCR screening at ICTC, and if detected positive, confirmation by Whole Blood Specimen (WBS) at the ART centre.

± Follow up as usual at ART centre for routine ART monitoring.

\* If pregnant woman is detected HIV positive do not delay initiation of ART as per National Guidelines.

§ If mother is detected as HIV positive AFTER DELIVERY, her infant should receive infant NVP prophylaxis for minimum of 6 weeks.and she should be linked to the closest ART Centre



**Chart 3: Antiretroviral Treatment for Women Presenting Directly-In-Labour, Immediately Postpartum and prophylaxis for their Infants, Including Infant Feeding Options**

Women with unknown status presenting in labour or immediately post-delivery and undergoes HIV screening	ART eligibility	Mother antiretroviral drug regimen				Infant feeding choice
		Mother	Antenatal (AN)	During labour and delivery	Postpartum (PP)	
Unknown CD4 at baseline	Women in direct labour who are detected HIV positive using whole blood finger prick testing	none		TDF+3TC+EFV	TDF+3TC+EFV	EBF (6 months, if already started on breast feeds) otherwise ERF (6months if alternate feeds already started)
Postpartum ART to be initiated as soon as possible (sample for CD4 testing collected by Lab Technician the following day during HIV confirmation and reached to ART Centre and CD4 report handed over to Mother before discharge if mother is not likely to go to ART centre within the next 2 days)		Infant NVP: Give first dose of NVP within 6 to 12 hours of delivery and continue for minimum of 6 weeks		EID results		
Mother needs ART for her own health*		After initial 6 weeks, continue infant NVP until mother has completed at least 6 weeks of maternal ART. Thereafter, infant NVP can be stopped		EID positive		
				EID negative		



Care and Follow-up of  
HIV Exposed Infants



**Table 10: A checklist for the care and follow up activities for all HIV exposed infants.**

**Any intervention or ARV prophylaxis given to the HIV exposed newborn should be documented in the child health card before discharge. The following should be noted in the card:**

- Whether the infant had received ARV prophylaxis and the duration received/advice
- What feeding choice the mother has made? Whether EBF or ERF?
- Date of next follow-up.

## 11.1 During the First Post-delivery Visit at 6 Weeks/ First Immunization Visit

All HIV exposed infants must be checked for the following at the first immunization visit to ICTC health facility:

- Co-trimoxazole Prophylactic Therapy (CPT) initiated at 6 weeks of age (decision on extending Syp NVP to 12 weeks).
- Adherence of infant NVP prophylaxis for the past 6 weeks.
- EID (DNA/PCR) as per National Guidelines.
- Decision made whether to stop infant NVP prophylaxis or continue as per guidelines (see below)
- For exclusively breastfed infants whose mothers are not taking ART:
  - o The pattern of feeding, attachment and positioning & mother's breast condition must be enquired.
  - o Any infant with problems must have a medical assessment.
  - o Provide 6 weeks supply of infant syrup NVP prophylaxis at ICTCs for all HIV exposed babies (3 bottles of Sy NVP:25 ml)
  - o Arrange for monthly follow-up of the infants.
  - o Such mothers have to be on life-long ART
- For infants on exclusive replacement feeding, check with the parents and family if any problems faced so far:
  - o Emphasise good hygiene, use of clean boiled water, hand-washing.
- Any infant with problems must have a medical assessment. NVP infant prophylaxis is to be stopped at 6 weeks:
  - o How and what are being given as exclusive replacement feeds?
  - o When has the mother been started on life-long ART to know the duration (atleast 24 weeks of ART)
  - o All infants with HIV DNA/ PCR positive results to be referred urgently to the ART centre as per guidelines.



- Confirmation with Whole Blood Specimen (WBS) test will be done at the ART centre.
- All infants/children less than 2 years of age with a confirmed Whole Blood Specimen(WBS) positive status at ART centre should be initiated on Paediatric ART, irrespective of CD4 % at the earliest.
- All HIV-exposed infants should be followed-up monthly, in the first year of life and every 3 months thereafter, regardless of the infant feeding practice being adopted.
- Any infant clinically suspected of having HIV should be tested for HIV, regardless of their age.
- All HIV exposed infants irrespective of prior status, should have the final confirmatory HIV tests at
- 18 months in any ICTC using 3 Rapid Anti-body tests, even if the first rapid test is negative.
- No DBS/WBS (DNA/PCR) testing to be done at or after 18 months.

Activities that need to be conducted at each visit are shown below:

**Table 10: Activities at Each Follow-up Visit for HIV Exposed Infants and Children < 18 Months**

Visit	Birth	6 wks	10 wks	14 wks	6 mths	9 mths	§12 mths	18 mths
Co-trimoxazole prophylactic therapy (CPT)		<ul style="list-style-type: none"> <li>█ Start CPT from 6 weeks (or first immunization visit) for all HIV-exposed infants and children</li> <li>█ Continue CPT for all babies up to 18 months irrespective of EID status and thereafter if confirms positive</li> </ul>						
Counselling for Infant feeding	Exclusive breast feeds for first six months	✓	✓	✓	BF+complementary feeds	✓	If EID is -ve stop BF. Continue BF if EID is +ve after 12 months up to 2 yrs	✓
Growth monitoring	✓	✓	✓	✓	✓	✓	✓	✓
Developmental assessment	✓	✓	✓	✓	✓	✓	✓	✓
Immunization & Vitamin A supplements	BCG HBV0* OPV0	OPV 1 DPT 1 HBV 1*	OPV 2 DPT 2 HBV 2	OPV 3 DPT 3 HBV 3		Measles + Vit. A		OPV DPT and Measles (Booster doses) Vit.A
Clinical assessment	✓	✓	✓	✓	✓	✓	✓	✓
HIV testing (✓-if required)		✓ (DNA/PCR)			✓ (Rapid Test + DNA/PCR)		+/- (12 months) ✓ Rapid Test + DNA/PCR)	✓ All 3 Rapid Tests(No DNA/PCR)

\*HBV vaccines as per state approved schedules

Note: 18 months – OPV and DPT booster

For any illness – educate parents/caregiver to bring infant/child back to ICTC at the earliest.

§ 6 weeks after cessation of breastfeeds, HIV testing to be done (Rapid and DNA/PCR, if former is positive).



## 11.2 Confirmation of HIV Status in HIV Exposed Infants should be done at 18 Months, Regardless of Earlier Diagnosis

- **All HIV exposed infants and children regardless of HIV status** will be followed-up until 18 months of age for care, monitoring and the final confirmatory HIV test at 18 months using 3 HIV Rapid tests (even if HIV-1 rapid test is negative).
- If any **HIV exposed infant or child develops clinical signs and symptoms** suggestive of HIV infection, the Medical Officer at the health care facility should start immediate treatment for the acute illness, stabilise and refer urgently to ART Centre. HIV testing according to the national testing algorithm for infants and children < 18 months also has to be done.
- **Follow-up of HIV infected infants and children started on ART** shall be done by ART centres in collaboration with the Paediatrician at the institution where ART Centre is located. Infants and children on ART must undergo the confirmatory three antibody tests at 18-months of age in the nearest ICTC, irrespective of the results of the first rapid antibody test.
- No DBS & WBS (DNA/PCR) testing to be done at or after 18 months.
- In case there is discordance with DNA/PCR tests (DBS and WBS) and subsequent 18 month anti-body test, such cases should be referred to NPO (ART) electronically for further guidance but to be on or continued paed. ART. (this guidance shall be finalised over the next six months and intimated accordingly)



12

Essential Gynaecologic Care for  
HIV Infected Pregnant Women





**During the long term follow-up of HIV infected pregnant women, apart from ART and pre-ART care, key areas which must be discussed, are:**

- Cervical screening
- Family planning and birth-spacing
- Contraception

## 12.1 Cervical Screening

Women infected with HIV are at higher risk of developing cervical dysplasia leading to cervical cancer. The Human Papilloma virus (HPV) infection is more common in HIV infected pregnant women, particularly Genotypes 16, 18 and others incriminated to be carcinogenic being IARC (WHO) 31,33,35,39,45,51,52,56, 58,59 & 68 more incriminated to cause cervical cancer. In the National ART Guidelines for adults and adolescents, cervical screening eg. Pap smear or trichloro-acetic acid screening of the cervix should be done annually for all HIV infected pregnant women.

## 12.2 Family Planning and Birth-spacing

With ART and PPTCT being increasingly available, HIV infected pregnant women and men are now living longer and healthier lives and desiring to have children. Accordingly, reproductive plans including pre- conception counselling, and counselling regarding reversible methods of contraception should be discussed with HIV infected pregnant women of child bearing age.

**Pre-conception counselling**–HIV infected pregnant women are similar to non-HIV infected pregnant women. The goals are to improve the health of the woman before conception and to identify risk factors for adverse maternal and foetal outcomes. These include:

- Safe sex practice
- Prevent test and treat STI.
- Reproductive history including numbers of pregnancies and outcomes of pregnancies.
- Length of relationship with current partner, HIV status of partner and couple's sexual history including condom use and sexual decision-making or control of reproductive choices.
- Patient's and partners reproductive desires and discussion of options.
- Reduce/avoid risky behaviour eg. smoking, substance abuse.
- Take folic acid before conception.

**Family planning counselling**<sup>5</sup> information includes:

- Information about effective contraceptive methods to prevent pregnancy, dual protection; the effects of progression of HIV disease on the woman's health;

<sup>5</sup>Sexual and reproductive health of women living with HIV/AIDS Guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings. WHO/UNFPA 2006.



- The importance of family planning and birth planning;
- The risk of HIV transmission to an uninfected partner while having unprotected intercourse (for instance, when trying to become pregnant);
- The risk of transmission of HIV to the infant and the risks and benefits of Antiretroviral prophylaxis in reducing transmission; and
- Information on the interactions between HIV and pregnancy, including a possible increase in certain adverse pregnancy outcomes.

### Contraceptive Methods

Most women with asymptomatic HIV and those who are on ART can safely use the available forms of contraception for preventing unintended pregnancies. However, prevention of cross-infection of HIV virus to the partner as well as STIs is important and hence **dual protection with consistent condom** use is important. Dual protection refers to simultaneous protection against both unplanned pregnancy and STIs and HIV by using:

- Condoms together with another effective method of contraception, including emergency contraception.

**Available forms of contraception for HIV infected pregnant women include: Hormonal contraception:** is safe in women living with HIV. These may be either:

- Oral contraceptives
- Depot medroxyprogesterone acetate (DMPA)

DMPA is safe to use in women living with HIV as well as those on ART. There is no hormone-drug interaction with several ARV drugs commonly used such as NVP, EFV and Nelfinavir.

In women living with HIV (whose CD4 is  $> 350$  cells/mm<sup>3</sup>), hormonal contraception is safe. Adherence to oral contraception needs to be counselled. Dual protection with consistent condom use is important.

In women taking ART for their own health, they should be assessed for oral contraception use according to the WHO Medical Eligibility Criteria for Contraceptive Use guidelines<sup>6</sup>. There may be hormone-drug interactions which need dosing to be adjusted or an alternative contraception to be used

### Ritonavir

- Combined oral contraception pills are generally not recommended for women taking ritonavir-boosted PIs, due to the potentially decreased efficacy of the contraception

<sup>6</sup>Medical Eligibility Criteria for Contraceptive Use. 4th edition. WHO 2009. [http://www.who.int/reproductivehealth/publications/family\\_planning/en/index.html](http://www.who.int/reproductivehealth/publications/family_planning/en/index.html)



- Nevirapine
  - NVP reduces the levels of combined oral contraception (ethinyl estradiol and norethindrone) but at present, no dosage modification are being suggested
- Efavirenz:
  - Women taking EFV may be able to take combined oral contraception without loss of contraceptive efficacy
- NRTI such as AZT and TDF:
  - Women taking AZT and TDF may take combined oral contraception without loss of contraceptive efficacy

**Lactational Amenorrhoea Method (LAM)** does not protect against STIs, pregnancy and HIV. Correct and consistent condom use should be adopted at every sexual encounter.

**Male sterilization (NSV):** Males should be motivated at every mother-baby pair follow-up visit to undergo sterilization. No Scalpel Vasectomy (NSV) when the baby attains 18 months/2 years of age (at 18 months confirmatory test, irrespective of the baby's HIV status). However, after NSV operation, male should continue to use a condom at every sexual encounter.



### Box 16

**Intra-Uterine Contraceptive Device (IUCD)** is a good contraceptive method for HIV infected pregnant women. IUCD<sup>8</sup> 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.

PP IUD - Postpartum IUD requires specialised training before the healthcare personnel undertake the same.

<sup>8</sup>IUCD Reference manual for Medical Officers 2007. Family Planning Division. MoHFW.



13



Monitoring and Evaluation Tools



Monitoring and evaluation facilitates the assessment of the performance of an individual as well as the performance of the programme, which forms the basis of decision making, policy planning and resource allocation and mid-term corrections, if required.

### Client Monitoring

Monitoring of HIV infected pregnant women is an essential component of quality patient care in PPTCT programme. It involves documenting all client encounters by maintaining regular and accurate records of key aspects of the services provided to the PPTCT beneficiaries and her baby.

A set of M&E tools have been devised to ensure that continuum of care from detection of HIV infection among pregnant women to their linkage to ART centre and for EID after delivery is well maintained. In addition to regular CMIS format of monthly reporting a PPTCT beneficiary Line-list has been designed, which shall be updated on an event basis by ICTCs and ART centres to ensure delivery of the complete package of PPTCT services to all pregnant women viz Anti-Retroviral Therapy, Delivery; Feeding history; Early Infant Diagnosis along with final confirmation at 18 months.

## 13.1 Guidance on Data Flow of PPTCT Beneficiaries

1. A line-list has been devised for the PPTCT beneficiaries and is labeled as Tool 1. This line-list is meant for all PPTCT beneficiaries (Pregnant Women in antenatal care, Direct-in-labour & Post-delivery; breastfeeding mothers). This line-list will originate at the concerned ICTC where a pregnant woman is detected to be positive. This will be an electronic format and shall NOT be printed in a register form at present.
2. The ICTC generating this line-list will fill up the column numbers 1 to 17 d; 29 to 37c and 42 & 43 (Colour coded in yellow).
3. When this line-list is shared by the ICTC with the ART centre, where the positive pregnant woman is registered, the concerned ART centre will fill up the column numbers 18 to 28; 38a to 38d; 39 to 41; 44a to 47 (Colour coded in green).
4. Columns 23, 24 and 25 can be filled up by ICTC counsellor if and when applicable.
5. The line-lists should be generated at ICTC on the first visit of a new HIV positive pregnant case presenting either during pregnancy, direct-in-labour or after delivery. One row should be assigned for each client. Most often, the first visit is at the ICTC when a women in ante-natal care is detected to have HIV infection. Hence, line-lists will be generated there and details shared with the ART Centre for entry of relevant information. Sometimes an HIV infected pregnant woman may have her first visit at the ART Centre, rather than ICTC eg. a positive female client already enrolled at ART centre, gets pregnant or has a second pregnancy after previously being detected. In such cases, the line-list will be generated at the ART Centre and after the relevant columns have been filled up, the line-list will be shared by the ART centre with the ICTC for further follow-up.



6. This line-list should be updated at each activity in the continuum of PPTCT care services eg. ANC/ICTC visits, CD4 test, ART initiation, delivery, Syp. NVP initiation, CPT initiation, EID visits, immunization etc. and shared on a weekly basis between ICTC and ART centre counsellors and staff. If it is not possible to share information weekly then the information about all newly detected HIV positive cases at ICTCs must be given to the ART Centre by the District Supervisor/ DAPCU officer where client wants to get enrolled for the early registration and initiation of ART. Print outs of this electronically shared line-lists on a monthly basis after updating them should be kept in a ring- binder file both at the ICTCs and ART Centres.
7. The updated line-lists should be shared between ICTCs and ART Centres on a monthly basis at DAPCU/District level monthly co-ordination meetings (which are held by the 5th of every month). List of LFUs should be generated during DAPCU/Monthly co-ordination meetings at District and shared with respective ICTCs/ANMs/ ASHAs /Outreach workers/District Level Networks for follow-up. District Nodal persons should take responsibility of linkages of all the newly detected HIV cases with ANMs/ASHAs /Community Out-reach Workers/District Networks of Positive People as well as tracking of LFU cases. Accompanied referral by them should be ensured so that the pregnant woman reaches the ART Centre as soon as possible.
8. In case the expected place of delivery is in another district, it is the responsibility of ICTC counsellor of the centre where her original registration was done, to inform the ICTC counsellor of expected place of delivery with copy to DAPCU/District Supervisor and other concerned officials at SACS. This is to ensure that this woman is not lost -to -follow-up and is not registered again at another ICTC where she delivers. This will ensure that there is no double counting of cases. The ICTC Counsellor at second ICTC will be responsible for updating the line- list of this woman, linking this patient to EID and ART services. Once this woman comes back to the original (previous) ICTC, the data in the line-list should also be transferred to this ICTC and ART Centre.
9. At district level, the updated line-lists from all ICTCs should be compiled into one Consolidated list and updated on a monthly basis by DAPCU/ Nodal Person for HIV in the district. The compiled district level line-list should be cross checked and validated by the nodal person in district and then sent to M&E officer at SACS with copy to JD (BSD) and PPTCT focal person in SACs by 10th of every month. The responsibility of compilation of District level, PPTCT beneficiaries line-lists lies with District Supervisor (in DAPCU Districts) and ICTC Counsellor/s (preferably located in Gynae OPD) of District headquarters.
10. The M&E officer at SACS will then compile these district level line-lists into one State level line-list. This State level line-list of PPTCT beneficiaries should be sent by JD (BSD) at SACS to BSD Division and CST Division at NACO with copy to RCs by 15th of every month.
11. The generation and compilation of line-lists at District/State/NACO level is primarily the responsibility of BSD division. Only the ART component of the line- list shall be filled in and updated by ART Centres and shared with ICTCs after each activity is accomplished electronically &/or in the monthly meetings.



12. The M&E officer at BSD Division, NACO shall compile and analyse these reports every month and give feedback to the concerned person at BSD and CST at NACO on gaps in the cascade of service delivery to PPTCT beneficiaries so that measures to fill in these gaps can be instituted.

13. Another tool shall be used by ART centre for reporting on PPTCT and EID indicators. This is presently being sent as a separate tool (**Tool-2**) but ultimately will be part of monthly reporting format from ART centres (once new form page format is rolled -out across the country.)

### 15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART)

Name of the State:	Updated for the month:
	Year:
District:	Name of MO I/c of ICTC:
	Contact No. of MO:
Name of ICTC:	e-mail id:
(where generated)	Name of SMO/MO of ART Centre:
	Contact No. of SMO/MO
Name of ART:	e-mail id:
(with whom shared)	Name of DAPCUO/Nodal Officer I/c of HIV Programme:
	Designation of I/c Officer
	Contact No.:
	e-mail id:
Pertains to ICTC	
Pertains to ART centre	

15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd...



... 15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd.

Clients Sl. No. (Expandable)	Name of the Pregnant Women in ANC/ Direct- in labour/ Post- delivery mother	Age (in years)	Husband's name and Current Address (including Door no./ Village/ Block/ Taluka/ District/ State) with Landmark, Pin Code and contact number	Father's name and Parental Address (including Door no./ Village/ Block/ Taluka/ District/ State) with Landmark, Pin Code and contact number	Date of HIV Test (Confirmatory test)	ICTC PID Number	Name of the ICTC where tested	Type of Client ANC/ Direct- in -Labour/ Post-delivery mother	Gestational Age (in weeks)	Expected Date of Delivery (EDD)
1	2	3	4	5	6	7	8	9	10	11
i										
ii										
iii										
iv										

15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd....





...15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd.

Expected Place of Delivery	Date of Delivery	Place of Delivery (refer to guidance)	Outcome of Pregnancy (Live Birth/ Still Birth/ MTP/ Abortion)	Status of Mother after delivery up to 6 weeks (Alive/ Dead)	17. Infant feeding practice				New Case/ Already Registered at ART	Date of Registration at ART Centre and Pre-ART Registration No.	Date of CD4 count and Baseline CD4 Count	WHO Clinical Stage
					at 6 weeks	at 6 months	at 12 months	at 18 months				
12	13	14	15	16	17a	17b	17c	17d	18	19	20	21

15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd....



...15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd.

Whether diagnosed as having TB (Yes/No)	If Column 22 is "Yes", date of starting ATT (DOTS/Non-DOTS) (dd/mm/yy)	Date of Completing ATT (DOTS/ Non-DOTS) (dd/mm/yy)	ART Registration no. dd/mm/yy	Date of ART initiation dd/mm/yy	Date of stopping ART dd/mm/yy	Reason for Stopping ART *	Date of starting NVP Syp at birth dd/mm/yy	Date of completing 6 weeks of NVP Syp dd/mm/yy	If stopped before 6 weeks, reason for stopping NVP Syp
22	23	24	25	26	27	28	29	30	31

15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd....



...15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd.

Date of initiation of CPT in baby dd/mm/yy	At 6 weeks, what temporary FP method is being followed (Copper-T or OCP) in addition to use of condoms (Dual Protection)	Name of Infant	ICTC ID of infant	Unique DNA infant code	37. DNA /PCR: DBS tests			38. DNA/ PCR: WBS tests			
					at 6 weeks (positive or negative)	at 6 months (positive or negative)	at 6 weeks after stopping of breastfeeds	WB specimen collection date (dd/mm/yy)	WB Specimen Result for test Positive or Negative	Result of 2nd WBS (in case of DBS & 1st WBS discordance) Positive or Negative	If infant is negative with 2nd WBS, Date of Referral back to ICTC (dd/mm/yy)
32	33	34	35	36	37a	37 b	37c	38a	38b	38c	38d

15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd....



...15.2 Tool 1: PPTCT Beneficiary Line-List (ICTC-ART) Contd.

HIV +ve infant		Date (dd/mm/yy) & result of Antibody Tests (Rapid) conducted at 18 months	Date of stopping CPT dd/mm/yy	44. ART Outcome (Mother)		45. ART/ ARV prophylaxis Outcome (Child)			46. Whether immunization completed	Remarks***
Registration Date (dd/mm/yy) and Pre ART Number	Baseline CD4 count or CD4 %	Date of Initiation of Paed ART (dd/mm/yy)	42	43	Alive & On Treatment	Date and reason for ART discontinuation**	Alive & On Treatment	Primary including measles and Vitamin A (Y/N)	First booster dose at 18 months (Y/N)	
39	40	41	42	43	44a	44b	45a	46a	46b	47

\*1. After one week of stopping breastfeeding  
 2. Death of baby  
 3. Death of mother  
 4. Parent/Guardian decision  
 5. Medical Reason

\*\*A – Maternal death,  
 B – Stopped on Medical advice,  
 C – Transfer out,  
 D – Lost to follow up.(LFU)  
 E – opted out of the programme

\*\*\*Relevant information to be captured, eg:  
 1. Client's current location with date  
 2. Information on authorized attendant to whom ART can be dispensed(from 6 months of pregnancy upto 2 months post delivery)  
 3. Any other important information on related or to client her baby



### 15.3 Definition of Tool 1 Variables in PPTCT Beneficiary Line-list

Tool 1: Definition of Different Variables in PPTCT Beneficiary Line List		
Sl. No.	Variable	Description
1	Sl. No.	It is a number provided to the each client coming to avail the PPTCT package of service on her first visit.
2	Name of the Pregnant Women/ Direct-in- labour ANC/Post-delivery mother	Write the complete name of the Client here in block letters.
3	Age (In Years)	Write the age of the Client in years.
4	Husband's name and Current Address (including Door No./ Village/Block/ Taluka/ District/State) with Landmark, Pin Code and contact number	Write the address of the client where currently residing: Husband's name, along with Door No./ Village/Block/Taluka/District/State with landmark and Pin code and Contact Numbers
5	Father's name and Parental Address (including Door no./ Village/Block/ Taluka//District/State) with Landmark, Pin Code and contact number	Write the name and address of father of the client along with Father's name/Door No./Village/Block/Taluka/District/State with landmark and Pin code and Contact Numbers
6	Date of HIV Test	Mention the Date (dd/mm/yy) when HIV Test of the client conducted. This should be a test at ICTC (and not the screening test)
7	ICTC PID Number	Mention the PID number provided to client from the ICTC, where she got tested for HIV
8	Name of ICTC where tested	Write the Name of the ICTC where the client got tested for HIV
9	Type of Client ANC/ Direct-in- Labour/ Post-delivery mother	Mention whether the Client is ANC case or Direct-in- Labour Case or a post-delivery case (who have been diagnosed/ registered post delivery)
10	Gestational Age (in Weeks)	If the client is ANC case write her Gestational Age in weeks.
11	Expected Date of Delivery (EDD)	For ANC case, write the date (dd/mm/yy) on which she is expected to deliver.
12	Expected Place of Delivery	For ANC Case, Write the name of the place (Health Facility) where she opts for delivery.
13	Date of Delivery	Write the date (dd/mm/yy) when she has delivered.
14	Place of Delivery (refer to guidance)	Write the name of the place (Health Facility, Home delivery etc) where she has delivered. In this case data needs to be transferred to ICTC at place of delivery. Refer to point 7 in data flow for description of this indicator.
15	Outcome of Pregnancy (Live Birth/ Still Birth/ MTP/ Abortion)	Write here the outcome of the Pregnancy whether it is a Live Birth, Still Birth, Medical Termination of Pregnancy or an Abortion.
16	Status of Mother after delivery up to 6 weeks (Alive/ Dead)	Mention here the status of client after delivery and up to 6 weeks (whether alive or dead)



**Tool 1: Definition of Different Variables in PPTCT Beneficiary Line List**

Sl. No.	Variable	Description
17	Infant feeding practice at: (a) 6weeks: 1. Exclusive Breast Feeding 2. Exclusive Replacement Feeding 3. Mixed feeding* (b) 6months: 1. Continued Breast Feeding + Complimentary feeds & semi solids 2. Continued Replacement feeding + semi solids 3. Whether mixed feeding occurred between 6 weeks to 6 months (Yes/No) (c) 12 months: 1. Continued Breast Feeding 2. Breast Feeds stopped (dd/mm/yy) (d) 18 months: 1. Continued Breast Feeding 2. Stopped Breast Feeding (dd/mm/yy)	Please ask the mother at each of the 4 visits: regarding infant feeding practice. (a) At 6 weeks, whether the baby is receiving Exclusive Breast feeds only or Exclusive Replacement feeds or if any Mixed feeding has occurred (Baby is receiving both breast feeds and replacement feeds within first 6 months). (b) At 6 months, enquire whether baby which is continued on breast feeds has also been started on complementary feeds and semisolids or whether the baby was getting exclusive replacement feeds for the first 6 months and now has been started on semi- solids. Enquire also whether any mixed feeding happened any time from 6 weeks up to 6 months. (c) At 12 months, enquire from the mother whether breast feeds has been stopped. If yes, indicate date (dd/mm/yy) (d) At 18 months, enquire whether 1. Breast feeding is being continued or 2. Breast- feeding has been stopped. If stopped, indicate date of stopping (dd/mm/yy).
18	New Case/ Already Registered at ART	Mention whether the client availing the service is a fresh case or has already been registered at ART with Pre ART number. Write “New Case” for fresh case and “Already Registered at ART” for client registered at ART.
19	Date of Registration at ART Centre and Pre-ART Registration No.	Mention the Date (dd/mm/yy) of registration of the client under HIV (Pre-ART) care at ART Centre.
20	Date of CD4 count and Baseline CD4 Count	Mention the date (dd/mm/yy) of assessment of CD4 count of the client. Mention the baseline CD4 count of the client.
21	WHO Clinical Stage	Write the WHO Clinical stage (whether I,II,III or IV) of the client here.
22	Whether Diagnosed as having TB (Yes/No)	If the client have been diagnosed as having TB write YES, if not write NO
23	If Column 22 is “Yes”, date of starting ATT (DOTS/Non-DOTS) (dd/mm/yy)	If yes, date of starting of TB treatment (ATT)
24	Date of completing ATT (dd/mm/yy)	Write the exact date when TB treatment (ATT) was completed
25	ART Reg no.	When initiated on ART, write the ART registration number allotted to the client.
26	Date of ART initiation	Write the date (dd/mm/yy) of initiation of ART to the client.
27	Date of stopping of ART	If ART stopped, write the date (dd/mm/yy)
28	Reason for Stopping ART* 1. 2. 3. 4. 5.	*Mention the Reason for stopping of ART here, The reason could be: 1. After one week of stopping breastfeeding 2. Death of Baby 3. Death of Mother 4. Patient/Guardian’s decision 5. Medical Reason



**Tool 1: Definition of Different Variables in PPTCT Beneficiary Line List**

Sl. No.	Variable	Description
29	Date of starting NVP Syrup at birth dd/mm/yy	Mention the date (dd/mm/yy) when NVP syrup was initiated after birth
30	Date of completing 6 weeks of NVP Syrup dd/mm/yy	Mention the date (dd/mm/yy) when NVP syrup (6 weeks) to baby has been completed and stopped.
31	If stopped before 6 weeks, reason for stopping NVP Syrup	Try to find out the reason as to why Syrup NVP was stopped
32	Date of initiation of CPT in baby dd/mm/yy	At 6 weeks, find out from the mother the date (dd/mm/yy) when baby was initiated on Co- trimoxazole prophylactic therapy (CPT)
33	At 6 weeks, what temporary FP method is being followed (Copper-T or OCP) in addition to condoms (dual protection)	At 6 weeks visit, enquire from the mother as to whether she has had a Copper-T inserted or is taking Oral Contraceptive pills in addition to her spouse or she using a condom as(dual protection)
34	Name of Infant	Write the name of the baby.
35	ICTC ID of infant	Write the ID given to infant by the ICTC.
36	Unique DNA infant code	Write the unique DNA infant code for all babies registering for DNA PCR testing
37	DNA PCR: (1) DBS tests: a) At 6 weeks: Positive/Negative b) At 6months: Positive/Negative c) At 6 weeks after stopping breast-feeds: Positive/Negative	The DNA PCR DBS test when done at 6 weeks is negative; repeat it again at 6 months. If negative again, it should be repeated 6 weeks after breastfeeds has been stopped.
38	DNAPCR: WBS tests a) WB specimen collection date (dd/mm/yy) for DBS test 37a or 37b or 37c b) WB Specimen Result for DBS test 38 (38a or 38b )-Positive or Negative c) Result of 2nd WBS(in case of DBS & 1st WBS discordance)Positive or Negative d) If infant is negative with 2nd WBS, Date of Referral back to ICTC	Write the date (dd/mm/yy) when whole Blood Specimen of infant is collected.
		Write the result of the Whole Blood Specimen of the infant. In case there is a discrepancy in DBS and first WBS, write the result of 1st and 2nd WBS in columns 38c & 38c
		If infant is negative, write the date (dd/mm/yy) of referral back of infant to ICTC.
39	HIV +ve infant	Registration Date (dd/mm/yy) and Pre ART Number
40		Baseline CD4 count or CD4 %
41		Date of Initiation of Paed. ART (dd/mm/yy)
42		Date (dd/mm/yy) & result of Antibody Tests (Rapid) conducted at 18 months - Confirmed negative or Confirmed positive
		Write the date (dd/m/yy) of antibody (Rapid) tests conducted for the infant at the age of 18 months for confirmation. Write the result whether the baby is confirmed as HIV positive or negative



**Tool 1: Definition of Different Variables in PPTCT Beneficiary Line List**

Sl. No.	Variable		Description
43		Date of stopping CPT dd/mm/yy	Write the date when CPT for infant has been stopped. It is advised that CPT be continued for 18 months in children even if the EID results are negative at 6 weeks or 6 months or after 6 weeks of stopping breastfeeds, as it reduces infant mortality due to inter-current infections, like diarrhoea and respiratory infections or other OIs.
44	ART** Outcome (Mother)	a) Alive & On Treatment b) Date and reason (code) for ART discontinuation	Tick this cell if the client is alive and on ART  **Put the appropriate Code in this Cell with date A – Death, B – Stopped on Medical advice, C – Transfer-out, D – Lost-to-follow-up (LFU) E – opted out of the programme
45	Antiretroviral treatment Outcome (Child)**	a) Alive & On Treatment a) Date and reason for ART/ ARVs discontinuation	Tick this cell if the client is alive and on ART  **Put the appropriate Code in this Cell with date A – Death B – Stopped on Medical advice C – Transfer-out, D – Lost-to-follow-up (LFU) E – Opted out of the programme on her own
46		Whether immunization completed: (a) Primary immunization, including measles and Vitamin A (Y/N) (b) Whether 1st booster dose at 18 months received (Yes/No)	(a) Write “Yes” if all primary immunization has been completed or “No” if any immunization, including measles and Vitamin A have not been received (the baby should be sent for completion of immunization schedule within a week)  Write “Yes” if DPT/ OPV have been received at 18 months or “No” if baby has not yet received (ensure baby receives the same within a week)
47		Remarks***	This column is common for both ICTC and ART centres ***Relevant information to be captured, eg: 1. Client’s current location with date 2. Information of authorized attendant to whom ART can be dispensed(from 6 months of upto two months post delivery)(refer letter of ADG, CST, NACO, dated 28 August 2012) 3. Any other important information related to client or her baby





## 15.4 Tool 2: Reporting on PPTCT and EID from ART Centres

3 a. PPTCT				
3.1a Cumulative number of Pregnant women ever registered/ reported in HIV care till the end of this month (Out of 2.5)				0
3.2a Cumulative number of pregnant women ever initiated on ART till the end of this month (out of 3.1a)				0
3.3a Cumulative number of pregnant women initiated on PPTCT ARV prophylaxis from 1st Sept 2012 till the end of December 2013 (Out of 3.1 a)(applicable for AP, Karnataka, Tamil Nadu)				0
3.4a Total number of pregnant women ever initiated on ART/ ARV prophylaxis (3.2a+3.3a) (applicable for AP, Karnataka, Tamil Nadu)	0		0	0
3.5a Number of pregnant women currently on ART				0
3.5a.1 Number of women currently on PPTCT ARV prophylaxis (dynamic figure, as and when pregnancy/ lactation completed and ARV prophylaxis stopped reduce from this section9 (applicable for AP, Karnataka, Tamil Nadu for breast feeding mothers: max period applicable is Dec 2014)				0
EID				
3.6a Cumulative number of children registered at ART centre with DBS reactive for DNA/PCR				0
3.7a Out of 3.6a cumulative number of children who underwent WBS testing at the ART centre				0
3.8a Out of 3.7a cumulative number of children who are WBS reactive for DNA/ PCR				0
3.9a Out of 3.8a cumulative number of children initiated on ART				0
3.10a Out of 3.9a cumulative number of children initiated on LPV/r based regimen				0
3.11a Out of 3.8a cumulative number of children found HIV+ve by 3 antibody tests at 18 months of age				0

### ART Centres Reporting

(Section 3a of CMIS – PPTCT)

**(Refer to the remarks column of the HIV column 6 and 23 of “Pre ART’ register, column no. 16 of ART enrolment register, any separate register maintained for pregnant women, if required from individual white card or from the PPTCT line-list)**

#### 3.1a Cumulative number of Pregnant women ever registered/ reported in HIV care till the end of this month (Out of 2.5)

Number of HIV positive pregnant women ever registered at your ART centre since the beginning. These can be new registrations or those already registered at the ART centre and then later on become pregnant. Generation of this figure will be a onetime exercise and can be done from column no. 16 and 23 of the HIV Care register, column no. 16 of ART enrolment register, any separate register maintained for pregnant women or if required from individual white cards. Once this is firmed up, new registrations to be added to this figure every month, from next month onwards.



**3.2a Cumulative number of pregnant women ever initiated on ART till the end of this month (out of 3.1a)**

Total no. of pregnant women ever initiated on ART (who are eligible for ART, for their own health) at this centre from the beginning of this centre.

**3.3a Cumulative number of pregnant women initiated on PPTCT ARV prophylaxis from 1st Sept 2012 till the end of December 2013 (Out of 3.1 a) (Applicable for AP, Karnataka and Tamil Nadu)**

Total no of pregnant women initiated on PPTCT ARV prophylaxis treatment for PPTCT (not for their own health) from 1st Sept 2012 onwards. This only includes those women who have been given triple drug ARV prophylaxis for PPTCT. **Applicable only for AP; Karnataka & Tamil Nadu States which rolled out triple drug ARV Prophylaxis. (This does not include sd NVP prophylaxis).**

**3.4a Total number of pregnant women ever initiated on ART/ ARV prophylaxis (AP, Karnataka and TN) (3.2a+3.3a)**

Total no of women ever initiated on ART/ ARV prophylaxis, sum of 3.2a and 3.3a

**3.5a Number of pregnant women currently on ART**

Total no.of pregnant women currently on ART at this centre. Remember to reduce the numbers as and when pregnancy is completed and then this particular women becomes like other women on ART (non pregnant) already being reflected in column no. 3.10 of monthly ART centre report.

**3.5a.1 Number of women currently on PPTCT ARV prophylaxis (dynamic figure, as and when pregnancy/ lactation completed and ARV prophylaxis stopped reduce from this section)**

Total no. of pregnant women currently on PPTCT ARV prophylaxis at this centre. Remember to reduce the numbers as and when pregnancy/lactation completed and ARV prophylaxis has been stopped.

## **EID**

(Refer to EID register and for 3.10a and 3.10b, patient white card)

**3.6a Cumulative number of children registered at ART centre with DBS reactive for DNA /PCR**

Cumulative no. of children entered in the EID register

**3.7a Out of 3.6a cumulative number of children who underwent WBS testing at the ART centre**

Out of the total children detected DBS positive, cumulative no. of children who have undergone Whole Blood Specimen (WBS) testing (column no. 10 of EID register)

**3.8a Out of 3.7a cumulative number of children who are WBS reactive for DNA /PCR**

Out of the total children who underwent WBS testing, cumulative no. of children who have had positive results (column no. 11 of EID register)

**3.9a Out of 3.8a cumulative number of children initiated on Paedtric ART**

Out of the total children who had positive WBS results (column no. 11 of EID register) how many were initiated on Paediatric ART (column no. 16 of EID register)



### 3.10a Out of 3.9a cumulative number of children initiated on LPV/r based regimen due to previous exposure to sd NVP.

Out of the total children who initiated on Paed ART under the EID programme, cumulative no. of children who have been started on LPV/r based regimen due to previous exposure to sd NVP

### 3.11a Out of 3.8a cumulative number of children found HIV+ve by antibody tests at 18 months of age:

Of all the patients with WBS positive, how many children had HIV +ve status at 18th month of age.

### 3.12 a. Out of the total no. of live births 18 months ago, no. of children reported to be living:

- b. No. of children born to HIV positive pregnant women born 18 months ago, reported to be dead
- c. No. of children born to HIV positive pregnant women born 18 months ago tested for confirmation of status at 18 months:

## 15.5 SIMS Monthly Progress Report for PPTCT

Monthly Input Formats for Integrated Counselling and Testing Centres (ICTC)					
NRHM-NACO Convergence Action Section D: Progress during the month (only for Pregnant Women )					
i. Pregnancy, delivery and breastfeeding					
S. No.	Indicators		During ANC	Directly-in-labour	Total
			During this Month	During this Month	
1	Number of New ANC Registrations				0
2	Number of pregnant women provided with pre-test counselling out of all registered				0
3	Number of pregnant women tested for HIV				0
4	Total number of pregnant women detected HIV Infected	Among those detected infected, number in first trimester			
		Among those detected infected, number in second trimester			
		Among those detected infected, number in third trimester			
5	Number of pregnant women who received post-test counselling and given test results				0
6	Number of pregnant women referred by the F- ICTC Govt(Fixed/Mobile) after HIV screening test				0
6.1	Out of the above, Number of pregnant women diagnosed HIV infected				0
7	Number of pregnant women referred by the PPP ICTC (Fixed/Mobile) after HIV screening test				0
7.1	Out of the above Number of pregnant women diagnosed HIV infected				0
8	Number of pregnant women referred by the PHC/Sub Centre/ ANM after HIV screening test				0



8.1	Out of the above, Number of pregnant women diagnosed HIV infected			0
9.a.	Number of spouses/partners of HIV infected pregnant women tested			0
9.b.	Number of spouses/partners of HIV infected pregnant women found HIV infected			0
10	Number of HIV infected pregnant women who underwent MTP during the month			0
11	Number of HIV infected pregnant women expected to deliver during this month			0

Monthly Input Formats for Integrated Counselling and Testing Centres (ICTC)

NRHM-NACO Convergence Action Section D: Progress during the month (only for Pregnant Women )

i. Pregnancy, delivery and breastfeeding

S. No.	Indicators		During ANC	Directly-in-labor	Total
			During this Month	During this Month	
12	Total number of HIV infected deliveries this month:	a. In same Facility			0
		b. In other Govt hospitals			0
		c. Pvt Hospitas/ any other facilities			0
		d. Home Deliveries			0
13.a.	Total number of normal (vaginal) deliveries of HIV infected pregnant women during this month				0
13.b.	Total number of deliveries by Caesarean section of HIV infected pregnant women during this month				0
14	Outcome of HIV infected deliveries this month	a. Number live male child			0
		b. Number live female child			0
		c. Still births			0
		d. Deaths			0
15	Total number of mother-baby pairs who received Nevirapine (single dose) (whenever new guidelines not rolled out)				0
16	Number of HIV infected pregnant women (only) received Nevirapine (single dose) during the month (whenever new guidelines not rolled out)				0
17	Number of babies(only) of HIV infected mothers received Sy. Nevirapine x 6 weeks during month				0
22	Number of HIV infected pregnant mother opting for exclusive breast feeding for first 6 months				0
23	Number of HIV infected pregnant mother opting for exclusive Replacement feeding for first 6 months				0
24	Number HIV infected pregnant women registered at ART centre				0
25	Number of HIV infected pregnant women whose CD4 count is < 350				0



Monthly Input Formats for Integrated Counselling and Testing Centres (ICTC)

ii. Age-wise distribution

Agewise Distribution	Number of pregnant women tested for HIV	Number of pregnant women detected infected
1. 15-19 years		
2. 20-24 years		
3. 25-34 years		
4. >35 Years		
Total		

iii. Follow -up

Description	This month				
	First Visit		Second Visit		Third Visit
A. Visit for DBS and WBS Test	6 weeks – 6 months	6 months – 18 months	6 months – 12 months	12 months – 18 months	12 months – 18 months
1. Number of infants/children visited					
2. Number of infants/children tested for HIV using DBS-DNA PCR/Antibody test					
3. No of infants/children who were found positive					
4. Number of infants on exclusive breast feeding (EBF)					
5. Number of infants on exclusive replacement feeding (ERF)					
6. Number of infants on CPT –initiated at 6 weeks and continuing					
7. No. of infants registered at ART centre					
C. Details at 18 months:					
1. Number of infants who came for follow- up at 18 months					
2. Number of infants who were tested (using 3 antibody tests)					
3. Number of infants HIV infected					
4. No. of infants registered at ART centre					



iv. Outreach Linkages for HIV Positive Pregnant Women (By Out Reach Worker)			Number		
1. Number of outreach workers (ORWs) (IL &FS)/ ANMs/ ASHAs/DLNs					
2. Number of HIV infected pregnant women visited at home by the outreach worker during the month (specify who visited)					
3. Number of HIV infected pregnant women who were expected to deliver this month, visited by the outreach worker (specify)					
4. Number of HIV infected women visited post delivery by ORWs/ANMs/ASHAs/DLNs					
i. Before 6 weeks					
ii. 6 weeks to 6 months					
iii. 6 months to 12 months					
iv. 12 months to 18 months					
v. 18 months until the time baby is breastfed					



14



Roles and Responsibilities of Staff at Different Levels



Roles and Responsibilities of programme managers and staff in PPTCT services is shown in (Table:11)

PPTCT program is to be implemented through the ICTC and ART centres and also needs to be an integrated response with general health system. Following table details terms of reference of staff at different level regarding their roles and responsibilities in implementation of PPTCT programme:

**Table 11: Roles and Responsibilities of Programme Managers and Staff in PPTCT Programme**

SI. No.	Designation of Official/staff	Role in PPTCT Implementation
1	Project Director State AIDS Control Society (SACS)	<ol style="list-style-type: none"> <li>1. Facilitate development of state micro-plan for implementation of PPTCT programme</li> <li>2. Facilitate establishment of Joint State PPTCT programme implementation committee</li> <li>3. Facilitate regular meetings of the implementation committee for programme review and policy decisions</li> <li>4. Advocacy with Principal Secretary, Health &amp; Family Welfare and MD-NRHM to ensure ownership of PPTCT programme by Director, Health &amp; Family Welfare Services, state RCH officer</li> <li>5. Facilitate formation of the Joint District PPTCT implementation committee and Case Management Team in all districts of the state</li> <li>6. Facilitate measures to ensure ownership of the programme at district level by District Health &amp; Family Welfare Officer, CMHO, Civil Surgeon, District RCH officer etc.</li> <li>7. Advocacy with Secretary Medical Education to ensure adherence to National programme guidelines so as to minimize linkage loss in medical college hospitals</li> <li>8. Facilitate joint review meetings of NACP-NRHM and Medical Education programme managers at regular intervals</li> <li>9. Facilitate involvement of professional organizations like FOGSI, IAP, IMA to ensure systematic involvement of private sector</li> <li>10. Overall leadership of programme with regular monitoring of progress</li> </ol>
2	Nodal Officer for PPTCT in the SACS	<ol style="list-style-type: none"> <li>1. Ensure close coordination between the Basic Services division and Care and Support &amp; Treatment division at state and district level</li> <li>2. Establish close liaison with State RCH officers and other key stakeholders in NRHM</li> <li>3. Establish close liaison with state level office bearers of professional organizations like FOGSI for systematic involvement of private nursing homes</li> <li>4. Facilitate formation of the Joint District PPTCT implementation committee and Case Management Team in all districts of the state</li> <li>5. Ensure regular meeting of Joint District PPTCT implementation committee through supportive supervision and monitoring</li> <li>6. Establish mechanisms for monitoring progress in linking up of HIV infected pregnant women to PPTCT services e.g. use of google doc. for tracking and monitoring at state level</li> <li>7. Establish Stand-alone ICTCs at all CHC level health facilities</li> <li>8. Ensure availability of HIV screening facilities at all high delivery points below CHCs in the form of F-ICTCs and sub-centre level screening using WBFP</li> <li>9. Ensure availability of PPTCT services at all high delivery points</li> <li>10. Ensure mechanisms for quick linkage of screened positive pregnant women to SA-ICTCs for confirmation, to ART Centre for life-long ART and EID services for HIV exposed babies</li> <li>11. Monitoring of compliance of infected pregnant women with PPTCT guidelines through regular follow-up visits of NACP outreach workers and other health system human resources</li> </ol>





SI. No.	Designation of Official/staff	Role in PPTCT Implementation
3	State RCH Officer	<ol style="list-style-type: none"> <li>1. Facilitate ownership of the PPTCT programme by the District Health &amp; Family Welfare Officers (CMHO, Civil surgeon)</li> <li>2. Facilitate ownership of PPTCT activities by PHC medical officers and the field staff</li> <li>3. Facilitate provision of support for confirmation of HIV status of pregnant women, travel to ART centre for enrolment and drug collection along with facilities for institutional delivery</li> <li>4. Facilitate establishment of HIV screening facilities at all high delivery points in the form of F-ICTCs and sub-centre level screening using WBFPT</li> <li>5. Ensure availability of PPTCT services at all high delivery points</li> <li>6. Facilitate regular meeting of the Joint District PPTCT implementation committee</li> <li>7. Facilitate involvement of PHC medical officers and concerned ANM and other health system functionaries in the Case Management Team</li> <li>8. Ensure involvement of medical officers at PHCs and ANMs in monitoring of linkages to ICTCs, ART centres and compliance of HIV infected pregnant women to PPTCT regimen</li> </ol>
4	District HIV programme Manager – DAPCU / DNO	<ol style="list-style-type: none"> <li>1. Ensure formation of the Joint District PPTCT implementation committee and Case Management Team in all districts of the state</li> <li>2. Ensure regular meeting of Joint District PPTCT implementation committee</li> <li>3. Establish Stand-alone ICTC at all CHC level health facilities</li> <li>4. Ensure availability of HIV screening facilities at all high delivery points below CHCs in the form of F-ICTCs and sub-centre level screening using WBFPT</li> <li>5. Ensure availability of PPTCT services at all high delivery points</li> <li>6. Ensure mechanisms for quick linkage of screened positive pregnant women to SA-ICTC for confirmation, to ART Centre for initiation of life-long ART and EID services for HIV exposed babies</li> <li>7. Monitoring of compliance of infected pregnant women with PPTCT guidelines through regular follow-up visits of NACP outreach workers and other health system human resources</li> <li>8. Training load assessment</li> <li>9. Establish close liaison with District Health &amp; Family Welfare Officers (CMHO/ Dy. CMHOs/ RCH Officers)</li> <li>10. Overall planning and implementation of programme at the district level</li> <li>11. Ensure up-to-date recording at all facilities and timely reporting to state level</li> <li>12. Supervisory visit to ART centres, ICTCs and other HIV screening centres</li> <li>13. Close liaison with professional association like FOGSI, IAP, IMA to facilitate involvement of private nursing homes &amp; institutions</li> <li>14. Advocacy, Communication and social mobilization activities for effective implementation of PPTCT services</li> </ol>
5	District RCH Officer	<ol style="list-style-type: none"> <li>1. Advocacy with District Health &amp; Family Welfare Officers (CMHOs Civil surgeons) for ownership of PPTCT programme</li> <li>2. Ensure ownership of PPTCT activities by PHC medical officers and the field staff</li> <li>3. Ensure provision of support for confirmation of HIV status of pregnant women, travel to ART centre for enrolment and drug collection along with facilities for institutional delivery</li> <li>4. Facilitate establishment of HIV screening facilities at all high delivery points in the form of F-ICTC and sub-centre level screening using WBFPT</li> <li>5. Ensure availability of PPTCT services at all high delivery points</li> <li>6. Ensure regular meeting of Joint District PPTCT implementation committee</li> <li>7. Ensure involvement of PHC medical officer, concerned ANM and other health system functionaries in Case Management Team so as to ensure linkage to screened positive pregnant women to ICTCs for confirmation, to ART centre for enrolment and to monitor compliance with PPTCT programme guidelines</li> </ol>



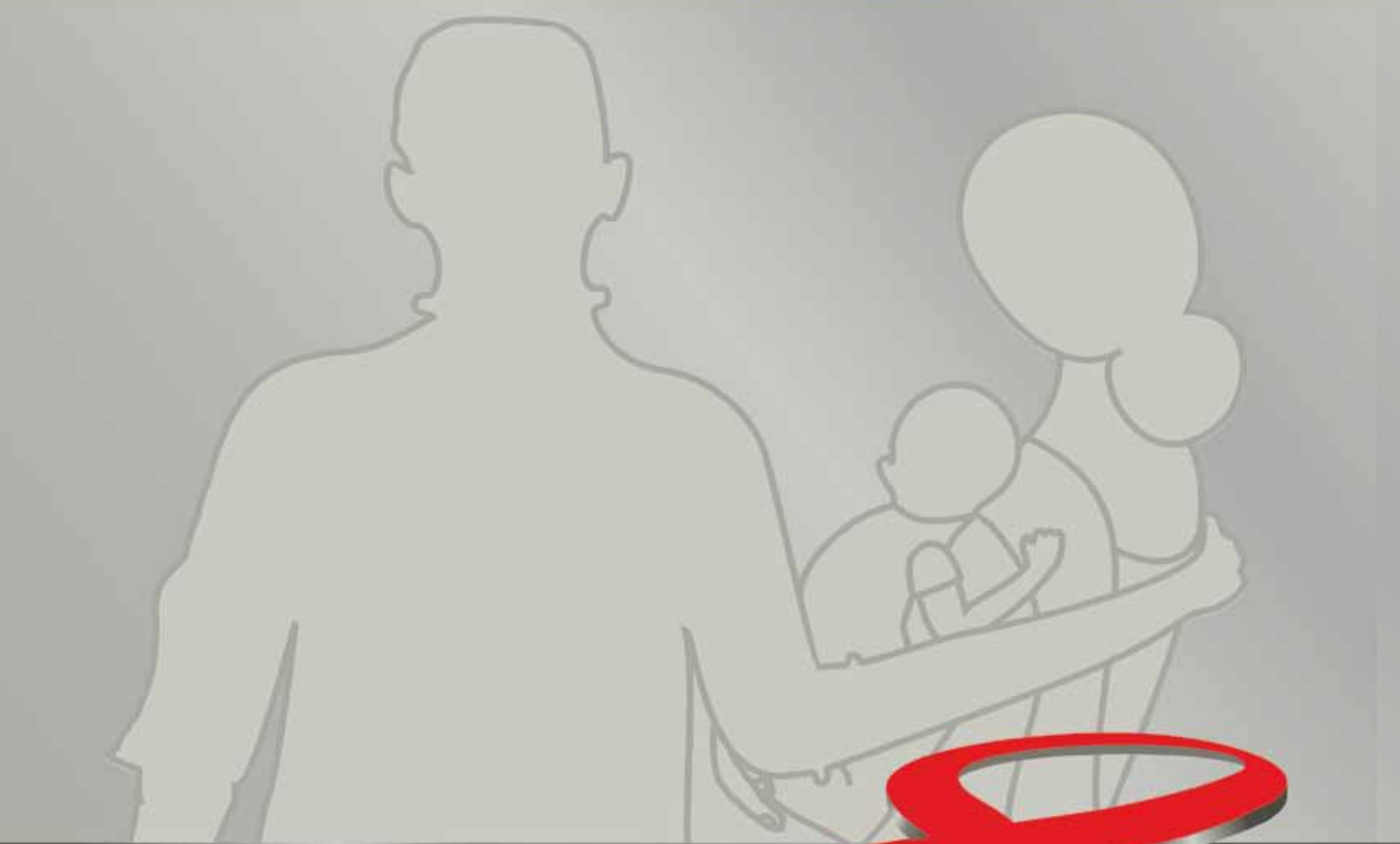
SI. No.	Designation of Official/staff	Role in PPTCT Implementation
6	Monitoring and evaluation assistant at DAPCU /ICTC counsellor at the district headquarter	<ol style="list-style-type: none"> <li>Maintenance of consolidated PPTCT line-lists</li> <li>Updating PPTCT line-lists with all events, compilation, analysis and interpretation etc.</li> <li>Timely reporting of PPTCT line-lists to SACS</li> </ol>
7	District ICTC supervisor	<ol style="list-style-type: none"> <li>Supervisory visit ART centres, ICTCs and other HIV screening centres (TB and STI)</li> <li>Supportive supervision of ICTC</li> <li>Facilitate co-ordination between ICTC/ART centre staff with general health staff (RCH / NRHM)</li> <li>Ensure preparedness for conducting HIV positive deliveries at delivery points</li> <li>Ensure linkage of HIV exposed infants (HEIs) to Early Infant diagnosis sites ICTCs where DBC is being done</li> <li>Ensure follow-up visits to HIV infected pregnant women by health staff / outreach workers/District Level Networks</li> <li>Facilitate reporting of all key events to district M and E assistants for updating line-lists</li> </ol>
8	In-charge medical officer at ICTC	<ol style="list-style-type: none"> <li>Measures to ensure 100% screening of all pregnant women enrolled into Ante-Natal Care</li> <li>Measure to ensure HIV, STI, TB screening early</li> <li>Ensure uninterrupted availability of test-kits, drugs, referral forms and registers</li> <li>Ensure prompt referral and linkage of HIV infected pregnant women to ART centres</li> <li>Ensure safe institutional deliveries</li> <li>Ensure provision of ARV prophylaxis for the baby for 6 weeks – Sy.NVP for 6 weeks (3 bottles each) 25ml</li> <li>Ensure linkage of the baby to EID services</li> <li>Clinical assessment and care of patients while on ART</li> <li>Monitoring adherence to ART</li> <li>Ensure home visits to the infected pregnant women at prescribed frequency</li> <li>Ensure timely follow-up visits of infected pregnant women to ART centres</li> </ol>
9	Counsellor stand-alone ICTC / F-ICTC	<ol style="list-style-type: none"> <li>Provision of preventive health education to all Ante-natal care women and explain about screening of women for HIV, Syphilis and TB</li> <li>Ensure coverage of all registered ANCs in the area of jurisdiction with HIV counselling testing Provision of psychosocial support to all infected women</li> <li>Ensure prompt referral of infected ANCs with ART centres</li> <li>Coordination with ART / LAC Plus / LAC for confirmation of linkages and follow- up</li> <li>Track evaluation at ART centre, initiation of ART and referral back for care</li> <li>Maintaining record of referral, its outcomes, planned place for delivery, planned follow -up dates, person responsible for follow-up etc.</li> <li>Ensure hospital delivery</li> <li>Ensure provision of ARV to baby as prescribed</li> <li>Ensure provision of ART to all direct-in- labour cases</li> <li>Maintain up- to-date recording of all events and communication of the same to District M&amp;E Assistants</li> <li>Ensure linkage of HIV exposed infants (HEIs) to EID</li> </ol>
10	Nurse	<ol style="list-style-type: none"> <li>Nurse at F-ICTCs –all activities mentioned for counsellors</li> <li>Administration of ART (TDF+3TC+EFV) to pregnant women presenting directly- in- labour and initiation of Sy. Nevirapine for 6 weeks to HIV exposed babies</li> </ol>



SI. No.	Designation of Official/staff	Role in PPTCT Implementation
11.	ANM	<ol style="list-style-type: none"> <li>1. Screening test for HIV and Syphilis using WBFPT for all ANCs registered. If reactive, refer to ART, STI and Gene-xpert testing/DMC for TB screening</li> <li>2. Screening the pregnant women for Syphilis using WBFPT, if reactive then refer to STI clinic/PHC for RPR confirmation</li> <li>3. Screening the pregnant women for TB if symptomatic refer to a health facility where Gene-xpert testing is done or PHC with DMC</li> <li>4. Ensure confirmation of HIV status among screened positive ANCs</li> <li>5. Establishing linkage of HIV infected pregnant women to ART CENTRE</li> <li>6. Facilitate institutional deliveries</li> <li>7. Follow-up with the mother after delivery to monitor compliance in ART consumption</li> <li>8. Facilitate linkages of HIV exposed babies to EID</li> <li>9. Provide reminders to mother on ART regarding visit to ART centre, CD4 test, etc.</li> </ol>
12	ICTC Lab technician	<ol style="list-style-type: none"> <li>1. Conduct HIV testing as per guidelines and provide feedback to referring PHC MO regarding status with concurrence of patient</li> <li>2. Liaison with F-ICTCs and Sub-centre screening facility staff for early information on screening positive women and track their arrival for confirmation collection and dispatch of blood specimen for CD4 testing</li> <li>3. Collection and dispatch of blood specimen for CD4 testing</li> <li>4. Maintaining stock of WBFPT for F-ICTCs and sub-centre screening facilities</li> <li>5. Ensure uninterrupted supply of test kits to Screening facility in the jurisdiction with cold -chain maintenance</li> <li>6. Record maintenance and timely reporting to district and state level</li> </ol>
13	Outreach worker (ILFS/ Link-workers, CSC outreach worker, etc.)	<ol style="list-style-type: none"> <li>1. Mobilize pregnant women screened positive with WBFPT to visit ICTC for confirmation</li> <li>2. Facilitate Linkage of HIV infected pregnant women to ART centre or STI clinic or Gene-xpert testing site/DMC for TB</li> <li>3. Facilitate institutional delivery</li> <li>4. Facilitate visit of the HIV Exposed Infants(HEIs) to ICTC for EID</li> <li>5. Facilitate regular follow-up visits to ART centre for ART, CD4 testing etc.</li> <li>6. Home visit to monitor adherence to ART medication</li> <li>7. Liaison with ANMs/ASHAs/Community Outreach Workers/DLNs for follow-up with the infected Pregnant women</li> </ol>
14	Medical Officer of facility conducting positive delivery	<ol style="list-style-type: none"> <li>1. Ensure safe delivery practices, availability of safe delivery KITS</li> <li>2. Ensure continuation of ART during labour and delivery</li> <li>3. Provide ART (TDF+3TC+EFV) for direct- in- labour positive pregnant women and Nevirapine suspension for 6 weeks to HIV exposed new borns</li> <li>4. Ensure confirmation of HIV status of direct-in- labour cases at earliest</li> <li>5. Counsel the infected pregnant women regarding importance of enrolling ART centre and receiving life-long ART</li> <li>6. Counsel infected pregnant women regarding importance of EID</li> </ol>



SI. No.	Designation of Official/staff	Role in PPTCT Implementation
15	ART centre SMO/MO	<ol style="list-style-type: none"> <li>1. Prompt evaluation of HIV infected pregnant women at ART centre</li> <li>2. Prompt initiation of life-long ART (TDF+3TC+EFV) to every infected pregnant women regardless of CD4 levels or clinical stage</li> <li>3. Ensure feedback to referring ICTC regarding receipt of case at ART centre, outcome of evaluation and prescribed drug regimen for the patients</li> <li>4. Formulation of Case Management Team comprising ICTC counsellor, concerned ANM, concerned out-reach worker</li> <li>5. Draw plan for follow-up visits including linkage to LAC in consultation with the infected pregnant women for assessment and drug collection</li> <li>6. Ensure uninterrupted supply of drugs and logistics to LAC-Plus, LAC</li> <li>7. Ensure provision of information on all events to the districts M&amp;E assistant for updating in PPTCT line-lists</li> </ol>
16	ART centre counsellor/ staff nurse	<ol style="list-style-type: none"> <li>1. Prioritisation of HIV infected pregnant women for ART preparedness and adherence counselling</li> <li>2. Counselling on important components of PPTCT programme like role of ART, duration, safe hospital delivery, EID, breastfeeding etc.</li> <li>3. Up-to-date record keeping and documentation of follow-up and ensure tracking of missed cases</li> <li>4. Liaison with referring ICTC counsellor, outreach workers to track compliance and adherence to schedule of follow-up visit to ART centre</li> <li>5. Liaison with referring ICTC counsellor for whole blood specimen testing of DBS positive babies at ART Centres</li> </ol>



Annexures  
(1-20)



## Annex 1: Guidelines for Rolling out NACP and NRHM Convergence Plan in No X-19020/17/2009-NACO (IEC), 10 August 2010



**K. Chandramouli**

*Secretary & Director General*

*Department of AIDS control, NACO, Ministry of Health and Family Welfare, Government of India*

No. X-19020/17/2009-NACO (IEC)

Dated Aug<sup>10</sup> 2010

To,  
Project Director  
All SACS

Dear Project Director


With a view to expand access to quality RCH and HIV services across the country, broad areas of convergence between NRHM & NACP have been identified by MuHFW & NACO to harness optimal utilization of available resources under both the programmes and avoid duplication. A letter under joint signature of undersigned & Secretary Mo HFW addressed to Principal Secretaries/ secretaries of Health & family welfare and Mission Director – NRHM of all states have been issued vide letter no. DO. NO. 4(1)/ 2009/NRHM-1 dated July 27, 2010. ( Copy attached).

PD SACS have to quickly get in touch with state Mission Director and take a lead role in initiating roll out plan with a view to achieve NACPIII objectives. Suggestive action plan and matrix is annexed with this letter to help roll out in the state.

I am sure under your able leadership, the state will be able to reach out to people with services they need under NACP & NRHM.

Encl. as above

Yours sincerely

  
K. Chandramouli  
16/8/10

Copy to:

1. Mission Director-NRHM, MoHFW
2. Mission Directors- NRHM all states.

6th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Phones : 011-23325331, Fax : 011-23731746

E-mail : naccasdg@gmail.com

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ



**Annexure 1 to letter no. No. X-19020/17/2009-NACO (IEC) Dated Aug, 2010**

**Guidelines for rolling out NACP & NRHM Convergence Plan in the state**

The purpose of NACP & NRHM convergence is to improve access of HIV counseling, screening, testing & PPTCT services nearest to people residences, to detect HIV infection on first contact with health system, reduce missed opportunities of early detection of infection, promote birth of HIV free child, improve longevity with quality of life of people living with HIV infection with supportive environment. To roll out plan in line with MoHFW letter no DO. NO. 4(1)/ 2009/NRHM-1 dated July 27, 2010 to improve access to HIV and RCH related services, following actions are required in relation to areas agreed for implementation.

1. **Arrange a meeting with Mission director NRHM to prepare convergence road map for the state and nominate nodal officer in SACS & SPMUs for keeping in regular touch and implement roll out plan.**
2. **Utilization of existing NACP resources for strengthening RCH services:**
  - **Counseling non HIV pregnant women on nutrition, birth spacing and family planning by ICTC counselors**
    - PD – SACS should issue circular to assign a) ICTC counselor the task of counseling non HIV pregnant women on nutrition, birth spacing and family planning in addition to current responsibilities and b) for link workers & outreach workers of NGOs under NACP to under take line listing of HIV as well as non HIV pregnant women and prepare birth plan for them and provide to concerned ASHA.
    - SACS should identify existing ICTC counselors with sub optimal workload for counseling non HIV pregnant and forward the list to state Mission Director.
    - MD- NRHM may arrange for training of ICTC counsellors as per requirement of state & share with PD-SACS.
    - Communication takeaways for the clients may also be developed by SPMU and provided to counselors through district societies.
    - SPMU( State Project management Unit) - NRHM should develop information & monitoring system to capture output from counselors and share with PD- SACS.
    - SPMUs may also compile, monitor & analyze information & provide feedback to PD-SACS.
    - SACS should identify link workers & outreach workers of NGOs under NACP and give list to MD- NRHM
    - Link workers and out reach workers of NGOs to under take line listing of HIV as well as non HIV pregnant women and prepare birth plan for them with referral & linkages with facilities providing maternal and child health services.
    - SPMU may develop Information & monitoring plan in consultation with SACS to review progress.
3. **ASHA training on module “Shaping Our Lives”**
  - All ASHAs are to be trained on module developed by NACO for grass root workers “Shaping Our Lives”
  - NACO is in touch with NHRC for integration of NACO module in ASHA training package VI and develop trainer’s module and training aids.



- MD – NRHM may issue circular expanding the role of ASHA to include HIV related counseling and community mobilization. It has to include apart from counseling, referral services (Maternal and Child Health services, STI, condom promotion, care support and treatment , TB screening) required by HIV positive persons and vulnerable section of village, mobilize VHSC and other panchayat level resources for nutritional, transport and rehabilitation support for PLHA. She should ask to include HIV agenda on VHSC meetings and mobilize VHSC to discuss on steps to reduce stigma & discrimination related to HIV. SACS may help Mission directors in preparing the circular.
- Current module (Shaping Our Lives) is being expanded at NACO level to emphasize:
  - Utilization of VHNDs, village & VHSC meetings for counseling, referral, and sensitization
  - Visit to ICTCs, PPTCT, STI clinic, CCC and ART centers to have experience on activity & approach to the clients
  - A chapter on males vulnerability to HIV, role of PRI
  - Feed back on referral and follow up
  - Reporting & monitoring system
- ASHA facilitators, ANMs and health supervisors should also be trained on the module so as to complement each other and avoid contradictory views.
- Trainers module and training aids are to be developed by NHRC and “Shaping Our Lives’ will be shared with state ASHA resource centers for training. NHRC is being requested to train state resources for training ASHAs and other related staff. NACO will fund for the same.
- MD-NRHM may be requested to provide for funds for state, district & block level trainings.
- SACS to procure district and block wise list of ASHA, ANM and supervisors to be trained from SPMU-NRHM
- State NRHM in consultation with SACS to plan training of district/ block training resources and training of ASHA, ANMs and supervisors
- Instructions may be issued from MD- NRHM for VHND session to have one hour program dedicated for HIV & STI prevention, discussing HIV vulnerabilities of community (adolescents, infected & affected children & women with HIV, migrant & truckers), promotion of correct & consistent use of condom, injection safety, need for stigma & discrimination free environment in village.
- Joint development of information and monitoring system to track training, quality and post training output by ASHAs
- SACS should compile and provide monthly feedback to NACO, MoHFW and MD –state NRHM on ASHA training & output.

#### 4. Inclusion of HIV screening in routine ANC check up

- MD state NRHM may issue instructions to *recommend* and offer routine HIV screening as an integral component of ANC checkup at VHNDs, sub centers and all health facilities. Clients to informed verbally on purpose of test is to facilitate birth of HIV free child (*unborn child has as much right to be born HIV free*) & *consent of the client will be taken and the client will have the right to opt out.*
- NACO will develop crash course to train ANM/ Nurses for undertaking rapid blood test to ensure provision of HIV screening at VHNDs, sub centers and all other health facilities. The training will be done at nearest 24x7 health facility.
- If screening test is positive for HIV, the client will be referred to nearest Integrated Counselling & Testing Centers (ICTCs) for confirmation (which includes a set of three tests).





- **Disclosure of HIV status will be done only at ICTCs after confirmatory test along with pre and post test counseling.**
  - In case of HIV positive pregnancy ( subject to disclosure by client) , outreach workers/ ASHA will prepare birth plan, provide nutritional counseling, arrange for institutional delivery along with PPTCT ( Prevention of Parent To Child Transfer) preventive care for mother & baby pair and post natal care & nutritional counseling for mother & child.
  - NACO will provide rapid blood test kits, training of ANMs/ Nurses/ Lab. technicians.
  - **MD NRHM may plan for wide publicity on availability of HIV screening test for birth of HIV free child (wall writing, posters, brochures and handbills) to sensitize community & service providers with NRHM funds. NACP approved prototype may be used.**
  - SACS and NRHM should have joint information & monitoring system to track progress, bottlenecks and evaluate outcome.
  - SACS should prepare feedback for NACO & NRHM
- 5. Expansion of ICTC & PPTCT services to all 24x7 health facilities**
- Circular from MD- NRHM to districts to upgrade facilities to provide ICTC & PPTCT services with training of existing staff (ANM, nurse, lab. technician) and mandate to provide ICTC and PPTCT services.
  - Existing staff (MO, Nurse, Lab. Technician and ANM) are to be trained on counselling and testing for HIV. STI is already integral component of NRHM, the same staff may be engaged for HIV counseling & testing also. NACO has already provided training courses & resources to the SACS and these should be utilized for the same.
  - All ANC cases found positive in rapid blood test screening for HIV, RTI/STI, vulnerable clients (FSW, IDUs, MSM, truckers etc) and TB patients must be referred to ICTC for counseling & testing to detect HIV infection at the earliest so as to prevent infection in other persons, provide them referrals for quality ART care, improve quality of life & survival and provision of psycho-social support for dealing with vulnerability and infection.
  - All PLHA must be referred to be screened for TB and, if positive, will be put on DOT and vice versa.
  - All 24x7 facility should provide treatment for opportunistic infection from routine budget for the facility
  - All 24x7 facilities must be equipped to undertake HIV screening during delivery and provide PPTCT care and prophylactic ARV to mother and child with nutritional counseling for both .
  - Emergency Post Exposure Prophylactic (PEP) drugs will be provided by NACO or else may be procured from untied funds under NRHM.
  - NACO through SACS will fund for training, testing kits, communication material and prophylactic ARV drug.
  - Facility must have a functional refrigerator for storing ICTC kits and drugs for PPTCT
  - Develop joint information & monitoring system
  - SACS should prepare feedback for NACO & NRHM
- 6. Incentives to Health Care Providers/ WLHIV for conducting deliveries in public health facilities**
- States must ensure stigma & discrimination free services to HIV positive pregnant women and children particularly in low prevalence states at all health facilities.
  - State to consider appropriate incentive per delivery to person conducting delivery of HIV positive women in a government 24x7 health facility.
  - State should consider appropriate additional transport support for pregnant WLHIV for ICTC testing, ART treatment & PPTCT through JSY or untied funds for VHSCs.



- NRHM funds for facility may be utilized for procuring Post Exposure Prophylaxis (PEP) drugs for service providers in case of accidental exposure to HIV at non ART centers. ( NACO is already providing PEP drugs for ART center).
  - Develop information & monitoring system to track progress, and bottlenecks.
  - PD-SACS & MD- state NRHM may coordinate for dissemination, implementation & monitoring of package.
  - SACS should prepare feedback for NACO, NRHM & SPMU
- 7. Training of FP counselors on PPTCT, ANC, STI & nutrition**
- Circular from MD- NRHM to expand role of FP counsellor to include counselling on PPTCT, ANC, STI and nutrition and provide list of FP counsellors to SACS for training
  - Training to be provided by SACS on package developed for ICTC counsellor developed by NACO
  - Funding support from NRHM
  - Develop joint information and monitoring system
- 8. National RTI/STI programme**
- MD- NRHM may issue instructions to concerned officials to adopt uniform service delivery protocols, operational guidelines, training packages & resources, jointly developed by NRHM & NACO for provision of STI/RTI services.
  - SACS will supervise and monitor STI/RTI programme at state level in close coordination with **NRHM/ RCH programme officer.**
  - SACS to provide technical support in training, quality supervision and monitoring of STI/RTI services at all health facilities, thus overseeing the implementation.
  - **Procurement and supply of drugs and testing kits for STI/RTI services for NRHM facilities will continue to be done by NACO with funding support of NRHM at central level**
  - **NRHM/RCH programme officer** will develop annual PIP content of STI/ RTI services in consultation with SACS for training and procurement needs.
  - SACS to prepare feedback for NACO, NRHM and SPMU.
  - **For tracking access, quality, progress and bottlenecks in RTI/STI programme implementation, the common information & monitoring system developed by NACO and NRHM is to be followed.**
- 9. Establishing 29 district level blood banks**
- MD-NRHM will plan for provision of infrastructure & essential manpower for districts without blood banks along with refurbishments while NACO will support with equipment & recurring cost for blood collection, testing, matching and transportation.
  - Districts without blood banks may contact through SACS to NACO when infrastructure and HR arrangements are in place for providing equipments & recurring grants
  - SACS should monitor functionality & quality issues related to blood transfusion services.
  - SACS should prepare feedback for NACO, NRHM and SPMU
- 10. Functioning of blood storage center**
- State NRHM is to ensure availability of essential manpower (existing MO & lab. Technician) and equipment at facility to be upgraded as FRU
  - NACO will fund for training and recurring expenditure for blood storage centers including transportation of blood through SACS.
  - NACP and NRHM will have common information & monitoring system to track progress, and bottlenecks.
  - SACS will prepare feedback for NACO, NRHM and SPMU



11. **Strengthening of Health facilities for OST( Opiate Substitution Therapy)**
  - NACO is in process of standardizing norms for OST. Once finalized, facilities will be identified in consultation with SACS
  - NRHM to provide infrastructure & HR, SACS to provide training and logistics
  - SACS to monitor functionality and quality issues and provide feed back to MD-NRHM, NACO & MoHFW
  - SACS in consultation with NACO will identify facility to be upgraded with OST including storage. NACO will also provide up-gradation and service delivery protocols for OST
  - NACO will support training & logistics
  - Develop joint common information & monitoring system to track progress, and bottlenecks.
  - SACS will prepare feedback for NACO, NRHM and SPMU
  
12. **Convergence management**
  - At state level PD SACS & Mission Director NRHM should meet every quarter along with their nominated officials, if feasible under chairmanship of Principal Secretary H& FW, to review planning, progress and identify bottlenecks in relation to implementation (training, logistics, uptake of services, community mobilization and issues of stigma & discrimination) to sort out problems in implementation. Minutes of meeting along with decisions made will be sent to NACO & NRHM along with compliance report of decisions of previous meeting.
  - By January every year PD- SACS and MD- NRHM should jointly develop training plan for ASHA, para-medical and doctors for next year, assess logistics needs, infrastructure requirement for STI, blood transfusion, ANC, delivery care & post natal services for Women & Children Living with HIV/ AIDS and ICTC services. These components may be reflected in respective annual NRHM- PIP and AWP of SACS in a separate chapter: Convergence with HIV/ NRHM.
  - Annual report of NRHM & NACO may reflect progress and challenges under convergence.
  
13. Single circular may be issued to state and field level functionaries immediately from MD- NRHM & PD-SACS each with consolidated instruction on policy decisions, roles, range of services to be provided, activities to be undertaken , mapping of HR, infrastructure, capacity building resources and other existing inputs.
  
14. Roll out plan will possibly require extensive consultation with state and district officials, bring every one on board, stocktaking, determining phasing and prioritization ( may begin with A&B category of districts) and preparatory phase before actual services are rolled out in the field. It is expected that all necessary ground work may be done by December 2010 so that roll out plans as determined by state may be incorporated in PIP/ AWP of NRHM and NACP respectively. It is further desirable that by end of FY 2010-11, state is able to roll out all the package of identified services in entire state.



10/10

Annexure 2 to letter No. X-19020/17/2009-NACO (TEC) dated August 10, 2010  
NRHM-NACP Convergence Action Matrix

Activity NO	Activity	Action	Action by	Universe	Target for current year	Time line
1	Nomination of state nodal officer	nomination of nodal officers	PD-SACS, MD-NRHM			
2	First Meeting to discuss direction from Govt	Fix date of meeting and invite nodal officers & officials concerned	PD-SACS in consultation with MD-NRHM	NA		
3	Utilization of existing NACP resources for strengthening RCH services	a) Circular on expanded role of ICTC counsellors	PD-SACS			
		b) Preparation of list of ICTC counsellors with sub optimal workload & provided to MD-NRHM	PD-SACS			
		c) Development of training material	MD-NRHM			
		d) Identification of state/regional trainers	MD-NRHM			
		e) Identification of training sites	MD-NRHM			
		f) Refurbishing of training site	MD-NRHM			
		g) Preparation of trainee list for year 2010-11	MD-NRHM			
		h) Training calendar/ plan	MD-NRHM			
		i) TOT	MD-NRHM			
		j) Training of ICTC counsellors	MD-NRHM			
		k) Monitor output of ICTC counsellors	MD-NRHM, PD-SACS, CMOs			
		a) Circular on expanded role of link workers & outreach workers of NGOs	PD-SACS			
		b) Preparation of list of link workers & outreach workers of NACP NGOs and provide to MD-NRHM	PD-SACS			
		c) Provision of list of functional health facilities providing maternal & child health services to link workers & outreach workers	CMO			
		d) Monitor output of LW / ORWs	MD-NRHM, PD-SACS, CMOs			
3	Training all ASHAs/ ANMs/ Supervisors on NACO training module "shaping our lives" for grass root workers	a) Circular on expanded role of ASHA & ANM, on dedicated session on services, counselling & referrals related to HIV in VHNDs, village meetings & VHSC to be utilized for discussion vulnerabilities of communities, condom promotion, migration, adolescent health issues, support of infected & affected persons with HIV, stigma & discrimination issues	MD-NRHM			
		b) Preparation of list of ASHA, ANM and supervisors	CMOs	ASHA: ANM: Supervisors:	To be trained ASHA: ANM: Supervisors:	
		c) Updation of training material including trainers module & tools	NACO in consultation with NHRC			
		d) Identification of state trainers/ resources	MD-NRHM/ state ASHA resource center			
		e) Identification/ list of training sites	MD-NRHM/ A, JI, resource centers			
		f) Refurbishing of training site	MD-NRHM/ ASHA resource centers			
		g) Preparation of trainee list for year 2010-11	MD-NRHM/ ASHA resource centers			
		h) Training calendar/ plan	MD-NRHM/ ASHA resource centers			
		i) procurement of training material	MD-NRHM/ ASHA resource centers			
		j) TOT of state resources	NACO/ NHRC			
		k) Training of regional/ district trainers	MD-NRHM/ ASHA resource centers			
		l) Training of ASHA, ANM & supervisors	CMO			
		m) post training follow up plan in place				
		k) Monitor output of ASHA, ANM	CMOs, PD-SACS, MD-NRHM			
4	Universal HIV screening as part of routine ANC check up	a) Circular on expanded ANC coverage to include recommendation and offer of HIV screening of all pregnant women at VHNDs and all health facilities ( including sub centers) for birth of HIV free child	MD-NRHM			



		b) Preparation of list of Nurses, ANM for training on utilization of rapid blood test kit	CMOs	Nurses ANM: LTs:	To be trained : Nurses ANM: LTs:
		c) Development of crash course for rapid blood testing to train ANM, nurses, & LTs	NACO		
		d) Identification of 24x7 facilities as training sites & ICTC LTs to train nurses, ANM & LTs (non ICTCs)	MD- NRHM, PD- SACS/ CMOs		
		e) Training calendar/ plan	CMOs/ PD-SACS		
		f) procurement of training material	PD- SACS		
		g) training of ANM, nurses & LTs	CMOs/ PD- SACS ( funded by NACO)		
		h) Forecasting & indenting of rapid blood test kits to PD-SACS	CMO, MD- NRHM		
		i) Procurement of referral slips for ICTC	PD-SACS/ CMOs		
		j) Order regarding Disclosure of HIV status only at ICTC after post referral confirmation, preparation of birth plan & PPTCT referral post confirmation	MD-NRHM, PD SACS		
		k) Procurement of rapid blood test kits	NACO		
		l) Publicity on availability of HIV screening	MD-NRHM/ CMOs		
		Development of information & monitoring system	PD-SACS in consultation with MD-NRHM		
5	Expansion of ICTC and PPTCT services to all 24x7 health facilities	a) Circular to strengthen all 24x7 health facilities with ICTC services, attend referral of all STL TB cases for testing HIV & vice versa, assured availability of PPTCT services	MD NRHM		
		b) provide list of 24x7 health facilities(non ICTCs) with names of nurses, ANMs & LTs to SACS	MD- NRHM	Nurses ANM: LTs:	To be trained : Nurses ANM: LTs:
		c) Identification of training sites & resources for ICTC / PPTCT training	PD-SACS		
		e) Training calendar/ plan	CMOs/ PD-SACS		
		f) procurement of training material	PD- SACS		
		g) training of ANM, nurses & LTs	CMOs/ PD- SACS ( funded by NACO)		
		d) Forecasting & indenting of ICTC kits, PPTCT ARV drugs	PD- SACS/ CMOs		
		h) Procurement of referral slips for ICTC	PD-SACS/ CMOs		
		i) Procurement of ICTC kits, PPTCT ARV drugs	NACO		
		l) Publicity on availability of ICTC/ PPTCT services	PD- SACS		
		Development of information & monitoring system	PD-SACS in consultation with MD-NRHM		
		Procurement of PEP drugs	NACO or untide funds for facility		
6	Incentive to health care providers conducting deliveries of HIV positive women & transport support to HIV positive pregnant women for additional visits to health facilities	a) Order to all health facilities to provide discrimination & stigma free services to all PLHA	MD-NRHM		
		b) states may decide appropriate incentive/ transport support per visit to service providers and pregnant WLHIV	MD- NRHM		
		c) Publicity of incentive/ support	MD-NRHM, PD- SACS		
		d) development of information & monitoring system	PD- SACS in consultation with MD-NRHM		
7	Training FP counsellors on PPTCT, ANC, STI & nutrition	a) Order to all FP counsellors to provide counselling on PPTCT, ANC, STI & nutrition	MD-NRHM		
		b) Prepare list of FP counsellors to be trained	MD-NRHM		
		c) Compilation of training material	PD- SACS: existing PPTCT & STI material MD- NRHM: ANC & nutrition		
		d) Preparation of training plan	PD- SACS		
		e) Monitoring plan	MD-NRHM		



8 National RTI/STI programme	a) Order to all CMOs regarding monitoring & supervision of the program, training, quality and access of services to community, health facilities to follow NACO approved standard operative protocols, procurement of colour coded drug kits by NACO through SACS	MD-NRHM			
	b) Prepare list of health facilities with MO & LT in place either regular or contractual	CMO/MD-NRHM			
	c) List of facilities where MO & LT are already trained on NACO modules	CMO/ MD-NRHM			
	d) List of facilities where MO& LTs are to be trained	CMO/MD-NRHM			
	e) Forecasting of drug kits	CMO/ MD-NRHM			
	f) Review & refine information, supervision & monitoring process for monitoring access & quality	PD-SACS/MD-NRHM			
9 Establishing district level blood bank	a) Identification of districts without district level blood banks	PD-SACS			
	b) Inclusion of establishing district level blood banks in NRHM annual PIP	MD-NRHM			
	c) Development of infrastructure, refurbishing & deployment of HR as per national blood safety norms & inform PD SACS once in place	Supdt, DH/MD-NRHM			
	e) Once infrastructure & HR are in place, NACO/ SACS to supply equipment, recurring cost for blood collection, testing, matching and transportation	DS-SACS/ NACO			
	f) Circular on SACS to monitor functionality & quality of blood transfusion services	MD-NRHM			
	10 Functioning of blood storage centers	a) Identification of FRUs without blood storage centers	CMO, MD-NRHM		
b) Inclusion of establishing blood storage centers in NRHM annual PIP		MD-NRHM			
c) Development of infrastructure, refurbishing & deployment of HR as per national blood safety norms & inform PD SACS once in place		CMO/MD-NRHM			
e) Once infrastructure & HR are in place, NACO/ SACS to supply equipment, recurring cost for matching and transportation		DS-SACS/ NACO			
f) Circular on SACS to monitor functionality & quality of blood transfusion services		MD-NRHM			
11 Strengthening Health facilities for OST		a) Identification of facilities to be strengthened with OST	NACO/ PD-SACS		
	b) Developing norm for infrastructure, HR and service delivery protocols	NACO			
	c) Provision of infrastructure & HR	MD- NRHM			
	d) training of HR & logistics	NACO, PD-SACS			



**K.Sujatha Rao**

Secretary (H&FW)  
Department of Health and Family Welfare  
Ministry of Health and Family Welfare

**K.Chandramouli**

Secretary & Director General (NACO)  
Department of AIDS Control, NACO  
Ministry of Health and Family Welfare

D.O. No. 4(1)/2009/NRHM-I

New Delhi, Dated 27<sup>th</sup> July, 2010

Dear \_\_\_\_\_,

**Sub: NRHM & National AIDS Control Programme (NACP) convergence.**

A joint meeting to take intra sectoral convergence further was held between the Department of Health & FW and Department of AIDS Control.

Based on deliberations, following decisions as actionable points for States have been firmed up to harness optimal utilization of resources under NRHM and NACP and also to avoid duplication, for your consideration:

- Universal HIV screening to be included as an integrated component of ANC check up. VHNDs may be utilized for rapid blood test and positive cases to be referred to ICTCs for confirmation. Positive status to be only disclosed to client at ICTCs along with pre and post test counseling.
- The counselors at ICTCs to also counsel the non HIV pregnant women on nutrition, STI and birth spacing.
- The link workers & outreach worker of NGOs under NACP to undertake line listing of all pregnant women and prepare birth plan for non HIV women as well.
- ASHAs to be trained also on the module " Shaping Our Lives" developed by NACO for all field level workers as part of package VI for training ASHA and to also cover ANM and supervisors.
- ASHAs to also provide ANC and STI counseling, referral, pre and post natal care for mother & newborn and mobilize VHSC and other panchayat level resources for nutritional, transport and other support required by HIV positive persons.
- All 24x7 health facilities to be strengthened to provide ICTC services through training of existing staff (Nurses, ANM and lab. Technician). SACS to train the staff and provide rapid HIV kits.
- All 24x7 facilities to also provide PPTCT services through existing trained staff along with labor room testing. SACS to provide prophylactic drugs.
- To improve access to maternal health services to HIV positive women, states may consider appropriate incentive to service providers conducting deliveries in 24x7 facilities. States may also consider additional transport support for HIV positive pregnant women visiting health facilities under untied funds for VHSC.




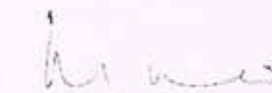
- FP Counselors may also be trained on STI, PPTCT, ANC and nutrition for improved range of counseling and access to services. SACS may be involved in insensinating training on STI and PPTC.
- For national STI programme, NACO/SACS to continue to monitor and supervise the programme through technical support in training, quality supervision and monitoring access of STI services at facility level and procurement of colour coded drug kits.
- Infrastructure upgradation including augmentation of human resources for the identified 29 districts in the country not having blood banks to be taken up by States on priority under NRHM. SACS to provide Kits, Equipment/ and may take up Refurbishment/ Retro-fitting works, if feasible.
- States to provide support of infrastructure development works under NRHM for Blood storage Centers at FRUs under NRHM and also to ensure that existing Medical Officers and Laboratory Technicians work for blood transfusion services in addition to their duties. SACS to be approached for procurement of equipments, training and recurring expenditure.
- SACS to identify public facilities to be strengthened for OST (Opiate Substitution Therapy) and frame norms for the same. States may support setting up of facility under NRHM.
- All HIV patients to be screened for TB and vice versa
- SACS to take care of Condom Promotion in high prevalence states & in the remaining areas support to be provided by States under NRHM.
- As a follow up to above points PD SACS and MD, NRHM may nominate nodal officers to develop implement and monitor the aforesaid plan.
- At state level PD SACS & Mission Director NRHM may meet each quarter along with their nominated officials, to review planning, progress and identify bottlenecks in relation to implementation.
- State may reflect above convergence plan in their respective Annual NRHM- PIPs and AWP of SACS in the chapter on Convergence.

We would be grateful for action taken and an early intimation to the Ministry on the aforesaid strategies.

With Regards,

Yours sincerely,

  
(K. Chandramouli)

  
(K. Sujatha Rao)

Secretary/Principal Secretary  
Department of Health and & FW  
All states/UTS (as per list enclosed)

Copy to  
Mission Director (NRHM)  
All States/ UTs (as per list enclosed)





## Annex 2: 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

## Annex 3: ART for Pregnant Women Presenting in Active Labour with No. Prior ART

Maternal Status	Intrapartum	Postpartum
Presenting in active labour, No Prior ARV prophylaxis	TDF 300mg once daily 3TC 300 mg once daily EFV 600mg once daily	TDF 300mg once daily 3TC 300 mg once daily EFV 600mg once daily

## Annex 4: 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 paediatrician 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

## Annex 5: WHO Clinical Staging for Adults and Adolescents

<b>CLINICAL STAGE 1</b>
Asymptomatic Persistent generalized lymphadenopathy
<b>CLINICAL STAGE 2</b>
Moderate unexplained 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 pruritic eruptions Seborrhoeic dermatitis Fungal nail infections

### CLINICAL STAGE 3

Unexplained<sup>a</sup> severe weight loss (over 10% of presumed or measured body weight)<sup>b</sup>  
Unexplained<sup>a</sup> chronic diarrhoea for longer than one month  
Unexplained<sup>a</sup> 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  
Unexplained<sup>a</sup> 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 jirovecii 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 leukoencephalopathy  
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.*

*Source: Revised WHO clinical staging and immunological classification of HIV for surveillance. 2006 (in press).*



## Annex 6: Grading of Selected Clinical and Laboratory Toxicities (Reference: WHO 2010 Guidelines for ART in Adults and Adolescents)

	Mild Grade 1	Moderate Grade 2	Severe Grade 3	Potentially life- threatening Grade 4
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### Estimating severity grade

	Mild Grade 1	Moderate Grade 2	Severe Grade 3	Potentially life- threatening Grade 4
Clinical adverse event Not identified elsewhere in the table	Symptoms causing no or minimal interference with usual social and functional activities	Symptoms causing greater than minimal interference with usual social and functional activities	Symptoms causing inability to perform usual social and functional activities	Symptoms causing inability to perform basic self-care or medical or operative intervention indicated to prevent permanent impairment, persistent disability or death
Haemoglobin	8.0–9.4 g/dl OR 80–94 g/l OR 4.93–5.83 mmol/l	7.0–7.9 g/dl OR 70–79 g/l OR 4.31–4.92 mmol/l	6.5–6.9 g/dl OR 65–69 g/l OR 4.03–4.30 mmol/l	< 6.5 g/dl OR < 65 g/l OR < 4.03 mmol/l
Absolute neutrophil count	1000–1500/mm <sup>3</sup> or 1.0–1.5/g/l*	750–999/mm <sup>3</sup> OR 0.75–0.99/g/l*	500–749/mm <sup>3</sup> OR 0.5–0.749/g/l*	<500/mm <sup>3</sup> OR <0.5/g/l*
Platelets	75000–99000/mm <sup>3</sup> OR 75–99/g/l*	50000–74999/mm <sup>3</sup> OR 50–74.9/g/l*	20000–49999/mm <sup>3</sup> OR 20–49.9/g/l*	<20000/mm <sup>3</sup> OR <20/g/l*

### Chemistries

Hyperbilirubinaemia	>1.0–1.5 x ULN	>1.5–2.5 x ULN	>2.5–5 x ULN	>5 x ULN
Glucose (fasting)	110–125 mg/dl	126–250 mg/dl	251–500 mg/dl	> 500 mg/dl
Hypoglycaemia	55–64 mg/dl OR 3.01–3.55 mmol/l	40–54 mg/dl OR 2.19–3.00 mmol/l	30–39 mg/dl OR 1.67–2.18 mmol/l	<30 mg/dl OR <1.67 mmol/l
Hyperglycaemia (nonfasting and no prior diabetes)	116–160 mg/dl OR 6.44–8.90 mmol/l	161–250 mg/dl OR 8.91–13.88 mmol/l	251–500 mg/dl OR 13.89–27.76 mmol/l	>500 mg/dl OR >27.76 mmol/l
Triglycerides	-	400–750 mg/dl OR 4.52–8.47 mmol/l	751–1200 mg/dl or 8.48–13.55 mmol/l	>1200 mg/dl or >13.55 mmol/l
Creatinine	>1.0–1.5 x ULN	>1.5–3.0 x ULN	>3.0–6.0 x ULN	>6.0 X ULN
AST (SGOT)	1.25–2.5 x ULN	>2.5–5.0 x ULN	>5.0–10.0 x ULN	>10.0 x ULN
ALT (SGPT)	1.25–2.5 x ULN	>2.5–5.0 x ULN	>5.0–10.0 x ULN	>10.0 x ULN
GGT	1.25–2.5 x ULN	>2.5–5.0 x ULN	>5.0–10.0 x ULN	>10.0 x ULN
Alkaline phosphatase	1.25–2.5 x ULN	>2.5–5.0 x ULN	>5.0–10.0 x ULN	>10.0 x ULN



	Mild Grade 1	Moderate Grade 2	Severe Grade 3	Potentially life-threatening Grade 4
<b>Chemistries</b>				
Bilirubin	1.1–1.5 x ULN	1.6–2.5 x ULN	2.6–5.0 x ULN	> 5 x ULN
Amylase	>1.0–1.5 x ULN	>1.5–2.0 x ULN	>2.0–5.0 x ULN	> 5.0 x ULN
Pancreatic amylase	>1.0–1.5 x ULN	>1.5–2.0 x ULN	>2.0–5.0 x ULN	> 5.0 x ULN
Lipase	>1.0–1.5 x ULN	>1.5–2.0 x ULN	>2.0–5.0 x ULN	> 5.0 x ULN
Lactate	<2.0 x ULN without acidosis	>2.0 x ULN without acidosis	Increased lactate with pH <7.3 without life- threatening consequences	Increased lactate with pH <7.3 without life- threatening consequences
<b>Gastrointestinal</b>				
Nausea	Mild OR transient; reasonable intake maintained	Moderate discomfort OR intake decreased for <3 days	Severe discomfort OR minimal intake for <sup>3</sup> 3 days	Hospitalisation required
Vomiting	Mild OR transient; 2-3 episodes per day OR mild vomiting <1 week	Moderate OR persistent; 4-5 episodes per day OR vomiting lasting <sup>3</sup> 1 week	Severe vomiting of all foods/fluids in 24 hours OR orthostatic hypotension OR intravenous treatment required	Hypotensive shock OR hospitalisation for intravenous treatment required
Diarrhoea	Mild OR transient; 3-4 loose stools per day OR mild diarrhoea lasting <1 week	Moderate OR persistent; 5-7 loose stools per day OR diarrhoea lasting <sup>3</sup> 1 week	Bloody diarrhoea OR orthostatic hypotension OR <sup>3</sup> 7 loose stools/day OR intravenous Rx required	Hypotensive shock OR hospitalisation required
<b>Respiratory</b>				
Dyspnoea	Dyspnoea on exertion	Dyspnoea with normal activity	Dyspnoea at rest	Dyspnoea requiring O <sub>2</sub> therapy
<b>Urinalysis</b>				
Proteinuria				
Spot urine	1+	2+ or 3+	4+	Nephrotic syndrome
24-hour urine	200 mg to 1 g loss/day OR <0.3% OR <3 g/l	1 g to 2 g loss/day OR 0.3% to 1.0% OR 3 g to 10 g/l	2 g to 3.5 g loss/day OR > 1.0% OR >10 g/l	Nephrotic syndrome OR >3.5 g loss/day
Gross haematuria	Microscopic only	Gross, no clots	Gross plus clots	Obstructive



	Mild Grade 1	Moderate Grade 2	Severe Grade 3	Potentially life- threatening Grade 4
<b>Miscellaneous</b>				
Fever (Oral, >12 hours)	37.7-38.5°C OR 100.0 -101.5°F	38.6-39.5°C OR 101.6 -102.90F	39.6- 40.5°C OR 103 -105°F	> 40.5°C OR > 105°F for <sup>3</sup> 12 continuous hours
Headache	Mild; no treatment required	Moderate OR non- narcotic analgesia Rx	Severe OR responds to initial narcotic treatment	Intractable
Allergic reaction	Pruritus without rash	Localized urticaria	Generalized urticaria, angioedema	Anaphylaxis
Rash hypersensitivity	Erythema, pruritus	Diffuse maculopapular rash OR dry desquamation	Vesiculation OR moist desquamation OR ulceration	ANY ONE OF: mucous membrane involvement, suspected Stevens- Johnson (TEN), erythema multiforme, exfoliative dermatitis
Fatigue	Normal activity reduced by < 25%	Normal activity reduced by 25-50%	Normal activity reduced by > 50%; cannot work	Unable to care for self

Source: Division of AIDS, National Institute of Allergy and Infectious Diseases, version 1.0 December 2004, clarification August 2009

NOTE: This clarification includes the addition of Grade 5 toxicity, which is death.

For abnormalities not found elsewhere in the toxicity table, use the information on estimating severity grade in the first column.



## Annex 7: Postpartum Depression Screening Tool—The Edinburgh Scale

### Edinburgh Postnatal Depression Scale<sup>1</sup> (EPDS)

Name: \_\_\_\_\_ Address: \_\_\_\_\_

Your Date of Birth: \_\_\_\_\_

Baby's Date of Birth: \_\_\_\_\_ Phone: \_\_\_\_\_

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

#### Here is an example, already completed.

I have felt happy:

-- Yes, all the time

Yes, most of the time

-- No, not very often

-- No, not at all

This would mean: "I have felt happy most of the time" during the past week. Please complete the other questions in the same way.

#### In the past 7 days:

1. I have been able to laugh and see the funny side of the things

-- As much as I always could

-- Not quite so much now

-- Definitely not so much now

-- Not at all

4. I have been anxious or worried for no good reason

-- No, Not at all

-- Hardly ever

-- Yes, sometimes

-- Yes, very often

2. I have looked forward with enjoyment to things

-- As much as I ever did

-- Rather less than I used to

-- Definitely less than I used to

-- Hardly at all

\*5. I have felt scared or panicky for no very good reason

-- Yes, quite a lot

-- Yes, sometimes

-- No, not much

-- No, not at all

\*3. I have blamed myself unnecessarily when things went wrong

-- Yes, most of the time

-- Yes, some of the time

-- Not very often

-- No, never

\*6. Things have been getting on top of me

-- Yes, most of the time I haven't been able to cope at all

-- Yes, sometimes I haven't been coping as well as usual

-- No, most of the time I coped quite well

-- No, I have been coping as well as ever



\*7. I have been so unhappy that I have had difficulty sleeping

- Yes, most of the time
- Yes, sometimes
- Not very often
- No, not at all

\*8. I have felt sad or miserable

- Yes, most of the time
- Yes, quite often
- Not very often
- No, not at all

\*9. I have been so unhappy that I have been crying

- Yes, most of the time
- Yes, quite often
- Only occasionally
- No, never

\*10. The thought of harming myself has occurred to me

- Yes, quite often
- sometimes
- Hardly ever
- Never

Administered/Reviewed by \_\_\_\_\_ Date \_\_\_\_\_

<sup>1</sup>Source: Cox, J.L. Holden, J.M. and Sagovsky, R.1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal

Depression Scale. *British Journal of Psychiatry* 150:782-786.

<sup>2</sup>Source: K.L. Wisner, B.L. Parry, C.M. Piontek, *Postpartum Depression N Engl J Med* Vol. 347, No 3, July 18, 2002, 194-199  
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## Edinburgh Postnatal Depression Scale<sup>1</sup> (EPDS)

Postpartum depression is the most common complication of child bearing.<sup>2</sup> The 10-question Edinburgh Postnatal Depression Scale (EPDS) is a valuable and efficient way of identifying patients at risk for “perinatal” depression. The EPDS is easy to administer and has proven to be an effective screening tool.

Mothers who score above 13 are likely to be suffering from a depressive illness of varying severity. The EPDS score should not override clinical judgment. A careful clinical assessment should be carried out to confirm the diagnosis. The scale indicates how the mother has felt *during the previous week*. In doubtful cases it may be useful to repeat the tool after 2 weeks. The scale will not detect mothers with anxiety neuroses, phobias or personality disorders.

Women with postpartum depression need not feel alone. They may find useful information on the web sites of the National Women’s Health information Centre <[www.4women.gov](http://www.4women.gov)> and from groups such as Postpartum Support International <[www.chss.iup.edu/postpartum](http://www.chss.iup.edu/postpartum)> and Depression after Delivery <[www.depressionafterdelivery.com](http://www.depressionafterdelivery.com)>

### Questions 1, 2, & 4 (without an \*) Scoring

Are scored 0, 1, 2 or 3 with top box scored as 0 and the bottom box scored as 3.

### Questions 3, 5-10 (marked with an \*)

Are reverse scored, with top box scored as 3 and the bottom box scored as 3.

Maximum score: 30

Possible Depression: 10 or greater

Always look at item 10 (suicidal thoughts)

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### Instructions for using the Edinburgh Postnatal Depression Scale:

1. The mother is asked to check the response that comes closest to how she has been feeling in the previous 7 days.
2. All the items must be completed.
3. Care should be taken to avoid the possibility of the mother discussing her answers with others. (Answers come from the mother or pregnant woman.)
4. The mother should complete the scale herself, unless she has limited English or has difficulty with reading.

<sup>1</sup>Source: Cox, J.L. Holden, J.M. and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786.

<sup>2</sup>Source: K.L. Wisner, B.L. Parry, C. M. Piontek, *Postpartum Depression N Engl J Med* vol 347, No 3, July 18, 2002, 194-199


















## Annex 8: Comparing Effectiveness of Family Planning Methods

### Comparing Effectiveness of Methods

#### More Effective

Less than 1 pregnancy per 100 women in one year

#### How to make your method most effective

 <p><b>Implants</b></p>  <p><b>Vasectomy</b></p>  <p><b>Female Sterilization</b></p>  <p><b>IUD</b></p>	<p>After procedure, little or nothing to do or remember</p> <p><b>Vasectomy:</b> Use another method for first 3 months</p>
 <p><b>Injectables</b></p>  <p><b>LAM</b></p>  <p><b>Pills</b></p>	<p><b>Injections:</b> Get repeat injections on time</p> <p><b>LAM (for 6 months):</b> Breastfeed often, day and night</p> <p><b>Pills:</b> Take a pill each day</p>
 <p><b>Male Condoms</b></p>  <p><b>Female Condoms</b></p>  <p><b>Diaphragm</b></p>  <p><b>Fertility-Awareness Based Methods</b></p>	<p><b>Condoms, diaphragm:</b> Use correctly every time you have sex</p> <p><b>Fertility-awareness based methods:</b> Abstain or use condoms when fertile. Newest methods (Standard Days Method and Two Day Method) may be easier to use.</p>
 <p><b>Withdrawal</b></p>  <p><b>Spermicide</b></p>	<p><b>Withdrawal, Spermicide:</b> Use correctly every time you have sex</p>

#### Less effective

About 30 pregnancies per 100 women in one year

Reference: *Reproductive Choices and Family Planning for People Living with HIV Counselling Tool* (<http://www.who.int/hiv/pub/toolkits/rhr/en/index.html>)



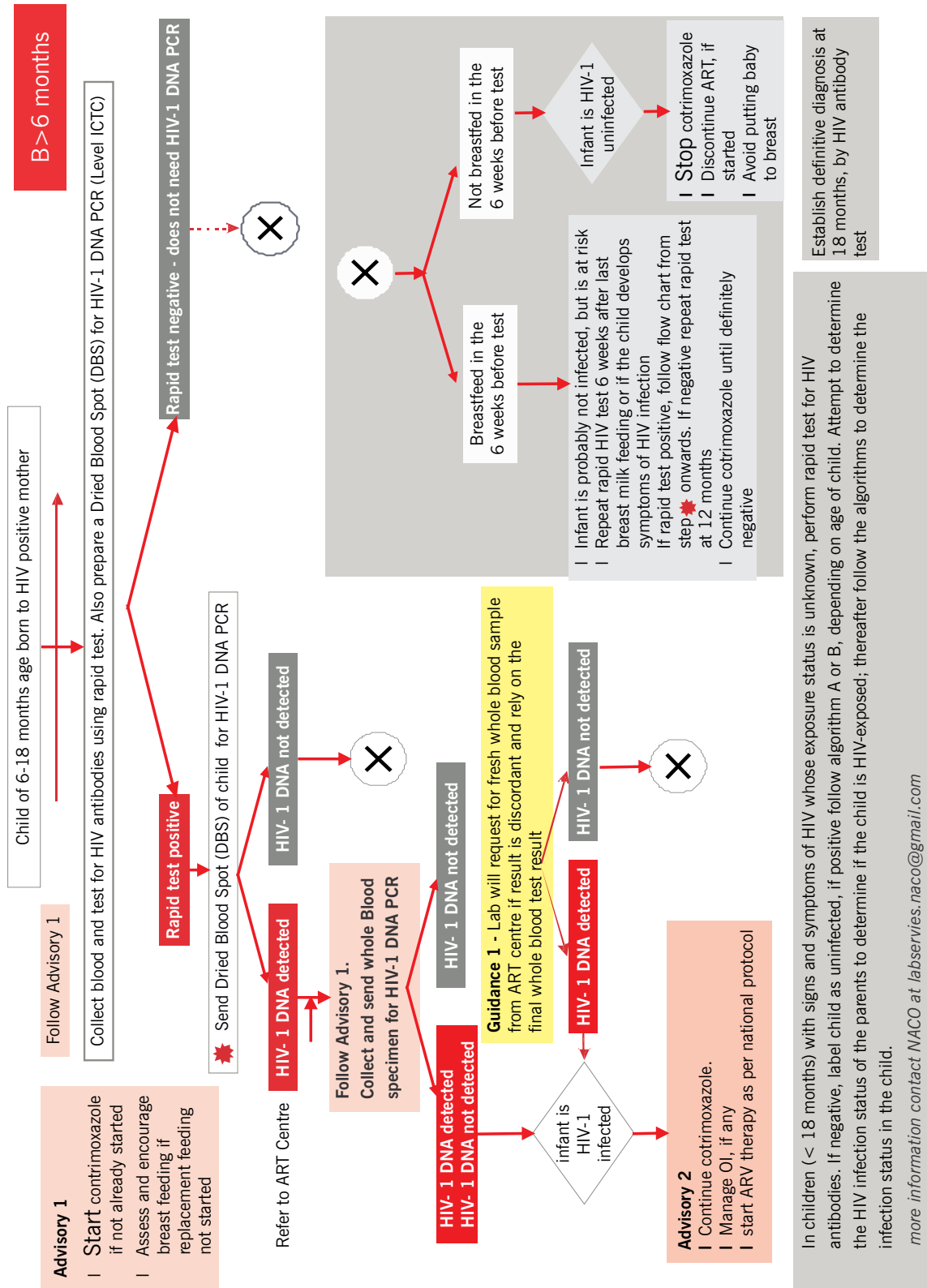
# Annex 9: Flowchart on Counselling Mothers and their Families on Infant Feeding Options 0-6 Months of Age Counselling the HIV infected mothers and her family for infant feeding options: 0-6 months

<p><b>1. Ask about the mother HIV/ART status, home &amp; family situation</b></p> <ul style="list-style-type: none"> <li>Does her family know her HIV status? Does she know her husband's HIV status?</li> <li><b>Is her husband/family supportive and willing to help baby care?</b></li> <li>Family income per month</li> <li><b>Source of drinking water</b> 1. Type of latrine/toilet used</li> <li>Can she prepare each feed with boiled water and clean utensils eg. up to 12-15 times per day in the first 4 months of baby's life</li> <li>Can she prepare feeds at night?</li> <li>What is her latest CD4 count and is she taking ART or PPTCT regimen?</li> <li>Does she plan to deliver in the health facility or go back to parent's house, somewhere else? (need to plan referral to other CFCs)</li> </ul>	<p><b>3. Discuss Exclusive Replacement Feeding (ERF) as a feeding option if mother cannot breastfeed and only if the 6 criteria for RF are fulfilled as below</b></p> <p><b>Advantages:</b></p> <ul style="list-style-type: none"> <li>Norsk of HIV transmission</li> <li>ERF milks can be given by other persons</li> </ul> <p><b>Disadvantages:</b></p> <ul style="list-style-type: none"> <li>Animal milk is not a complete food for baby</li> <li>Formula milk is a complete food but expensive (about 8,000 to 10,000 Rupees for 6 months)</li> <li>Baby has more risk of infections-diarrhoea, respiratory and ear infections and malnutrition</li> <li>Careful and hygienic preparation required each time: Sterilize feeding cups, using boiled water and fresh preparation of all feeds 12-15 times in the first 4 months of baby's life.</li> </ul>	<p><b>6. Explain the chosen feeding option</b></p> <p>Exclusive breastfeeding for 6 months:</p> <ul style="list-style-type: none"> <li>ERF means giving <b>only</b> breast milk and no other liquids or solids, not even water with the exception of medicines</li> <li><b>NO "mixed" feeding</b> (ie. breastfeeding and giving other feeds) - animal or formula milk can irritate the lining of the infant's stomach, causing inflammation and making it easier for the HIV virus in breast milk to get into the baby's body</li> <li>Breastfeeding: Discuss and demonstrate correct attachment to nipple and positioning of baby</li> <li><b>Discuss</b> prevention and treatment of cracked nipples, expressed some breast milk after baby has finished and rub over nipple</li> <li><b>Discuss</b> prevention and treatment of mastitis: breastfeed frequently and feed until the breast is empty. Avoid breast engorgement.</li> <li><b>Discuss</b> prevention and treatment of oral ulcers and oral thrush in infant</li> <li><b>Discuss</b> breast and hand hygiene for mother, and oral hygiene for baby</li> </ul> <p><b>Exclusive Replacement Feeding for 6 months:</b></p> <ul style="list-style-type: none"> <li><b>Discuss and</b> demonstrate the amount to be fed</li> <li>Tell mother to prepare according to instructions with scoop (if formula feeding)</li> <li><b>Discuss</b> hygienic preparation of feeds: <ul style="list-style-type: none"> <li>Hand washing with soap</li> <li>Clean utensils and surface</li> <li>Boiled water</li> <li>Prepare enough for one feed</li> <li>Throw away leftover feed if baby does not finish</li> <li>Do not re-use leftover feeds as it may lead to food poisoning</li> </ul> </li> </ul>	<p><b>7. Provide follow-up counselling and support at every visit</b></p> <p><b>About Baby:</b></p> <ul style="list-style-type: none"> <li>Ask about the progress on infant feeding</li> <li>Ask about baby's immunization: cotrimoxazole dosing, EID status; infant NVP prophylaxis adherence and monthly refill</li> <li>Ask about baby's growth &amp; health, look for signs of illness and malnutrition</li> <li>Assess if further action or doctor's check is required and advise</li> <li><b>Discuss about</b> complementary feeding at 6 months of age and whether to continue or stop breastfeeding</li> </ul> <p>For HIV-infected Children &lt;2 years old: check that baby is initiated on ART, encourage breastfeeding to continue till 2 years of age</p> <p>For breastfeeding infants still on infant NVP daily prophylaxis or mothers on ART or PPTCT option B: check baby's adherence to daily NVP; encourage mother to continue breastfeeding till 12 months. Infants should start complementary feeding at 6 months of age</p> <p>Follow IMNCI guidelines for complementary feeding, see National Guidelines for nutrition for HIV affected and infected infants and children, NACO 2011.</p> <p><b>About mother</b></p> <ul style="list-style-type: none"> <li>Ask how mother &amp; family is coping with the baby</li> <li>Ask for mother's mood changes (screen for postpartum depression)</li> <li>Family planning/contraception and birth spacing</li> <li>Give condoms and reinforce consistent condom use</li> <li>Ask status and progress for pre-ART or ART care</li> <li>Reinforce adherence to ART or PPTCT regimen</li> <li>Refer to ART centre as appropriate</li> </ul>	<p><b>8. Counselling for stopping breastfeeding</b></p> <ul style="list-style-type: none"> <li>Form other on ART for her own health; continue ART</li> <li>For infants still on infant NVP prophylaxis or mothers</li> <li>Do not stop breastfeeding abruptly; gradually cut down the number of breastfeeding sessions a day according to comfort of mother and infant over one month</li> <li>Ensure complementary feeding is nutritionally adequate and safe</li> <li>Check for growth and nutritional status of baby</li> <li>Once breastfeeding is stopped completely, <b>DO NOT</b> put baby back to breast for any suckling</li> </ul>
<p><b>2. Counsel for breastfeeding</b></p> <ul style="list-style-type: none"> <li>Exclusive breastfeeding is recommended during the first 6 months of life, as it has more benefits to baby and mother</li> </ul> <p><b>Explain: Breastfeeding is recommended</b></p> <p><b>Advantages:</b></p> <ul style="list-style-type: none"> <li>Complete nutrition for baby for 6 months</li> <li>Antibodies in breast milk protect against infections</li> <li>Babies on breastfeeding do not usually have health problems like diarrhoea, pneumonia, ear infections</li> <li>Always available, free of cost</li> <li>Most convenient, no need to prepare or get out of bed at night</li> </ul> <p><b>Disadvantages:</b></p> <ul style="list-style-type: none"> <li>Breast milk contains HIV virus, however ART or PPTCT regimen will significantly prevent the transmission of HIV virus during breastfeeding</li> </ul>	<p><b>4 Explain the risks of parent-to-child transmission</b></p> <p><b>If mother or baby is taking ART or PPTCT regimen drug schedules, explain:</b></p> <ul style="list-style-type: none"> <li>That the risk of HIV transmission from mother to child is very low because the ART drugs will reduce the numbers of HIV virus in the breast milk</li> <li>When mother or baby is taking ARV drugs, less than 5 babies out of 100 babies may be HIV infected</li> <li>It is important to take the ART drugs as prescribed -reinforce adherence of ART or PPTCT regimen.</li> </ul> <p><b>If mother is not on ART or mother/infant not receiving new PPTCT regimen (eg. in the districts which are still using AZ-NVP during the scale up of new PPTCT guidelines), explain:</b></p> <ul style="list-style-type: none"> <li>During the first 6 months of life, it is important to keep the child healthy by good feeding practices</li> <li>ERF is recommended because breast milk contained antibodies which protect the babies from infections-unless ERF can be safely done according to the criteria</li> <li>ERF must be correctly done otherwise a child will not grow well or may develop malnutrition</li> <li>Although there is a small risk of transmission of HIV through breast milk this must be balanced with the risks of other health problems (diarrhoea, respiratory infections) due to replacement feeding.</li> </ul>	<p><b>5. Help mother and family decide on feeding choice</b></p> <p>Clarify questions</p> <p>Go through points 2-4 again, if necessary</p>	<p><b>7. Provide follow-up counselling and support at every visit</b></p> <p><b>About Baby:</b></p> <ul style="list-style-type: none"> <li>Ask about the progress on infant feeding</li> <li>Ask about baby's immunization: cotrimoxazole dosing, EID status; infant NVP prophylaxis adherence and monthly refill</li> <li>Ask about baby's growth &amp; health, look for signs of illness and malnutrition</li> <li>Assess if further action or doctor's check is required and advise</li> <li><b>Discuss about</b> complementary feeding at 6 months of age and whether to continue or stop breastfeeding</li> </ul> <p>For HIV-infected Children &lt;2 years old: check that baby is initiated on ART, encourage breastfeeding to continue till 2 years of age</p> <p>For breastfeeding infants still on infant NVP daily prophylaxis or mothers on ART or PPTCT option B: check baby's adherence to daily NVP; encourage mother to continue breastfeeding till 12 months. Infants should start complementary feeding at 6 months of age</p> <p>Follow IMNCI guidelines for complementary feeding, see National Guidelines for nutrition for HIV affected and infected infants and children, NACO 2011.</p> <p><b>About mother</b></p> <ul style="list-style-type: none"> <li>Ask how mother &amp; family is coping with the baby</li> <li>Ask for mother's mood changes (screen for postpartum depression)</li> <li>Family planning/contraception and birth spacing</li> <li>Give condoms and reinforce consistent condom use</li> <li>Ask status and progress for pre-ART or ART care</li> <li>Reinforce adherence to ART or PPTCT regimen</li> <li>Refer to ART centre as appropriate</li> </ul>	<p><b>8. Counselling for stopping breastfeeding</b></p> <ul style="list-style-type: none"> <li>Form other on ART for her own health; continue ART</li> <li>For infants still on infant NVP prophylaxis or mothers</li> <li>Do not stop breastfeeding abruptly; gradually cut down the number of breastfeeding sessions a day according to comfort of mother and infant over one month</li> <li>Ensure complementary feeding is nutritionally adequate and safe</li> <li>Check for growth and nutritional status of baby</li> <li>Once breastfeeding is stopped completely, <b>DO NOT</b> put baby back to breast for any suckling</li> </ul>
<p><b>Support the decision for infant feeding</b></p> <p><b>Breastfeeding is recommended as it is</b></p> <ul style="list-style-type: none"> <li>Affordable,</li> <li>Safer with ART drugs,</li> <li>Feasible and</li> <li>Convenient.</li> </ul>		<p><b>Box 5 : Six Criteria for replacement feeding</b></p> <p>Mothers known to be HIV- infected should give replacement feeding to their infants only when All of the following conditions are met:</p> <ul style="list-style-type: none"> <li><b>Safe water and sanitation</b> are assured at the household level and in the community, and</li> <li>The mother, or other caregiver can <b>reliably afford</b> to provide sufficient RUF (milk), to support normal growth and development of the infant, and</li> <li>The mother, or caregiver can, in the first six months <b>exclusively give replacement feeding</b>, and</li> <li>The mother, or caregiver can <b>prepare it frequently enough in a clean manner</b> so that it is safe and carries a low risk of diarrhoea and malnutrition, and</li> <li>The mother, or caregiver can <b>access health care</b> that offers comprehensive child health services</li> </ul>		<p><b>8. Counselling for stopping breastfeeding</b></p> <ul style="list-style-type: none"> <li>Form other on ART for her own health; continue ART</li> <li>For infants still on infant NVP prophylaxis or mothers</li> <li>Do not stop breastfeeding abruptly; gradually cut down the number of breastfeeding sessions a day according to comfort of mother and infant over one month</li> <li>Ensure complementary feeding is nutritionally adequate and safe</li> <li>Check for growth and nutritional status of baby</li> <li>Once breastfeeding is stopped completely, <b>DO NOT</b> put baby back to breast for any suckling</li> </ul>





# Annex 11: Testing Algorithm for HIV-1 Exposed Infants and Children < 18 Months





## Annex 12: ICTC- ART Centre Referral form

State AIDS Control Society			State AIDS Control Society			State AIDS Control Society		
<b>Referral Form</b>			<b>Referral Form</b>			<b>Referral Form</b>		
Name & Address of ICTC:			Name & Address of ICTC:			Name & Address of ICTC:		
Copy-1 (to be retained at the ICTC)			Copy-2 (to be carried by the client to the ART centre and retained at ART centre)			Copy-3 (to be sent to ART centre through e-mail or post)		
<i>Part-1 to be filled by the ICTC Counsellor/Staff Nurse</i>			<i>Part-1 to be filled by the ICTC Counsellor/Staff Nurse</i>			<i>Part-1 to be filled by the ICTC Counsellor/Staff Nurse</i>		
Name & signature of Counsellor/Staff nurse:			Name & signature of Counsellor/Staff nurse:			Name & signature of Counsellor/Staff nurse:		
PID No.		Date of referral	PID No.		Date of referral	PID No.		Date of referral
Name of the client (optional):			Name of the client (optional):			Name of the client (optional):		
Age:		Sex:	Age:		Sex:	Age:		Sex:
Ph. No.:			Ph. No.:			Ph. No.:		
Category of the client (Tick Mark): ANC/General/Exposed infant			Category of the client (Tick Mark): ANC/General/Exposed infant			Category of the client (Tick Mark): ANC/General/Exposed infant		
Name and address of the ART centre referred to			Name and address of the ART centre referred to			Name and address of the ART centre referred to		
Counsellor's signature:			Counsellor's signature:			Counsellor's signature:		
<b>Part-2 to be filled by the ICTC staff after feedback from ART centre</b>			<b>Part-2 to be filled by the ART centre staff</b>			<b>Part-2 to be filled by the ART centre staff@</b>		
Has the patient reached ART centre: Yes/No			Has the patient reached ART centre: Yes/No			Has the patient reached ART centre: Yes/No		
If Yes			If Yes			If Yes		
Pre ART Regn No.	Baseline CD4 Count	ART Initiated (Yes/No)	Pre ART Regn No.	Baseline CD4 Count	ART Initiated (Yes/No)	Pre ART Regn No.	Baseline CD4 Count	ART Initiated (Yes/No)
If ART not initiate reason			If ART not initiated reason			If ART not initiated reason		
ART Counsellor Name & Signature			ART Counsellor Name & Signature			ART Counsellor Name & Signature		
To be filled for all patients detected positive at ICTC and sent to ART centre/LAC plus.								
@ Copy 3 to be sent back to the referring ICTC by ART centre/LAC plus through email/post/patient								



## Annex 13: OM for Laboratory Investigations

T-11020/36/2005-NACO (ART)  
Department of AIDS Control  
Government of India  
National AIDS Control Organisation  
(Care, Support & Treatment Division)

6<sup>th</sup> Floor, Chanderlok Building  
36 Janpath, New Delhi- 110001  
Date-January, 2012

### OFFICE MEMORANDUM

**Subject:** Revised Technical Guidelines on Laboratory Monitoring for patients at ART centres/LAC/LAC plus centres

#### 1. Essential/Mandatory Tests for all Patients Registering in HIV Care at Art Centre/ LAC Plus

- Haemogram/CBC, Urine for routine and microscopic examination, fasting blood sugar, blood urea, ALT (SGPT), VDRL, CD4 count, Gene-xpert in institutions where located X-ray Chest PA view. Pregnancy test if required.
- Symptoms and signs directed investigations for ruling out OIs.

#### 2. Additional Tests for all Patients to be Started on ART

- Other investigation like USG abdomen, sputum for AFB, CSF analysis etc. as per the physician's decision depending on clinical presentation. Efforts to be made to fast track these investigations so that ART initiation is not delayed.
- Serum creatinine is essential when considering TDF.
- PAP smear, fundus examination also to be done but ART initiation not to be delayed for these tests.

#### 3. Tests for Special Situation

- HBs Ag-for all patients if facility is available but mandatorily for those with history of IDU, multiple blood & blood products transfusion, ALT > 2 times of ULN, on strong clinical suspicion. But ART not to be withheld if HBsAg testing is not available.
- Anti-HCV antibody only for those with history of IDU, multiple blood & blood products transfusion, ALT > 2 times of ULN, on strong clinical suspicion.
- For patients with Hepatitis B or C co-infection, further tests may be required to assess for chronic active hepatitis.
- For patients to be switched to a PI based regimen, Blood Sugar, LFT and Lipid profile to be done at baseline.



#### 4. Tests for Monitoring Purpose

- Essential - CD4, Hb, TLC, DLC, ALT(SGPT)/creatinine clearance (if on TDF), every 6 months or earlier if required. For patients started on AZT Based regimen, Hb at 15 days, then every month for initial 3 months, 6 months and then every 6 months/as & when indicated. For patients started on EFV based regimen, lipid profile should also be done yearly. For patients started on ATV, LFT to be done at 15 days, 1 month, 3 months, 6 months and then every 6 months. Blood sugar and Lipid profile every 6 months for patients on PI based regimen. All the above tests can be done earlier based on clinician's assessment/discretion.
- Other investigations during follow-up as per requirement/availability.

All above investigations other than CD4 and viral load estimations (when required), shall be done from the health facility where the centre is located with support from State Health Department.

Yours faithfully

(Dr. Mohammad Shaukat)  
ADG (CST)

Copy to:

1. Project Director, All State AIDS Control Society
2. Nodal Officers of all ART centres
3. ADG (Lab Services), NACO



## Annex 14: List of Items that can be Procured under Universal Work Precautions

- 1) Disposable latex Gloves–2 Boxes (100 per Box)
- 2) Disposable Laboratory gowns–As per Number of positive deliveries in years.
- 3) Disposable Plastic aprons–24 Number
- 4) Disposable Face Mask–2 Boxes (100 per Box)
- 5) Disposable Caps–4 Boxes (25 per box)
- 6) Shoe covers–2 Boxes (25 pairs per box)
- 7) Rubber boots–2 pairs
- 8) Hand rubs/disinfectant solution for hand wash- 6 bottles.
- 9) Needle destroyer–1 Number
- 10) Sharp disposal containers–2 Numbers
- 11) 1% Sodium hypochlorite–24 cans per year (5 litres canister of 4–5%)
- 12) 10% Sodium hypochlorite–1 can per year (5 litres canister of 40% solution)
- 13) Spirit/70% alcohol–6 bottles (500 ml/bottle)
- 14) Cotton-6 Bundles (large 500 gm/pack)
- 15) Tissue paper rolls–24 Numbers
- 16) Cloth Aprons/Laboratory coats–4 Numbers
- 17) Colour coded waste disposal bags–4 Dozen
- 18) Colour coded waste disposal bins–8 Numbers
- 19) Biohazard labels–2 Dozen
- 20) Band-aids –100 Numbers
- 21) Needles/Syringes–3 Boxes (100 per box)
- 22) Rubber gloves for dirty washing and waste handling-8 Numbers
- 23) Measuring cylinder glass 1 litre –2 Number
- 24) Covered discard jars/discard buckets with lid–4 Number
- 25) Hepatitis B vaccination and antibody titres for staff employed under NACO–4 vials of 6 doses each
- 26) Any other item with prior approval of NACO





## Annex 15: CF- Consent form for Patients Registering into HIV Care & Starting ART

I, (name)....., (address).....  
CONSENT to share all information pertaining to my health and HIV/AIDS status with the service providers who will be part of the management of my condition.

And

I AGREE to receive Antiretroviral Therapy provided under the National programme.

I fully understand the information that has been provided by the health care staff in the following:

- That the ART is not an emergency and thus will be started as per the decision of the doctor. I shall attend the ART centre as per appointment for timely initiation of ART and regular follow- up.
- That receiving ART involves shared confidentiality with other service providers such as CBO/ NGO/CCC/positive network who may support my treatment and other welfare measures through outreach and home-based care activities at home.
- That ART requires 100% adherence to drugs and I shall abide by the same.
- That I understand the side effects of ART.
- That I shall not stop the drugs on my own and will return to the centre if there is any problem. In case I stop the drugs on my own accord/do not adhere to the regimen, I shall not hold the health care staff of the ART Centre responsible for any complication arising out of the same.
- In case, I am on ART from outside on a different regimen, I agree to receive the drugs/regimen provided under the national programme.
- In case, I want to take ART from other centre or to go other city for livelihood or other reasons, I will inform my ART Centre and get a “transfer out” letter before leaving.

.....

Signature of patient with date

.....

Signature of witness

(Doctor/nurse/counsellor)

*(This should be translated in local language &/or explained to patient before taking patients signature)*



## Annex 16: Transfer out form (Form for Transfer of PLHIV to Other ART Centre)

Name and address of the transferring ART Centre \_\_\_\_\_

Name and address of ART Centre where patient is being transferred \_\_\_\_\_

Name of Patient: \_\_\_\_\_

HIV Care (Pre-ART) Registration No. \_\_\_\_\_

Address and contact details: \_\_\_\_\_

–

Reason for transfer (Specify) 1. Patient Choice 2. Provision of second line ART/ Alt First line

Date of transfer: \_\_\_\_\_

ART regimen (pls. specify): \_\_\_\_\_

Date of starting ART: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_/ (Date/Month/Year); Latest CD4 \_\_\_\_\_

Next date for dispensing drug is \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Please find the following original documents handed over to the patient:

1. Patient Treatment Record (White Card)
2. Patient Booklet (Green Booklet)
3. Others, if any (Mention)

*Name and Signature of SMO/MO Phone no. and e-mail of SMO/MO:*

**(To be filled by the receiving ART Centre and sent to the transferring ART Centre by post/email)**

(Name of Patient), referred by you on date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ has reported and been registered with us on \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ along with the documents sent by you. Her/ His HIV Care (Pre- ART) registration no. is \_\_\_\_\_ and ART registration no. (if applicable) is \_\_\_\_\_

*Name and Signature of SMO/MO Phone no with e-mail of SMO/MO*

Address of the ART Centre, transferring out the patient: \_\_\_\_\_



## Annex 17: OM Regarding Provision of ART/ ARV Prophylactic Drugs at ART Centre to HIV Infected Pregnant Women

Government of India  
Ministry of Health and Family Welfare  
Department of AIDS Control National  
AIDS Control Organization  
(Care, Support & Treatment Division)

6<sup>th</sup> Floor, Chanderlok Building  
36 Janpath, New Delhi-110001  
Date - 28th August, 2012

### OFFICE MEMORANDUM

**Subject:** ART/ARV Proyhylaxis for pregnant positive women

It has been decided that ART/ARV prophylaxis for pregnant positive women will be initiated only at the ART centres. After 6 months of pregnancy, in case the pregnant woman is not able to come to ART centre, the ARV drugs may be given to an authorized member of her family. This drug supply to authorized member can continue till 2 months after delivery. After that drugs will be dispensed to the women only on her attending the "ART centre".

(Dr. Mohammed Shaukat)  
ADG (CST)  
Ph: 011- 23731805

To,

1. Project Director, State AIDS Control Society, Andhra Pradesh & Karnataka
2. Regional Coordinator (CST), Andhra Pradesh & Karnataka
3. Programme Director, CoE, Gandhi Hospital, Secunderabad & Bowring Hospital, Bangalore
4. Nodal Officer, All ART Centres in Andhra Pradesh & Karnataka (To be coordinated by SACS)

Copy to,

1. DDG (BSD), NACO
2. NPD (ICTC), NACO



## Annex 18: List of Reference Doctors for Advice on PPTCT Services Including Care of HIV Exposed Child

S. No.	Name of Centre	Contact Person	E-mail	Mobile	Other Contact No.



## Annex 19: National Coordination Committee for PPTCT-NRHM Integration Activities

**T-11025/15/2013- NACO/BSD**  
Ministry of Health and Family Welfare,  
Department of AIDS Control,  
Government of India.  
(National AIDS Control Organisation)

6<sup>th</sup> Floor Chandralok Building  
36 Janpath, New Delhi 110001  
Dated: 21<sup>st</sup> October, 2013

### ORDER

#### **Sub: Constitution of National PPTCT-NRHM Co-ordination Committee - Reg**

India is committed to the UN General Assembly Goal to Work towards Elimination of Paediatric HIV and the Department of AIDS Control has developed a National Strategic Plan (NSP) to scale up the Prevention of Parent to Child Transmission of HIV (PPTCT) services across the country. The NSP envisages close collaboration between the Department of AIDS Control (DAC) and the Reproductive and Child Health Programme (RCH) under National Rural Health Mission (NRHM). Considering the common objectives and the beneficiaries, it is necessary that the services be implemented jointly so as to optimize the coverage.

Accordingly to work towards the common goal, with the approval of competent authority a "National PPTCT-NRHM Co-ordination Committee" has been constituted, to establish coordination mechanism between NACP and NRHM in the country. The terms of reference (TOR) of the "National PPTCT-NRHM Co-ordination Committee" are as follows:-

1. Policies to facilitate HIV counseling and testing and prophylaxis to pregnant women for Prevention of Parent to Child Transmission of HIV (PPTCT),
2. Facilitating and implementation of joint PPTCT – RCH services across the country,
3. Establish co-ordination mechanisms between NACP and NRHM at National, State and District level, and
4. Establish mechanisms for joint Supervision, Monitoring and Review of PPTCT – NRHM collaborative services

The composition of the National PPTCT-NRHM Co-ordination Committee is as under:-

1. Chairperson: Secretary, Department of AIDS Control, Ministry of Health and Family Welfare, Government of India
2. Vice Chairperson: Additional Secretary, Department of AIDS Control, Ministry of Health and Family Welfare, Government of India

#### Members:

3. Nominee from Ministry of Health and Family Welfare, Government of India (Joint Secretary dealing with Maternal and Child Health)

Contd / P.T.O



4. Dy. Commissioner, Maternal Health, Ministry of Health and Family Welfare, Government of India
5. Dy. Commissioner, Child Health, Ministry of Health and Family Welfare, Government of India
6. Director, National AIDS Research Institute (NARI), Pune
7. Deputy Director General, Care, support and Treatment Division, DAC, MOHFW, GOI
8. Deputy Director General, Laboratory Services Division, DAC, MOHFW, GOI
9. Country Director, CDC India
10. PPTCT Focal Point, UNICEF India
11. HIV Focal Point, WHO India
12. Project Director, Andhra Pradesh AIDS Control Society, Hyderabad, AP
13. Project Director, Odhisa State AIDS Control Society, Bhubaneswar, Odhisa
14. Vice President, IL&FS Education and Technology Services Limited, Noida, UP
15. Civil Society Representative:- President, Positive Women's Network (PWN)
16. National Programme Officer (ART), DAC, MOHFW, GOI
17. National Programme Officer (PPTCT), DAC, MOHFW, GOI
18. National Programme Officer (ICTC), DAC, MOHFW, GOI
19. Member Secretary:- Deputy Director General, Basic Services Division, DAC, MOHFW, GOI

This committee will meet quarterly or need based with permission of Chairperson.

Expenditure towards organization of the meeting will be borne through DAC budget and respective SACS budget, and National Institutes and development partners will bear the expenditure for respective nominee.

(Subhash Chandra),  
Deputy Secretary to Government of India.  
Telefax: 23731958

1. Members of "National PPTCT-NRHM Co-ordination Committee"

Copy for information to:-

1. PPS to Secretary (HFW), Ministry of Health and Family Welfare, GOI
2. PPS to Secretary, Department of AIDS Control, MOHFW, GOI
3. PS to Additional Secretary, Department of AIDS Control, MOHFW, GOI
4. The Director General of Health Services, Dte. GHS, GOI, Nirman Bhavan, New Delhi.
5. The Pay and Accounts Officer, MOHFW / GOI, New Delhi,
6. All Heads of Divisions, DAC / MOHFW / GOI



# Annex 20: OM from DDG(BSD) for Roll-out of PPTCT Multi-Drug Regimen in India from 1st January 2014



**Dr. Ashok Kumar, M.D.**  
F.I.S.C.D & F.I.P.H.A  
**Dy. Director General**

Tel: 91-11-23721956  
Fax: 91-11-23721748  
E-mail: ddgjak.dac@gmail.com



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण विभाग  
एड्स नियंत्रण विभाग  
5th floor, Chandralok Building, 36 Janpath, New Delhi - 110 001  
**Government of India**  
**Ministry of Health & Family Welfare**  
**Department of AIDS Control**

Ref. No. T.11012 / 1 / 2010- NACO / BSD (PPTCT)  
Dated the 01st January, 2014

**Sub: PPTCT – Diagnosis of HIV amongst Pregnant Women and Life Long ART for all HIV Positive Pregnant Women Irrespective of CD4 Count in India – Reg**

Dear Project Directors Of All State AIDS Control Societies

**Government of India is committed** to work towards achievement of the global target of “Elimination of new HIV infections among children”. Based on the WHO (June 2013) guidelines, the Department of AIDS Control (DAC) / GOI, has decided to provide lifelong ART (triple drug regimen) for all pregnant and breast feeding women living with HIV in India. Henceforth it is planned to provide all HIV positive pregnant women with a triple-drug ART regimen regardless of CD4 count or WHO clinical stage, both for their own health and to prevent vertical HIV transmission as well as for additional HIV prevention benefits. This regimen has the potential to dramatically reduce HIV transmission from mother-to-child to less than 5%. **This would also help in** (a) increasing coverage of ART for those requiring anti-retroviral treatment, (b) provide early protection against mother-to-child transmission, (c) reduce the risk of HIV transmission to HIV sero discordant partners and (d) improve maternal health.

The National Guidelines as well as National Strategic Plan for Prevention of Parent to Child Transmission have now been **updated (December 2013)** while incorporating the above mentioned strategy for nationwide implementation

**It is requested** that with immediate effect all the States / UTs may ensure linkage of all HIV positive pregnant women to ART Centres for provision of care, support and treatment services as per these new guidelines. Henceforth all HIV positive pregnant women should be started on Tenofovir (TDF) 300mg + Lamivudine (3TC) 300mg + Zidovudine (ZDV) 600mg lifelong, and all HIV exposed infants should be provided with Syrup Nevirapine daily for minimum 6 weeks (refer to PPTCT Technical Guidelines for details).

The drugs required for implementing the PPTCT multi drug regimen are available under the ART services. However, the requirement for Syrup Nevirapine may be met through local procurement for which orders from this office have already been issued on 21<sup>st</sup> November, 2013 vide Letter No P-11014/17/2013-NACO (Proc)

The **Operational Guidelines** for implementing the above referred PPTCT multi drug regimen is **attached** for ready reference.

It may be appreciated that to successfully implement the above said strategy under PPTCT, the **States / UTs must ensure** that all pregnancies are offered HIV counselling and testing services, all HIV positive pregnant women are linked to the nearest ART centre and all HIV exposed infants are linked to services for care of HIV exposed child including ICD, with immediate effect.

In this context, **kindly advise the BSD, CST and all other divisions concerned** to efficiently implement this strategy with close co-ordination, collaboration and on the spot supervision along with well functioning monitoring & reporting mechanisms, etc.

Together we shall work towards achievement of the global target of “Elimination of new HIV infections among children”.

Action(s) taken in this regard be kindly informed to this Department.

Regards & Greetings for 2014

Yours Sincerely,

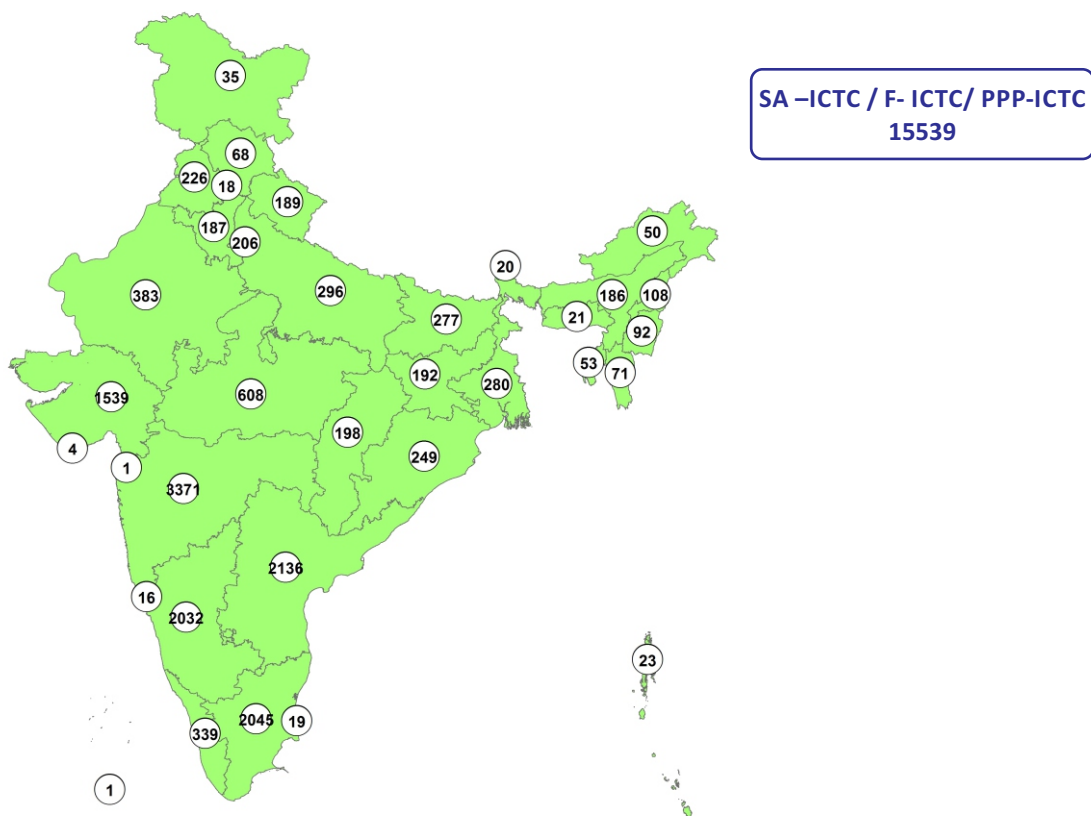
(Dr. Ashok Kumar)

01/01/14

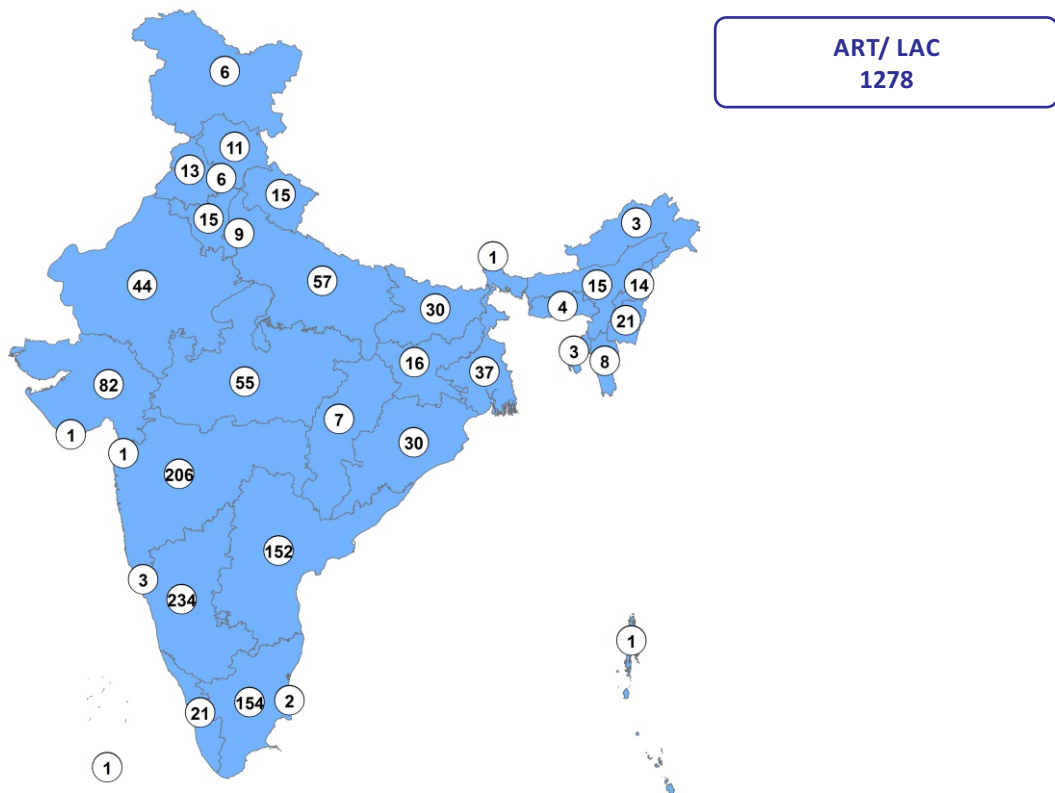
**Kindly note that** this letter along with said enclosures “Operational Guidelines” has already been sent to you through email on 01<sup>st</sup> Jan '14.

अपनी एचआईवी अवस्था जाने, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ  
**Know Your HIV status. go to the nearest Government Hospital for free Voluntary Counselling and Testing**

State / UT wise Number of HIV Counseling and Testing Centers (ICTCs) In India (December, 2013)



State / UT wise Number of HIV / AIDS Treatment Centers In India (December, 2013)



The HIV Counseling & Testing and Treatment Facilities are being rapidly further scaled up during NACP- IV (2012-17)



