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MINISTRY OF HEALTH AND FAMILY WELFARE

NACO
National AIDS Control Organisation
India's response to HIV & Sexually Transmitted Infections
Ministry of Health & Family Welfare, Government of India
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National Guidelines for Elimination of Vertical Transmission of HIV and Syphilis

September 2024

NACO, MoHFW, GoI, 2024

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For additional Information about National Guidelines for Elimination of Vertical Transmission of HIV & Syphilis (EVTHS) 2024, **Please contact**: Basic Services Division (BSD), National AIDS Control Organisation (NACO), Ministry of Health and Family Welfare, Government of India, 6th & 9th Floor, Chanderlok Building, 36 Janpath, New Delhi-110001

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September 2024

अपूर्व चन्द्रा, भा.प्र.से.
सचिव
APURVA CHANDRA, IAS
Secretary

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आज़ादी का अमृत महोत्सव

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

FOREWORD

Vertical Transmission of HIV and Syphilis remains a significant public health challenge, with the potential to cause lifelong health issues for affected infants and to contribute to the burden of these infections within our communities. On behalf of the Ministry of Health and Family Welfare, it is an honour to introduce this crucial set of EVTHS Guideline 2024 aimed at addressing the vertical transmission of HIV and Syphilis. It is our duty to ensure that no child is born with these infections, which are preventable, can be effectively managed and controlled.

This guideline is a result of a thorough review conducted of evidence-based Global and National practices as well as rigorous and extensive consultation with experts under joint collaboration of National AIDS and STD Control Programme and National Health Mission. The document provides a comprehensive framework for the prevention, diagnosis, and management of HIV and Syphilis in pregnant women and their new-born. The aim of the document is to eliminate the vertical transmission of HIV and Syphilis, improve maternal and child health outcomes, and contribute to the global efforts to eliminate these preventable infections. This document reflects India's unwavering commitment to safeguarding the health and well-being of our youngest and most vulnerable population—our children.

It is our hope that EVTHS Guideline 2024 will serve as a practical tool for policymakers, healthcare providers, and community health workers. The effective implementation of the approaches will require the concerted effort of all stakeholders, including healthcare systems, government agencies, non-governmental organizations and private sector. By working together, we can ensure that every pregnant woman receives the care and support she needs and that every child has the best possible start in life.

Therefore, let us again reaffirm our commitment to the health of our nation and work collectively to realize the vision of a future where vertical transmission of HIV and syphilis is a distant memory.

Dated 25th September, 2024

(Apurva Chandra)

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O) 011-23061863, 23063221, E-mail : secyhfw@nic.in

सत्यमेव जयते

वी. हेकाली झिमोमी, भा.प्र.से.
अपर सचिव एवं महानिदेशक
V. Hekali Zhimomi, IAS
Additional Secretary & Director General

राष्ट्रीय एड्स नियंत्रण संगठन
स्वास्थ्य और परिवार कल्याण मंत्रालय
भारत सरकार
National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India

PREFACE

India has come a long way since the launch of the initiative of Prevention of Parent to Child Transmission (PPTCT) of HIV in 2002. Significant progress has been made towards reducing the vertical transmission of HIV and Syphilis during various phases of implementation of National AIDS and STD Control Programme (NACP). This guideline is a key element in advancing the efforts in line with the goals outlined in the Strategic Document for National AIDS and STD Control Programme (NACP) Phase V. Wherein, Goal 3 reiterates the continued focus of Government of India on Elimination of Vertical Transmission of HIV and Syphilis, providing a broader direction for the strategic framework under NACP.

The goal emphasizes the critical need to prevent mother-to-child transmission and to ensure that every infant born to an HIV or Syphilis positive mother has the opportunity for a healthy life. It envisions that 95% of pregnant and breastfeeding women living with HIV have suppressed viral load towards attainment of elimination of vertical transmission of HIV. NACP Phase V underscores the commitment to reducing new infections and mitigating the impact of HIV and Syphilis, particularly in vulnerable populations and pregnant women. This guideline is designed to provide a structured approach to achieving the goal, while ensuring that the efforts are both comprehensive and effective.

The EVTHS guideline have been meticulously prepared for program managers and service providers across both National AIDS and STD Control Programme and National Health Mission (NHM). The document outlines a comprehensive four-pronged strategy designed to address and eliminate vertical transmission effectively, wherein central to this strategy is the emphasis on early screening of all pregnant women for HIV and Syphilis using dual HIV-Syphilis test kits. This approach ensures timely diagnosis and facilitates access to prompt treatment of the HIV/Syphilis positive pregnant women. For HIV-positive pregnant women, the guideline advocate for lifelong antiretroviral therapy (ART) while ensuring that each pregnant woman is optimally virally suppressed. Simultaneously, the guideline also reiterates that the Syphilis-positive pregnant women should receive treatment according to the standard protocols within the health system.

The guidelines lay stress on the importance of conducting deliveries in a non-stigmatizing and non-discriminatory manner within the health facilities. Infants born to HIV and Syphilis-positive mothers will receive follow-up care, including prophylactic and curative treatment supplemented with diagnostic monitoring to ensure their health and well-being. The document not only provides detailed technical instructions but also clarifies the roles and responsibilities of NACP and NHM staff and outline methods for monitoring progress toward achieving the EVTHS goals.

We extend our deepest gratitude to all those involved in the development of the guideline. We believe the EVTHS Guideline 2024 will provide all the necessary guidance to the policy makers, program managers and the field functionaries for effective implementation of the strategy for eliminating vertical transmission of HIV and syphilis and in improving the health outcomes for the children across the country.

(V. Hekali Zhimomi)

6th Floor, Chandralok Building, 36 Janpath, New Delhi-110001 Tel. : 011-23325331 Fax : 011-23351700
E-mail : dgoffice@naco.gov.in

आराधना पटनायक, भा.प्र.से.
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Aradhana Patnaik, IAS
Additional Secretary & Mission Director (NHM)

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली-110011
Government of India
Ministry of Health and Family Welfare
Nirman Bhawan, New Delhi-110011

PREFACE I

It is my pleasure to present the guideline on the Elimination of Vertical Transmission of HIV and Syphilis (EVTHS). Ministry of Health and Family Welfare is committed to support States in their efforts to achieve substantial reduction in maternal and child mortality and morbidity. The development of these guidelines is a testament to the collaborative efforts of National AIDS and STD Control Programme (NACP) and the National Health Mission (NHM) to fast-track the interventions for achieving EVTHS, thus contributing to optimal maternal and child health.

The importance of this collaboration cannot be overstated, as it brings together the strengths, expertise, and resources of both the programs to address a critical public health issue. The EVTHS Guideline 2024 provided herein are designed to ensure that the interventions for EVTHS are seamlessly integrated across all levels of healthcare delivery at the national, state, district and field level. The guideline is designed to provide the necessary flexibility for adapting and adopting the approaches to meet local challenges and conditions at State level. While at the District level, they will facilitate the execution of the interventions for pregnant women and their new-born child.

The key interventions are aimed at ensuring timely access to screening for HIV & Syphilis at the point of Antenatal Care Services for pregnant women. The provisioning of HIV and Syphilis Dual RDT Kit in PIP of NHM for States is of paramount importance. These kits are distributed to healthcare facilities and VHSND settings to ensure comprehensive screening of pregnant women which is the first and a crucial step in early identification that leads to preventing vertical transmission. The joint monitoring by the program officers at the State and District level will also enhance the efficiencies in program implementation and timely course correction.

The care of exposed infants of HIV and Syphilis require the support of Paediatricians in the general health system for providing specialized care, treatment and follow-up. By incorporating this aspect into the general health system, we will ensure that every child receives the best possible start in life, regardless of their exposure to risk.

As we move forward, let us continue to work together with renewed vigour and determination. By fostering collaboration and coordination at every level of our health system, we can achieve our goal of Elimination of Vertical Transmission of HIV and Syphilis.

Dated: 19th, Sept., 2024

(Aradhana Patnaik)

Tel : 011-23063618, 23061097 E-mail : asmd-mohfw@nic.in

Ms.Meera Srivastava, IRS

Joint Secretary (RCH)

Latha Ganapathy, IAS

Joint Secretary (NACO)

PREAMBLE

Government of India, in its continued endeavours has introduced this guideline of Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) as a critical milestone for establishing the collaborative efforts by various health programs to achieve the common goal of eliminating the vertical transmission of HIV and Syphilis. EVTHS guideline outline the strategic pillars envisioned to provide guidance towards achievement of the National AIDS and STD Control Programme (NACP) phase V, Goal 3 on EVTHS. The guideline focuses on the highest level of advocacy and commitment for critical health interventions, accessible and comprehensive quality of service package for maternal and child health care while ensuring robust monitoring of the implementation of the program.

The guideline delineates the key strategy of joint intervention amongst the different health programs providing varied set of services within the health system to mother and her child with a common objective of EVTHS. The guideline also outlines the major strategies like bringing synergy between NACP and National Health Mission, introduction and scale up of dual testing of HIV and Syphilis, promotion of primary prevention, prioritization of family planning services, strengthening of screening confirmation and treatment linkages, retention and adherence to ART among the Women Living with HIV, provision of complete treatment for Syphilis in pregnant women and care cascade for HIV and Syphilis exposed child. It also details strategies for "at risk" women, identification of key geographies that require focussed attention, stakeholder and private sector engagement and that the outlined interventions are implemented under the aegis of HIV and AIDS (Prevention and Control) Act 2017.

The guideline promotes the leveraging of the Health Management Information System (HMIS), the RCH Portal and the Information Management Portal of NACP (SOCH) for effective monitoring of the program implementation. The guideline also provides a strategic roadmap towards the attainment of validation of elimination of vertical transmission of HIV and Syphilis. It also fosters the integration of EVTHS interventions in all relevant policy documents, standard operating procedures and training modules of Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition (RMNCAH+N) to ascertain capacity building of workforce.

As we roll out this guideline, we urge State Health Departments to prioritize and embed these practices into their existing health care framework. With the help of this guideline, States are encouraged to develop State and District specific strategies to address local challenges and foster collaboration among various stakeholders to streamline the implementation process and regularly review and report progress to identify gaps and make necessary course corrections. By taking these steps, States will significantly contribute to and strengthen our collective goals of eliminating vertical transmission and improving maternal and child health outcomes.

(Meera Shrivastava)

(Latha Ganapathy)

डॉ. शोभिनी राजन
मुख्य चिकित्सा अधिकारी (एसएजी)
Dr. Shobini Rajan, M.D. (Pathology)
Chief Medical Officer (SAG)
Tel. : +91-11-23731810, 43509956
Fax : +91-11-23731746
E-mail : shobini@naco.gov.in

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
राष्ट्रीय एड्स नियंत्रण संगठन
9वां तल, चन्द्रलोक बिल्डिंग,
36, जनपथ, नई दिल्ली-110 001

Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation
9th Floor, Chandralok Building,
36, Janpath, New Delhi - 110 001

MESSAGE

Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) is a national priority to prevent not only vertical transmission but to reduce preventable mortality and morbidity. It is a crucial initiative in our ongoing commitment to improving maternal and child health. These guidelines are an essential component of our strategy to eliminate mother-to-child transmission of HIV and syphilis and reflect our dedication to achieving the highest standards of care.

The EVTHS guidelines are designed to facilitate universal screening of HIV and syphilis during pregnancy, preferably in the first trimester with the use of HIV and Syphilis dual test kits. This approach ensures that every pregnant woman receives timely and accurate testing, thereby enabling early identification of infections. Early linkages to appropriate treatment is the cornerstone of these guidelines, ensuring that positive cases are promptly connected to the necessary care and support services.

Primary prevention services for HIV and Syphilis are to be delivered in an integrated manner under National AIDS and STD Control Programme and Adolescent Health. The guideline also highlights and lays emphasis on the need for stigma-free family planning services, recognizing that inclusive and respectful care is vital for the well-being of women and families. For HIV and Syphilis exposed infants born to HIV and syphilis-positive mothers, the guidelines recommends follow-up care by paediatricians to monitor their health and provide necessary interventions.

Furthermore, the guidelines also emphasizes the importance of integrating reporting into the Health Management Information System (HMIS), RCH and SOCH, enhancing our ability to monitor and track progress of the implementation effectively. The guidelines has given all necessary guidance on the data entry points and the monitoring framework for the interventions under EVTHS. The guideline has also provided the necessary guidance on the validation framework for Elimination of Vertical Transmission of HIV and Syphilis.

We are thankful to HoD's and consultants of various divisions of MoHFW which comprises Maternal Health, Child Health, Adolescent Health, Family Planning, Nutrition and Statistics for their valuable contribution in finalising this guideline.

In summary, the guidelines not only outline essential technical procedures but also reinforces our commitment to a holistic and equitable approach to maternal and child health. We extend our gratitude to all those involved in the development of these critical guidelines. Your efforts are instrumental in achieving our goal of eliminating mother-to-child transmission and fostering a healthier future for the nation.

Shobini

(Dr. Shobini Rajan)

Dr. Saiprasad Bhavsar
M.B.B.S., M.D. (PSM)
Deputy Director
Tel: +91-11-43509989
E-mail: sp.bhavsar84@cghs.nic.in
spbhavsar.phs@yahoo.com

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
राष्ट्रीय एड्स नियंत्रण संगठन
9वां तल, चंद्रलोक बिल्डिंग, 36, जनपथ
नई दिल्ली-110001

Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation
9th Floor, Chandralok Building
36 Janpath, New Delhi-110001

Acknowledgement

The Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) Guidelines have been meticulously developed as a comprehensive reference document and guiding resource material for policy makers, program managers and the health care personnel across the health systems. The guideline aims to provide all the necessary guidance and technical details towards building the capacities of all concerned staff as well as facilitate the delivery of high-quality services for the elimination of vertical transmission of HIV and syphilis throughout the country. It also enables the service provider to provide effective and standardized care in the realm of interventions for elimination of vertical transmission of HIV and syphilis.

We, on behalf of National AIDS Control Organization (NACO) express profound gratitude to Ms. V. Hekali Zhimomi, IAS, Additional Secretary & Director General, NACO, for her visionary leadership and guidance in the development of these EVTHS guidelines. We extend our sincere gratitude to Shri Nikhil Gajraj IAS, Joint Secretary, NACO, for his unwavering support and direction in shaping these guidelines.

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A lot of effort has been put by many experts through their technical inputs and experience in the development of the EVTHS guideline. The list is exhaustive to be covered in the acknowledgement letter here but would be incomplete without expressing gratitude and appreciation to them. Name of each one of the significant contributor who has supported in the development of this guideline is placed in the list of contributor attached.

(Dr. Saiprasad Bhavsar)

ABBREVIATIONS

Abbreviations	Full Form
AEP	Adolescent Education Program
AAP	Annual Action Plan
AFHC	Adolescent Friendly Health Clinic
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase
ANC	Ante-natal care
ANM	Auxillary Nurse Midwife
ANMOL	ANM Online
API	Application Programming Interface
ART	Antiretroviral Therapy
ARTC	Antiretroviral Therapy Centre
ARV	Antiretroviral
ASHA	Accredited Social Health Activist
AZT	Zidovudine
BCG	Bacillus Calmette-Guérin
BMI	Body Mass Index
BPG	Benzathine Penicillin G
CBC	Complete Blood Count
CBO	Community-Based Organizations
CD4	Cluster of Differentiation 4
CDC	Centre for Disease Control and Prevention

CEmONC	Comprehensive Emergency Obstetric and Newborn Care
CHC	Community Health Centre
CLHIV	Children Living with HIV
CMEs	Continuing Medical Education
CMO	Chief Medical Officer
CPM	Cluster Program Manager
CPT	Cotrimoxazole Preventive Therapy
CS	Congenital Syphilis
CSOs	Civil Society Organizations
Cu-IUD	Copper Intrauterine Device
DAPCU	District AIDS Prevention and Control Unit
DBS	Dried Blood Spot
DGHS	Directorate General of Health Services
DH	District Hospital
DISHA	District Integrated Strategy for HIV/ AIDS
DLC	Differential Leukocyte Count
DM	Data Manager
DMC	Designated Microscopy Centre
DMDO	Data Monitoring and Documentation Officer
DMPA	Depot Medroxyprogesterone Acetate
DPM	District Program Manager
DPT	Diphtheria, Pertussis, Tetanus
DQAC	District Quality Assurance Committee
DSRC	Designated STI/RTI Clinic
DTG	Dolutegravir
Dual RDT	Dual Rapid Diagnostic Test
EBF	Exclusive Breastfeeding
ECP	Emergency Contraceptive Pill
EID	Early Infant Diagnosis
EMTCT	Elimination of Mother-to-Child Transmission
ERF	Exclusive Replacement Feeding
EVTHS	Elimination of Vertical Transmission of HIV and Syphilis
FIDU	Female Injecting Drug User
fIPV	Fractional Inactivated Polio Vacc
FNAC	Fine Needle Aspiration Cytology
FOGSI	Federation of Obstetric and Gynaecological Societies of India
FP	Family Planning

FRU	First Referral Unit
FSW	Female Sex Workers
FY	Fiscal Year
GAM	Global AIDS Monitoring
GVAC	Global Validation Advisory Committee
GVS	Global Validation Secretariat
H/TG	Hijra/Transgender
Hb	Haemoglobin
HBIG	Hepatitis B Immunoglobulin
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCTS	HIV Counselling and Testing Services
HEI	HIV-exposed Infants
Hep	Hepatitis B
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRG	High-Risk Groups
HRP	High-Risk Pregnancy
HSS	HIV Sentinel Surveillance
HTSP	Healthy Timing and Spacing of Pregnancy
HWC	Health and Wellness Centre
IAP	Indian Academy of Paediatrics
ICTC	Integrated Counselling and Testing Centre
IEC	Information, Education, and Communication
IESE	Integrated and Enhanced Surveillance & Epidemiology
IIMS	Integrated Information Management System
IMA	Indian Medical Association
IPC	Interpersonal Communication
IRIS	Immune Reconstitution Inflammatory Syndrome
IUD	Intrauterine Device
JE	Japanese Encephalitis
JSSK	Janani Shishu Suraksha Karyakaram
LAC	Link ART Centre
LAC Plus	Link ART Centre Plus
LFT	Liver Function Test
LNG-IUD	Levonorgestrel Intrauterine Device
Lopinavir/ritonavir	A combination of antiretroviral drugs

LPV/r	Lopinavir/ritonavir
LT	Laboratory Technician
LWS	Link Worker Scheme
MCH	Maternal and Child Health
MCP	Mother-Child Protection
MCV	Meningococcal Conjugate Vaccine
MEC	Medical Eligibility Criteria
MIS	Management Information System
MO	Medical Officer
MOHFW	Ministry of Health and Family Welfare
MPA	Medroxyprogesterone Acetate
MR	Measles-Rubella
MSM	Men who have Sex with Men
MTCT	Mother to Child Transmission
NAAT	Nucleic Acid Amplification Test
NACO	National AIDS Control Organisation
NACP	National AIDS and STD Control Programme
NCD	Non-Communicable Disease
NFHS	National Family Health Survey
NFPP	National Family Planning Program
NHM	National Health Mission
NICU	Neonatal Intensive Care Unit
NNF	National Neonatology Forum
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NSSK	Navjaat Shishu Suraksha Karyakram
NTD	Neural Tube Defect
NTEP	National Tuberculosis Elimination Programme
NVC	National Validation Committee
NVHCP	National Viral Hepatitis Control Program
NVP	Nevirapine
OI	Opportunistic Infections
OPV	Oral Polio Vaccine
ORW	Outreach Workers
OST	Opioid Substitution Therapy
P&C	Prevention and Control
PCR	Polymerase Chain Reaction
PCV	Pneumococcal Conjugate Vaccine

Pentavalent	Pentavalent Vaccine (combines DTP, Hib, and Hep B vaccines)
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Centre
PHI	Public Health Institution
PI	Protease Inhibitor
PID	Pelvic Inflammatory Disease
PIP	Programme Implementation Plan
PLHIV	People Living with HIV
PMA	Professional Medical Associations
PMSMA	Pradhan Mantri Surakshit Matritva Abhiyan
PMTCT	Prevention of Mother-To-Child Transmission
PoC	Point of Care
POSHAN	Prime Minister's Overarching Scheme for Holistic Nutrition
PPE	Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
PW	Pregnant Women
PWC	Primary Wellness Centre
PWID	People Who Inject Drugs
PWLHIV	Pregnant Woman Living with HIV
RCH	Reproductive and Child Health
RDT	Rapid Diagnostic Testing
RKSK	Rashtriya Kishor Swasthya Karyakram
RMNCAH+N	Reproductive, Maternal, Neonatal, Child, Adolescent Health, and Nutrition
RPR	Rapid Plasma Reagin
RRC	Red Ribbon Clubs
RTI	Reproductive Tract Infections
RVC	Regional Validation Committee
RVS	Regional Validation Secretariat
RVV	Rotavirus Vaccine
SACEP	State AIDS Clinical Expert Panel
SACS	State AIDS Control Societies
SC	Sub-Centre
SCM	Supply Chain Management
SDG	Sustainable Development Goal
SEARO	South-East Asia Regional Office
SEI	Syphilis-exposed Infants

SGPT	Serum Glutamic Pyruvic Transaminase
SHWP	School Health and Wellness Program
SNCU	Sick Newborn Care Unit
SOCH	Strengthening Overall Care for HIV Beneficiaries
SOPs	Standard Operating Procedures
Spectrum	A model used for estimating HIV indicators
SRH	Sexual and Reproductive Health
SSK	Sampoorna Suraksha Kendra
STI	Sexually Transmitted Infections
TB	Tuberculosis
Td	Tetanus-Diphtheria
TI	Targeted Intervention
TLC	Total Leukocyte Count
TLD	Tenofovir, Lamivudine, Dolutegravir
TNA	Total Nucleic Acid
TNA	Targeted Nucleic Acid Polymerase Chain Reaction
TND	Target Not Detected
TPHA	Treponema Pallidum Hemagglutination Assay
TPPA	Treponema Pallidum Particle Agglutination
TPT	Tuberculosis Preventive Therapy
TRG-R&E	Technical Resource Group-Research & Evaluation
TWG	Technical Working Group
U=U	Undetectable = Untransmittable
UIP	Universal Immunization Program
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VDRL	Venereal Disease Research Laboratory
VHSND	Village Health Sanitation and Nutrition Day
Vit	Vitamin A
VL	Viral Load
WBFPT	Whole Blood Finger Prick Test
WHO	World Health Organization
3TC	Lamivudine

CONTRIBUTORS' LIST

Contribution and support received from the leadership and experts are as follows:

National AIDS Control Organization

- Ms. V. Hekali Zhimomi, IAS, Additional Secretary & Director General
- Mr. Nikhil Gajraj, IAS, Joint Secretary
- Dr. Anoop Kumar Puri, Deputy Director General – IEC & MS
- Dr Uday Bhanu Das, Sr. CMO (SAG), HoD – PMR, Lab Services & GF
- Dr. Shobini Rajan, Sr. CMO (SAG), HoD – Prevention, BSD & STI
- Dr. Chinmoyee Das, PHS Grade I and HoD-SI, CST, IT & SCM
- Dr. Saiprasad Bhavsar, Deputy Director-Prevention, BSD & STI
- Dr. Bhawna Rao, Deputy Director-Lab Services, IEC, MS & GF
- Dr. Bhawani Singh, Former DD – CST, PMR, NACO

Other National Programmes, MoHFW

- Ms. Meera Srivastava, Joint Secretary - RCH
- Dr. Indu Grewal, Additional Commissioner - Family Planning
- Dr. Pawan Kumar, Additional Commissioner - Maternal Health & Immunization
- Dr. Govind Bansal, Director - Maternal Health
- Dr. Shobhna Gupta, Deputy Commissioner & In-charge - Child Health & RBSK
- Dr. Anupama Prasad, Deputy Commissioner, Maternal Health Division & Family Planning
- Dr. Zoya Ali Rizvi, Deputy Commissioner, Nutrition & Adolescent Health
- Dr. Urvashi Singh, DDG, NTEP
- Dr. Sanjay Kumar Mattoo, Jt. Commissioner & Additional Deputy Director General, NTEP

- Dr. Sandhya Kabra, Deputy Commissioner, NVHCP
- Dr. Preeti Madan, Joint Director, NVHCP
- Dr. Partha Rakshit, Joint Director, NVHCP
- Dr. Divya Valecha, Assistant Commissioner, Nutrition & Adolescent Health
- Dr. Hema Gogia, Assistant Director, NVHCP

Consultants, NACO

- Dr. Pradeep Kumar, National Consultant – SI
- Ms. Nidhi Rawat, National Consultant – IEC
- Dr. Shantanu Kumar Purohit, National Consultant – Prevention
- Dr. Vibhavari Deshmukh, National Consultant – BSD
- Dr. Harsh Hora, National Consultant – CST
- Mr Tongbram Arpan Meity, National Consultant – IT
- Dr. Shivali Kamal, Consultant – Lab Services
- Ms. Smita Mishra, Consultant – Lab Services
- Dr. Purnima Parmar, Consultant - CST
- Dr. Sujith P, Consultant – SI
- Dr. Vishal Yadav, Consultant -STI
- Mr. Mubarak Ansari, Consultant – BSD
- Mr. Murugan Thirunavukkarasu, Associate Consultant –BSD
- Ms. Hansa Lala, Associate Consultant - BSD
- Mr. Ajin Ayodh Karayil, Associate Consultant –BSD
- Ms. Surbhi Srivastava, Associate Consultant –BSD

Technical Experts

- Dr. Abhishek Royal, Technical Expert, STI
- Dr. Sheikh Mohd Saleem, Technical Expert, EVTHS
- Dr. Rohini Gupta, Technical Expert
- Mr. Chaitanya Bhatt, Technical Expert, HCTS
- Mr. Ajit Sahi, Technical Expert , CST
- Mr Samresh Kumar, Technical Expert, Prevention
- Ms. Ira Madan, Technical Expert – CSS & Virtual Intervention
- Dr. Payal Sahu, Technical Expert – SSS & OSC
- Ms. Gunjan Pandey, Technical Expert - Prevention
- Dr. Surabhi Priya Geetika, Technical Expert – EVTHS

Consultant, Ministry of Health and Family Welfare

- Dr. Santosh Ojha, Lead Consultant, Maternal Health
- Dr Vishal Kataria, Lead Consultant, Child Health
- Dr. Tushar Purohit, Senior Technical Officer, Maternal Health
- Dr. Vaibhav Rastogi, Lead Consultant, Child Health
- Dr. Sumitra Dhal Samanta, Senior Consultant, Child Health
- Dr. Dileepan S, Senior Consultant, NVHCP, MoHFW, New Delhi
- Dr. Deepak Kumar, Consultant, Adolescent health
- Dr. Meenakshi Agarwal, Consultant, Adolescent health
- Dr. Rajesh Pachauri, Consultant, Family Planning

Technical Resource Group

- Dr. DCS Reddy (Chairperson) - Former Professor & HoD, PSM, IMS, Banaras Hindu University (BHU), Varanasi
- Dr. SD Khaparde, Former-DDG NACO and Senior Public Health Expert
- Dr. Vanita Gupta, Former-Project Director at Chandigarh State AIDS Control Society and STI Specialist
- Late Dr. P.Elangovan, Professor, Chettinad Hospital, Kelambakkum, Chennai
- Dr. Suneela Garg - Chairperson Prog Advisory Committee NIHFW, Ex-Head & Professor Community Medicine, Sub-Dean MAMC New Delhi
- Dr. Sumathi Muralidhar - Professor and Microbiologist, Apex Regional STD Centre and SRL for HIV, Safdarjung Hospital, New Delhi
- Dr. Anju Seth - Professor of Paediatrics, Programme Director, Paediatric Centre of Excellence in HIV, Lady Hardinge Medical College, New Delhi, Member of TWG-EVTHS
- Dr. S. Anuradha - Professor, Dept of Medicine, Maulana Azad Medical College, New Delhi, Member of TWG-EVTHS
- Dr. Ramesh Bhosale, Professor, Gynecology and Obstetrics, B.J. Medical College, Pune, Member of TWG-EVTHS
- Dr. Mina Chandra - Professor and Head of Department of Psychiatry and Head of Centre of Excellence in Mental Health, ABVIMS and Dr Ram Manohar Lohia Hospital, New Delhi
- Dr. Manisha Kiran - Associate Prof. and Head, Deptt. of Psychiatric Social Work, Ranchi Institute of Neuropsychiatry & Allied Sciences (RINPAS)
- Dr. Madhuri R Thakar - Scientist G, ICMR National AIDS Research Institute, Pune
- Dr. Sanjay Chauhan, Director Grade Scientist G at ICMR-National Institute for Research in Reproductive Health, Mumbai
- Dr. Beena Thomas, Former Deputy Director and HOD, Department of Social and Behavioural Research, National Institute for Research in Tuberculosis.
- Dr. Nilesh Gawde - Assistant Professor, School of Health System Studies, TISS, Mumbai

- Dr. Lalita Umraskar, Health Officer, Directorate of Health Services, Goa
- Dr. Sheela Godbole, Scientist F (Deputy Director SG) and Head Division of Epidemiology, ICMR-National AIDS Research Institute, Pune
- Dr. Manju Bala, Additional Director & HOD, Dept. of Microbiology, National Centre for Disease Control, Delhi
- Dr.Sanjay Rai, Professor at Centre for Community Medicine, AIIMS, New Delhi
- Dr. Somesh Gupta, Professor of Dermatology & Venereology at AIIMS, New Delhi, India
- Dr. Yogesh Marfatia Professor, Skin VD at SBKS Medical Institute and Research Centre, Piparia, Vadodara
- Dr. Hema Divakar, Consultant and Medical Director Divakar's Speciality Hospital, Bengaluru. Former President of FOGSI
- Dr. Chitra Naik, Prof & HOD (Dermatology and Skin Department), B.Y.L Nair Charitable Hospital, T.N Medical College Mumbai
- Dr. Sushena Reza Paul, Assistant Professor, University of Manitoba, Canada
- Dr. Kabir Sardana, Dermatologist, Dr Ram Manohar Lohia Hospital, Delhi
- Late Dr. TLN Prasad, Director (Gvt. Engagement) Dy. Chief of Party & Project Lead, USAID PEPFAR CLM Project, Swasti, New Delhi
- Dr. Aman Kumar Singh, Program Lead, Tata Trust
- Dr. Venkatesh Chakrapani, Chairperson of Centre for Sexuality and Health Research and Policy (C-SHaRP)
- Dr. Lalit Dar, Professor- Department of Microbiology, AIIMS, New Delhi
- Dr. D. Raghunatharao, Chief Oncologist, KIMS Hospital, Vizag
- Dr. Bitra George, Country Director- FHI360 and Senior Technical Expert, STI
- Ms. P. Kaushalya, Community Representative
- Mx. Putul Singh, Community Representative
- Mr. Nikunj K. Joshi, Community Representative
- Mx. Simran Shaikh, Community Representative
- Mr. Abou Mere, Community Representative

Technical Working Group

- Dr. Mohammad Shaukat, Chairperson-TWG and Former DDG NACO and Public Health Expert
- Dr. Naresh Goel, Former DDG NACO and Senior Public Health Specialist
- Dr. Radhey Shyam Gupta, Senior Public Health Expert
- Late Prof. Arvind Pandey, National Chair (Medical Statistics), ICMR and former Director, ICMR, New Delhi
- Dr. Rohit Chawla, Professor, Maulana Azad Medical College, New Delhi
- Dr. Tarun Bhatnagar, Scientist F, NIE, Chennai

- Dr. Asha Hegde, Deputy Director Operations HIV/TB-PATH
- Dr. Dinesh Baswal, Lead MNCH Chief of Party Saksham MNCH Accelerator supported by USAID, PATH
- Dr. Pankaja Raghav, Prof. Dept of Community Medicine, AIIMS Jodhpur
- Ms Alpana Dange, Research Director, The Humsafar Trust and Senior Public Health Specialist
- Dr. Anu George, Technical Expert, SAATHII

Representative from State AIDS Control Society:

- Dr. Vijay kumar Karanjkar, Additional Project Director MDACS
- Dr. Latika Shivkar, DD-STI MDACS
- Dr. Shahnaz Zothanzami, JD-BSD & STI, Mizoram SACS
- Dr. Anup Amin, DD-BSD & STI, Gujarat SACS
- Dr. Geeta Agarwal,JD BSD, Uttar Pradesh SACS
- Dr. Chitra Suresh,JD-STI , Uttar Pradesh SACS
- Dr. Maya Bajpai,DD PPTCT, Uttar Pradesh SACS
- Mr. Ajay Shukla,AD-ICTC, Uttar Pradesh SACS

Developmental Partners

- Dr. Polin Chan, Regional Advisor, HHS–WHO SEARO
- Dr. Reshu Agarwal, NPO – HHS, WHO India
- Dr. Ziaul Matin, Health Specialist–UNICEF India
- Dr. Syed Hubbe Ali, Health Specialist–UNICEF India
- Mr. David Bridger, Country Director UNAIDS India
- Dr. Nandini Kapoor Dhingra, Advisor, Policy & Strategy, UNAIDS
- Dr. Melissa Nyendak, Ex-Director, Division of Global HIV and TB, CDC India
- Dr. Sunita Upadhyay, Associate Director, Programs, CDC India
- Ms. Deepika Joshi Srivastava, HIV Division Chief, USAID India
- Ms. Sai Subhasree Raghavan - President – SAATHII
- Mr. Rajiv Dua, Chief Executive - India HIV/AIDS Alliance
- Mr. Mohammed Asif, Executive Director, PLAN India
- Dr. Rajesh Rana, Director Plan India
- Dr. Rita Prasad, Advisor HIV (Care, Support and Treatment), USAID India
- Dr. Lalit Mahendru, Technical Expert, WHO

Representative from Professional Medical Association

- Dr. Anju Soni, FOGSI
- Dr. Narendra Saini, Past Honorary Secretary General, IMA

- Dr. Alok Bhandari, Joint Secretary-liaison, IAP
- Dr. Surender Singh Bisht, Secretary General, National Neonatology Forum

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INTRODUCTION AND BACKGROUND

INTRODUCTION AND BACKGROUND

Introduction

The National AIDS and STD Control Program (NACP) is a flagship program of the Government of India that focuses on preventing and controlling HIV/AIDS and Syphilis in the country. The program has made significant progress in reducing the spread of HIV and increasing access to antiretroviral therapy for people living with HIV.

The term "vertical transmission" refers to the spread of infection from mother to child, which can occur during pregnancy (in utero), childbirth (peri-natal) or postpartum through breastfeeding.

The intervention for prevention of vertical transmission of HIV in India was initiated in 2002 under the second phase of the NACP by the Government of India. The National Strategy and Operational Guidelines for the Elimination of Congenital Syphilis was launched in 2015 under NACP in collaboration with NHM. Since then, the elimination of vertical transmission of HIV and syphilis has been one of the key objectives of the NACP. National AIDS and STD Control Program phase V is dedicated towards achieving the global 95-95-95 targets for Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) by 2026 and ending the AIDS epidemic by 2030.

According to the WHO validation guidelines, achieving this dual elimination involves achieving and maintaining the below mentioned impact indicators and program indicators. (1)

The Impact Indicators are the following:

- Mother to Child Transmission (MTCT) rate of HIV <5% in breastfeeding populations
- Case rate of new paediatric HIV infection due to MTCT ≤ 50 per 100,000 live births
- Case rate of Congenital Syphilis (CS) ≤ 50 per 100,000 live births

The impact indicators are to be achieved and maintained for at least one year

The Process indicators are the following:

- ≥95% ANC-1 coverage (at least one visit)

- ≥95% coverage of HIV testing among pregnant women
- ≥95% coverage of syphilis testing among pregnant women
- ≥95% ART coverage of pregnant women living with HIV
- ≥95% adequate treatment coverage of syphilis-seropositive pregnant women

The process indicators must be achieved and maintained for two consecutive years.

Several countries are now poised to eliminate vertical transmission of both these diseases. As of 2024, globally, 19 countries and territories have been certified for eliminating mother-to-child transmission of HIV and/or syphilis. In 2015, Cuba made history by becoming the first country in the world to achieve the dual elimination of HIV and syphilis. *(For further details, refer to weblink at: https://www.unicef.org/press-releases/belize-jamaica-and-st-vincent-and-grenadines-eliminate-mother-child-transmission-hiv).*

In South-East Asian Region, three countries have been validated for achieving the elimination of vertical transmission of HIV and Syphilis (EVTHS), Thailand in 2016, Maldives and Sri Lanka in 2019. (2) *For further details refer to Chapter-13 on Validation framework of EVTHS services.*

Scope of the Document

India is resolutely dedicated to the dual elimination of vertical transmission of HIV and Syphilis, with the primary goal of preventing children from being born with these diseases and ensuring the well-being of infected mothers.

To realize this objective, it is essential to meticulously revise operational processes and strategies in alignment with the goals and strategies outlined in NACP phase V. These strategies focus on eliminating vertical transmission of HIV and Syphilis, reducing HIV-related stigma and ensuring universal access to quality STI/RTI services for at-risk and vulnerable populations. The updated EVTHS guidelines are designed to enhance the efficiency and optimization of beneficiary, commodity and data flow, ensuring a more effective approach towards achieving these critical public health goals.

This document is a comprehensive resource for the successful implementation of the Elimination of vertical transmission of HIV and Syphilis (EVTHS) services under NACP phase V. It provides a standardized approach to implement clear and concise instructions, comprehensive indicators, and guidance on resource management, reporting and documentation, and capacity building. By following the guidance provided in the document, health care providers can effectively prevent vertical transmission of HIV and Syphilis and improve the health outcomes of mothers and their infants.

Key content of the National Guidelines for EVTHS are described as follows:

1. Standardized Implementation: The document provides a standardized approach to implementing the EVTHS services across India. This ensures consistency and quality of care provided to pregnant women and their exposed infants, leading to better health outcomes for mothers and infants.
2. Step-by-Step Approach: The document provides a step-by-step approach, from strategic, to technical and operational aspect including planning monitoring and evaluation. This ensures that all essential components of the program are included and implemented effectively.
3. Clear and Concise Instructions: The document provides clear and concise instructions for implementing the core interventions to prevent vertical transmission of HIV and Syphilis.

This includes guidance on antenatal care, HIV and Syphilis testing and treatment in pregnant women, and care of babies exposed to HIV and/ or Syphilis.

4. Comprehensive Indicators: The document includes a set of comprehensive indicators to monitor and evaluate the EVTHS program implementation and effectiveness. This helps to identify gaps and areas for improvement, ensuring that the program is effective in reducing the number of new infections and ultimately providing a guidance for validation of EVTHS.
5. Resource Management: The document provides guidance on resource management, including roles and responsibilities of key functionaries involved in EVTHS services. This ensures that resources are allocated effectively and efficiently to achieve EVTHS.
6. Reporting and Documentation: The document provides guidance on reporting and documentation, ensuring that data is collected and analysed to inform decision-making and improvement.
7. Capacity Building: The document provides guidance on capacity building, ensuring that health care providers have the knowledge and skills to effectively implement the EVTHS services.

The document is primarily intended for use by policy makers, program managers and care providers, both for general health system and the NACP. The document shall be utilized at the following sites:

At National Level: This will be a reference document for policy decisions about newer approaches to address any gaps identified while monitoring the EVTHS program.

At State/District Level: This will serve as a reference document for any operational decision involving implementation of EVTHS in national health programs, private and public facilities, and also while monitoring the standard of care provided to pregnant women, maintaining a seamless supply chain process, and implementing any special campaign.

At Facility Level: This document will give medical officers, paramedics and the program managers the required guidance to ensure that standard practices of comprehensive care are followed to achieve EVTHS.

SECTION I: STRATEGIC FRAMEWORK FOR ELIMINATION OF VERTICAL TRANSMISSION OF HIV AND SYPHILIS (EVTHS)

Chapter 1: Elimination of vertical transmission of HIV and Syphilis (EVTHS)

1.1 Basics of HIV and Syphilis

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CHAPTER-1

Elimination of Vertical Transmission of HIV and Syphilis (EVTHS)

Elimination of vertical transmission of HIV and Syphilis (EVTHS)

1.1 Basics of HIV and Syphilis

Human Immunodeficiency Virus (HIV)

HIV, or Human Immunodeficiency Virus, is a retrovirus that targets the immune system, specifically the CD4 cells. By altering the immune system and the CD4 cell count, HIV renders the infected individual highly vulnerable to life-threatening opportunistic infections and certain types of cancers. If left untreated, HIV can progress to AIDS (Acquired Immuno-deficiency Syndrome), which represents the advanced stage of HIV infection.

HIV is a complex virus with various strains. There are two main types: HIV-1 and HIV-2. While HIV-1 is the more common and virulent type and is generally more easily transmitted than HIV-2, making it the primary focus of HIV research and treatment efforts. On the other hand, HIV-2, which is less prevalent and mainly found in West Africa, has a lower transmission rate than HIV-1. Although HIV-2 infection also leads to immunodeficiency, it tends to progress more slowly and is generally less severe than HIV-1 infection. Program data has shown the presence of HIV 2 in India too. A person can be infected by either HIV-1 or HIV-2 or with both the subtypes of virus at a time.

The National Program launched the "test-and-treat" strategy in 2017, which involves early and regular HIV testing and immediate antiretroviral therapy (ART) provision, regardless of CD4 count, for individuals diagnosed with HIV infection. This effectively implies that all the newly diagnosed HIV infected pregnant women, should be rapidly started on ART. Antiretroviral Therapy (ART) works by reducing the HIV viral load in the bloodstream, thereby, restoring immune function. Adherent ART can cause the HIV viral count to become so less, that it cannot be detected in the test. This is known an undetectable viral load. This helps in keeping PLHIV healthy as well as prevent transmission to their sexual partners. This concept is known as Undetectable = Untransmittable or U=U and will be applicable to all pregnant Women Living with HIV (WLHIV) for prevention of vertical transmission of HIV. (*For further reading, refer to National Guidelines for HIV Care and Treatment, 2021)*

Syphilis

Syphilis is considered as one of the most common sexually transmitted infections (STI) worldwide, with approximately 6 million new cases reported annually across the world (4). It is a bacterial infection that spreads through sexual and transplacental route. If left untreated, it can lead to serious health problems. The infection has three stages, wherein the first stage begins with a painless ulcer at the site of inoculation, that can last up to 6 weeks. The second stage presents with a rash, fever and muscle pain. The infected person may then enter a latent stage without symptoms. This stage can last for years and may affect all organs in the body. The final stage, called tertiary syphilis, can occur after many years and can result in serious complications, such as neurosyphilis, cardiovascular syphilis or late benign syphilis.

Pregnant women with syphilis can transmit the disease vertically, resulting in adverse birth outcomes, including stillbirth and congenital syphilis. To prevent vertical transmission and related outcomes, all pregnant women should receive screening and adequate treatment for syphilis. In addition to this, the children born with congenital syphilis should be managed appropriately.

1.2 Risk factors associated with increase in Vertical Transmission of HIV and Syphilis

Risk of HIV Transmission

Vertical transmission is a significant mode of HIV transmission in children. Vertical transmission can happen from HIV-positive pregnant women to child during pregnancy, childbirth or breastfeeding. The number of Annual New HIV Infections in 2022 was estimated to be 66.41 thousand. Out of this, children between the age of 0-14 years accounted for 6% of the total annual new infections (5). Several risk factors are associated with increase in vertical transmission, including maternal and obstetric factors as well as infant-related factors. The Maternal, Obstetrical and Infant factors that increase the risk of HIV transmission are depicted in Table 1.2.1

Table 1.2.1: Maternal, obstetrical, and infant factors that increase the risk of HIV transmission

	Maternal Factors	Obstetrical factors	Infant factors
1.	Recent HIV infection in mother	Uterine manipulations (external cephalic version)	Immature Immune System
2.	High viral load	Prolonged rupture of the membranes (>4 hours)	Preterm baby
3.	Resistant strains	Placental abruption, chorioamnionitis	Low birth weight (<2.5kg)
4.	Advanced clinical stage	Intrapartum hemorrhage	First infant of multiple births
5	Concurrent STI	Invasive delivery techniques: episiotomies, forceps, use of metal cups for vacuum deliveries	Immature Gastro-Intestinal tract
6.	Viral, bacterial, and parasitic (esp. malaria), placental infection	Invasive fetal monitoring	Mouth sores or an inflamed GI tract in baby

7.	Malnourishment		Mixed feeding: Breast milk along with other feeds during the first six months
8.	Conditions of breasts (sore nipple, breast abscess, mastitis, etc.)		
9.	Mother acquired HIV infection during the breastfeeding period		

The table 1.2.2 depicts the risk of vertical transmission of HIV with or without interventions. Without interventions, about one-third of HIV-positive mothers transmit the virus to their infants during pregnancy, labour, delivery and breastfeeding. However, ART in the mother and ARV prophylaxis to her baby can significantly reduce the risk of HIV transmission to 2% in breastfeeding babies and to 1% in babies on replacement feeding.

Table 1.2.2: Risk of Vertical transmission of HIV with or without interventions

ARV Intervention	Risk of HIV Transmission from mother to child
No ARV; breastfeeding	30-45%
No ARV; No breastfeeding	20-25%
3 ARVs (ART) with breastfeeding	2%
3 ARVs (ART) with No breastfeeding	1%

(Source: Table 3.1.2, Chapter-3.1, National Guidelines for HIV Care and Treatment, 2021)

Risk of Transmission of Syphilis and Impact of Maternal Syphilis on Pregnancy Outcome

Treponema pallidum can be transmitted to the foetus in the early stages of the infection. Most of the untreated women in their early stage of infection can transmit their infection to the foetus. The transmission can occur as early as in the 9th week of gestation, but mostly it occurs during 16 to 28 weeks of pregnancy. The chance of vertical transmission is as high as 80% in early stages of syphilis infection. (4)

According to the Global Burden of Diseases report by WHO in 2000, untreated maternal syphilis resulted in a 75% rate of adverse birth outcomes. Additionally, 57% of these adverse outcomes were estimated in pregnant women who attended ANC but were not screened for syphilis, while 16% occurred in pregnant women who were screened for syphilis but either did not receive treatment or received inadequate treatment (4). The table 1.2.3 depicts the adverse outcomes seen in Maternal Syphilis. (6)

Table 1.2.3: Adverse Birth Outcomes in Maternal Syphilis

Adverse Birth Outcome	Rates
Still Birth or Miscarriage	20%
Perinatal Death	15%
Infected infant	20%
Prematurity or low birth weight	20%
Any adverse outcome	75%

1.3 Burden of HIV and Syphilis in pregnant women and children

Burden of HIV

As per 2022-23 epidemiological data, the HIV epidemic level continues to be low nationally with adult (15-49 yrs) HIV prevalence at 0.20%. With estimated 25.44 lakh PLHIV in the country, India has the second largest HIV epidemic in the world, accounting for about 6.3% of all PLHIV worldwide. In 2022, adult male and female populations accounted for 53% and 44% of the total estimated PLHIV respectively. (5)

The HIV prevalence among the high-risk groups continue to be much higher than the overall adult prevalence. In 2022, HIV prevalence among high-risk groups was 9 to 43 times as compared to adult prevalence. HIV prevalence in 2022, was 1.8% among female sex workers (FSW), 1.9% among inmates in prison and other closed settings, 3% among men who have sex with men (MSM), 3.8% among hijra/ transgender (H/TG) persons and 9.0% among people who inject drugs (PWID). (5). Female injecting drug users (FIDU) are at increased vulnerability to HIV infection, due to unsafe drug injecting practices and also are often involved in unsafe sexual activities.

High-risk women face unique challenges in accessing and adhering to prevention and treatment services. These populations bear a disproportionate burden of HIV and STI infection and are at greater risk of transmitting the virus to their children due to following reasons:

a) Multiple vulnerabilities: High-risk persons often face intersecting social and economic disadvantages, including poverty, limited education, stigma and discrimination, further hindering their access to health care and adherence to treatment.

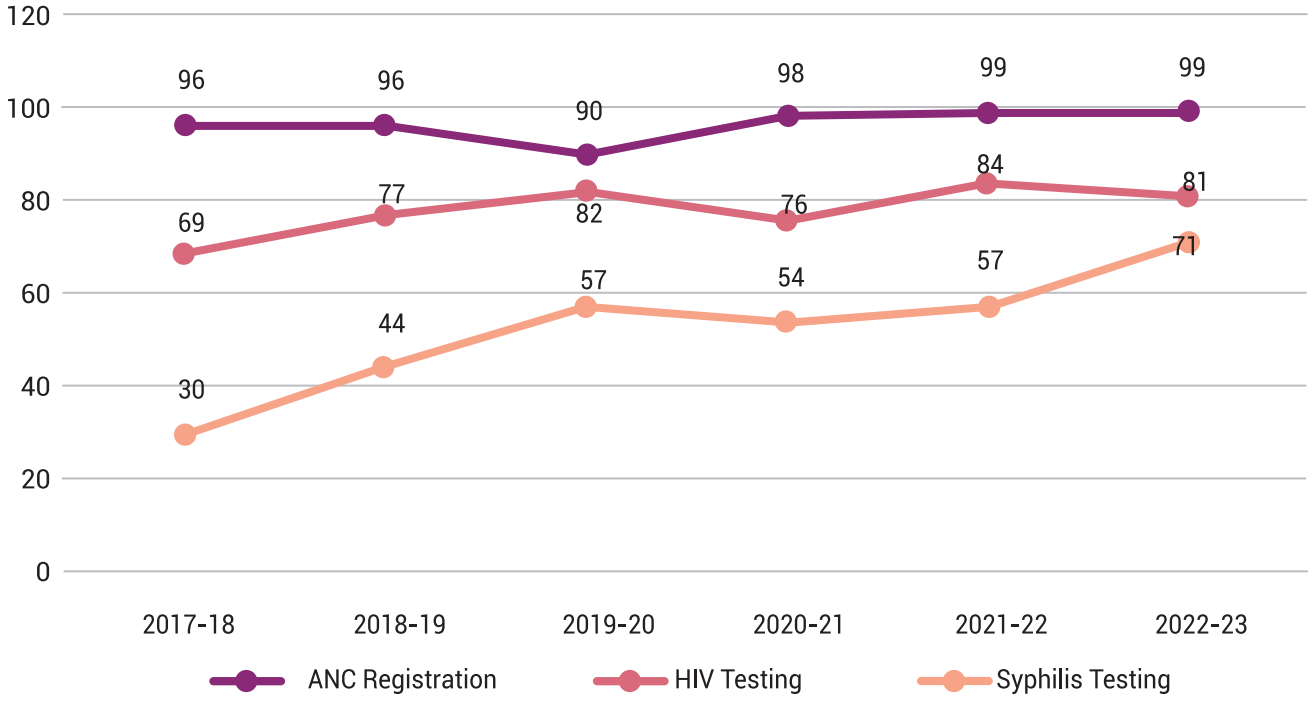
b) Missed opportunities: Delaying or failing to reach these populations can have irreversible consequences, affecting not only the mothers' health but also the lives of their children.

Need for EVTHS services for HIV

As per India HIV Estimates 2023, it was estimated that around 19,960 pregnant WLHIV may need EVTHS services for HIV. The pattern over the last six years indicates that the highest annual HIV detection amongst pregnant women was in FY 2022-23. A total of 8877 (52%) known cases of WLHIV and 8050 (48%) newly diagnosed pregnant WLHIV infections were reported in FY 2022–2023. Additionally, 509 WLHIV were diagnosed with HIV after childbirth or during the breastfeeding period and where the child was less than 18 months. (7)

Figure 1.3.1 depicts the trends of ANC registration, HIV Testing, Syphilis Testing against estimated Pregnant Women, over the period 2017-18 to 2022-23.

Figure 1.3.1: ANC registration, HIV Testing, Syphilis Testing against estimated Pregnant Women



Source of Figure: Sankalak: Status of National AIDS Response, Fifth Edition, 2023. https://naco.gov.in/sites/default/files/Sankalak%20Booklet.pdf

Early Infant Diagnosis of HIV

Early infant diagnosis (EID) of HIV is a crucial component of vertical transmission of HIV. can be vertically transmitted from a Pregnant Woman living with HIV (PWLHIV) to the baby during pregnancy, labour, delivery or breastfeeding. Without timely diagnosis and treatment, up to 50% of infants born to HIV-positive mothers die before reaching their second birthday. EID refers to the testing of HIV-exposed infants (infants born to HIV-positive mothers) for HIV and aims to identify HIV-positive infants early so they can receive prompt treatment and care to improve their chances of survival and reduce the risk of developing AIDS-related illnesses.

EID involves follow-up care services for HIV-exposed infants to detect HIV infection early and provide timely access to antiretroviral treatment. During FY 2022-23, a total of 41,425 EID tests were conducted which led to identification of 576 (1.39%) HIV-positive children. Out of them, a total of 486 (84%) children were initiated on ART. During FY 2022-23, out of a total 13,070 eligible infants, 12714 (97%) infants underwent first EID at 42 days. Out of above, a total of 94 (0.74%) infants were diagnosed HIV-positive. Among them, around 77 (82%) infants were linked to ART and initiated on treatment. (5)

Burden of Syphilis

The prevalence of syphilis, as detected by seroprevalence in HIV sentinel surveillance, was 0.38% in 2010-11. However, according to the HSS 2022 estimates, the seropositivity decreased to 0.10%. The prevalence of HIV-Syphilis co-infection among pregnant women was at 0.004%. (8)

The progress on syphilis testing is noteworthy, as it increased from 57% in 2021-22 to 71% in 2022-23.

Among syphilis positive pregnant women, treatment coverage was at 89% nationally. During FY 2022-23, a total of 7,444 syphilis infected pregnant women were reported in India. (6)

The actual incidence of congenital syphilis in India is not known due to the lack of active surveillance or specific programs focused on investigating infants born to syphilis reactive mothers. In 2012, it was estimated that 16,324 newborns had clinical evidence of syphilis due to vertical transmission. These estimates were calculated using the WHO tool for estimating maternal syphilis and its adverse outcomes. (9)

The diagnosis of congenital syphilis is made based on clinical examination, radiology (if available) and laboratory tests at birth (comparison of RPR/VDRL titres with maternal titre at birth) and follow up tests. In FY 2022-23, a total of 2,583 (84%) infants were treated for congenital syphilis. (5)

1.4 Achievements of NACP-V strategies in context with Care cascade of pregnant women and their children

The progress of a country on EVTHS is measured through standard indicators and targets as prescribed by WHO in its periodic global guidance (1). The progress of the impact and process indicators and the targets for EVTHS in India during the period 2022-23 are depicted in table 1.4.1. (5)

Table 1.4.1: Progress against impact and process indicators and targets for EVTHS, 2022-2023

Infection	Indicator Type	Indicator	Target	Progress 2022-2023
HIV	Impact	HIV MTCT rate,	<5% (breastfeeding populations) OR <2% (non-breast feeding populations)	11.75% (HIV Estimates 2023)
		Case rate of new paediatric HIV infections due to MTCT	<50 per 100,000 live births	21 per 100,000 live births (2021-22)
	Process	ANC-1 coverage (at least one visit)	≥95%	>95%
		Coverage of HIV testing among pregnant women	≥95%	81%
		ART coverage of pregnant women living with HIV	≥95%	78%
Syphilis	Impact	Case rate of Congenital Syphilis (CS)	≤50 per 100,000 live births	-
	Process	ANC-1 coverage (at least one visit)	≥95%	>95%
		Coverage of Syphilis testing among pregnant women	≥95%	81%*
		Adequate treatment coverage of Syphilis-seropositive pregnant women	≥95%	89%*

*Based on the facility-level denominator

CHAPTER-2
Strategic Framework

Strategic Framework

2.1 Context for the Strategic Framework

The strategic framework to achieve EVTHS is based on the strategic pillars envisioned to provide guidance towards achievement of the NACP phase V, Goal 3 on EVTHS. The strategic framework is essential to guide the concentrated efforts and develop care cascade mechanisms and implement interventions to achieve EVTHS.

The NACP phase V Goals, EVTHS pillars and strategic framework is presented in figure 2.1.1.

Figure 2.1.1: NACP phase V Goals, EVTHS Pillars and Strategic Framework

Goals				
Goal 1	**Goal 2**	**Goal 3**	**Goal 4**	**Goal 5**
Reduce annual new HIV infections by 80%	Reduce AIDS-related mortalities by 80%	Eliminate vertical transmission of HIV and Syphilis	Promote universal access to quality STI/RTI services to at-risk and vulnerable populations	Eliminate HIV/ AIDS- related stigma and discrimination

Pillars of EVTHS			
Ensure advocacy and sustained political commitment for a successful health initiative	Increase access to, quality and comprehensive maternal and new-born health services.	Screen and treat pregnant women, breast feeding mothers, infants, and their partners.	Establish robust surveillance, monitoring, and evaluation systems.

Strategic Framework of EVTHS under NACP V			
Augment comprehensive synergy with National Health Mission (NHM) for implementation of EVTHS intervention	Advocacy to increase access and improve the quality of maternal, and new- born care and child health services	Introduce and scale-up utilization of HIV and Syphilis dual rapid diagnostic screening to fast-track progress on the dual elimination	Strengthen the primary prevention through coordinated actions
Prioritize family planning services for eligible PLHIV	Strengthen linkages between screening, confirmatory and treatment centres	Strengthen retention on-ART and its adherence among WLHIV	Strengthen care, support, and treatment for HIV/Syphilis infected pregnant women
Strengthen care cascade of HIV-exposed and Syphilis-exposed infants and children	Strategies to reach and provide EVTHS services to At-Risk' women	Prioritization and customized strategies for high-burden and low-identification geographies	Strengthen the strategic information for EVTHS
Decentralization of essential commodities for EVTHS services	Engage with private sector augmenting their role in attainment of dual elimination	Implementation of EVTHS interventions on the principles of human rights, HIV & AIDS (Prevention & Control) Act 2017, gender equality and community	Prepare strategic roadmap to guide actions towards attainment of validation of elimination of vertical transmission

2.2 Strategies for Elimination of Vertical Transmission of HIV and Syphilis

The strategies for the Elimination of Vertical Transmission of HIV and Syphilis are described in the following sections:

I. Augment comprehensive synergy with National Health Mission (NHM) for implementation of EVTHS interventions

a) Foster joint ownership and strengthen coordination between the NACP and NHM at all levels (national, state, district as well as below district level) to optimize availability, utilization of resources and harmonize activities to achieve EVTHS.

b) Ensure universal screening of all pregnant women for HIV and Syphilis during first trimester (preferably at first ANC visit).

c) Develop and implement joint monitoring and evaluation systems and ensure effective data sharing mechanism for regular tracking and reporting of the programmatic progress. Ensure adequate and timely data flow between the Information Management Systems under NACP and NHM.

d) Implement a case reporting system for syphilis-exposed children to monitor progress indicators related to congenital syphilis.

e) Integrate EVTHS interventions in all relevant policy documents, standard operating procedures and training modules of Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition (RMNCAH+N) to ascertain capacity building of workforce.

f) Roll-out of coordinated IEC campaigns on EVTHS.

g) Ensure robust and coordinated supply chain mechanism to ensure availability of all essential EVTHS commodities.

h) Combined research to ensure evidence-based implementation of EVTHS interventions.

i) Establish effective coordination between SACS and NHM through provisioning of sufficient budget under PIP for undertaking various activities under EVTHS (including procurement of HIV and Syphilis Dual RDT kits for screening of pregnant women and Cotrimoxazole Preventive Therapy (CPT) for HIV-exposed infants etc.).

II. Advocacy to increase access and improve the quality of maternal, and new-born care and child health services

a) Enhance identification of high-risk pregnancies through systematic screening and risk assessment.

b) Ensure linkages to specialized Maternal and Child Health (MCH) programs including Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) and Antenatal Care (ANC).

c) Ensure provisioning of benefits of public health programs (including PMSMA and JSSK, etc.) and social protection schemes to pregnant women and infants infected with HIV and Syphilis

d) Partner with local organizations, women's and youth groups and religious organizations to identify barriers and promote stigma free access to health care services.

e) Promote incorporation with existing maternal and child health services, including immunization and family planning.

f) Promote spouse/partner engagement through education and active involvement in the HIV and Syphilis care cascade.

g) Utilize media platforms such as radio and television for public service announcements and dramas by community to raise awareness about maternal and child health services for enhanced uptake.

III. Introduce and scale-up utilization of HIV and Syphilis dual rapid diagnostic screening to fast-track progress on the dual elimination

a) Enhance HIV and Syphilis screening of pregnant women during ANC and labour using HIV and Syphilis Dual Rapid Diagnostics Testing (RDT) kits.

b) Ensure uninterrupted supply of HIV and Syphilis Dual RDT kits at sites providing ANC services.

c) Capacity building of workforce on utilization of HIV and Syphilis Dual RDT kits and ensuring appropriate referral and linkages for confirmation of HIV and Syphilis.

IV. Strengthen primary prevention through coordinated actions

a) Implement 360-degree awareness generation campaigns on EVTHS. Develop and implement effective communication strategies to promote HIV and STI prevention and combating associated stigma and discrimination against HIV and STI.

b) Ensure implementation of dedicated interventions for awareness generation on HIV, AIDS and STI including Syphilis, amongst the adolescents and young populations through various programmes under NHM and NACP including Rashtriya Kishor Swasthya Karyakram (RKSK), School Health Programmes, Red Ribbon Clubs (RRC) and Adolescent Education Program (AEP)

c) Provide focused information and education to high-risk populations, including sex workers, men who have sex with men and people who inject drugs (PWID).

d) Increase access and utilization of condoms and other barrier methods for effective prevention of HIV and STI.

e) Ensure access to clean needles and syringes for PWID (including FIDU) to minimize the risk of HIV transmission.

f) Enhance universal access and utilization of services for HIV and STI prevention, testing, care, support and treatment.

V. Prioritize family planning services for eligible PLHIV

a) Implementation of comprehensive assessment of eligible PLHIV to ascertain needs for family planning.

b) Integrate family planning services into HIV care settings to enhance accessibility and convenience for PLHIV. Ensure that family planning services are available at the same location as HIV care, promoting a holistic approach to health care.

c) Provision for condom distribution to all eligible PLHIV at ARTC.

d) Ensure detailed counselling on family planning to all eligible PLHIV during ARTC visits. Strengthen coordinated referrals and linkages between HIV and family planning services to prevent unintended pregnancies.

e) Conduct regular training sessions to update health care providers on the latest contraceptive methods, counselling for planning the pregnancy and management of unintended pregnancies among WLHIV.

f) Involve partners and family members to reduce stigma and provide necessary support for informed decision-making.

g) Combat stigma and discrimination associated with HIV and family planning at health facility level through sensitization and awareness generation.

VI. Strengthen linkages between screening, confirmatory and treatment centres

a) Develop interventions to ensure appropriate and timely referral and linkages of pregnant women screened reactive for HIV and/or Syphilis to confirmatory sites and treatment centres.

b) Utilize Information Management Systems and digital interventions to streamline communication and ensure timely information-sharing between screening, confirmatory, and treatment facilities.

VII. Strengthen retention on ART and adherence among WLHIV

a) Pregnant women to be prioritized and fast tracked for service delivery at treatment centres, including management of opportunistic infections, rapid ART initiation, timely viral load testing, etc.

b) Ensure intensive counselling and follow-up to strengthen retention and adherence on-ART for all pregnant and breastfeeding WLHIV.

c) Implement a targeted approach to ensure viral suppression among pregnant and breastfeeding WLHIV by employing differentiated and community-led health care services.

d) Ensure that services are delivered with utmost sensitivity eliminating any form of stigma and discrimination.

VIII. Strengthen the care cascade of HIV-exposed and Syphilis-exposed infants and children.

a) Integrate care for HIV and syphilis-exposed infants within maternal and child health services to streamline comprehensive care.

b) Implement updated protocols of Early Infant Diagnosis (EID) of HIV-exposed infants and ensure prompt initiation of Antiretroviral prophylaxis for HIV-exposed infants, following the established treatment guidelines.

c) Ensure screening of all syphilis exposed infants for congenital syphilis as per the updated protocols and facilitate access to appropriate treatment for syphilis-exposed infants through paediatric treatment facilities.

d) Collaboration with paediatricians to optimize care strategies for HIV and syphilis-exposed infants. Capacity building of health care providers on screening and management of HIV and syphilis-exposed infants.

e) Encourage and support research initiatives focused on improving care protocols for HIV and syphilis-exposed infants.

f) Provide counselling and support to parents and caregivers of HIV and syphilis-exposed infants, reinforcing treatment adherence and proper follow-ups.

g) Establish a robust monitoring and evaluation system to track progress, including regular monitoring, treatment adherence and follow-up for HIV and syphilis exposed infants and children.

h) Leverage digital interventions to ensure timely interventions for HIV and syphilis-exposed infants.

i) Provision of holistic health care services to ensure adequate interventions to all HIV and syphilis-exposed infants (including routine immunization services, monitoring of growth and development and appropriate specialized services through referral and linkages).

IX. Strengthen care, support, and treatment for HIV and/or Syphilis infected pregnant women.

a) Ensure pregnant and lactating women diagnosed with HIV receive appropriate and timely treatment and follow-up care.

b) Ensure adequate treatment of all pregnant women screened reactive for syphilis (using injection benzathine penicillin G) and follow-up care.

c) Effective implementation of initiatives to ensure treatment monitoring among HIV infected pregnant women and lactating mothers and syphilis infected pregnant women.

d) Implement peer support initiatives to reduce isolation, stigma and enhance adherence by fostering connections among clients.

e) Enhance provider-patient communication to boost patient engagement and adherence to treatment plans.

f) Conduct regular sensitization sessions for care providers from general health system on syphilis management and the use of injection benzathine penicillin.

X. Strategies to reach and provide EVTHS services to at-risk women

a) Utilize peer educators for awareness campaigns and linking at-risk women to EVTHS services.

b) Establish mobile clinics in areas with at-risk population for ensuring access to EVTHS services.

c) Conduct targeted outreach using community leaders and health workers to educate at-risk women and their partners.

d) Provide adequate and regionally customized IEC services and referrals through mobile clinics, creating a comprehensive service delivery model to ensures that all at-risk women not only receive testing and treatment services but also necessary support and guidance.

e) Develop specialized outreach programs for specific at-risk groups (e.g., sex workers, females who inject drugs, adolescents with risk behaviour, etc.) offering tailored counseling, testing and treatment services.

f) Sensitization of health care providers to offer gender-sensitive, non-judgmental and respectful care to at-risk women.

XI. Prioritization and customized strategies for high-burden and low-identification geographies

a) Focus on district level estimates for pregnant women and identification of gaps.

b) Strengthen district-wise monitoring of new HIV and Syphilis infections through enhanced surveillance and reporting mechanisms.

c) Develop tailored strategies for regions with low identification despite high coverage, emerging new infection and high prevalence districts.

d) Implement targeted outreach programs in high-risk communities, including peer-led support groups. Establish mobile clinics in hard-to-reach areas for testing, treatment, education and counseling on HIV, syphilis, and family planning.

e) Strengthen referral networks between health facilities in high-burden areas to ensure timely patient care.

f) Establish partnerships with community organizations for facilitating referrals and support services.

XII. Strengthen the strategic information for EVTHS

a) Implement a data-driven process, emphasizing the strategic use of information for evidence-based policy decisions.

b) Develop complementary systems that integrate program monitoring, surveillance, epidemiology and research to track newly identified pregnant women (both HIV and Syphilis) and WLHIV.

c) Establish regular and structured reviews and data triangulation at the granular level within the health care system to assess the HIV and Syphilis care cascade for pregnant women and exposed infants

XIII. Strengthening of supply-chain mechanism of essential commodities for EVTHS services

a) Support State AIDS Control Societies (SACS) for procurement and/or supply of antiretroviral (ARV) prophylaxis, paediatric penicillin (crystalline/ procaine penicillin) and EID commodities.

b) Enhance supply chain management systems, including forecasting, procurement, storage and distribution.

c) Empower local health care facilities with training, infrastructure and equipment for effective commodity management.

d) Use digital technology for real-time data collection, reporting and monitoring of stock levels. Establish a robust monitoring and evaluation system to assess commodity availability, accessibility and usage for EVTHS services.

e) Conduct regular surveys and assessments to identify gaps, to inform decision-making and improve the supply chain management system.

XIV. Engage with private sector augmenting their role in attainment of dual elimination

a) Strengthen collaboration with the private health care sector to achieve EVTHS.

b) Conduct regular capacity-building of professional medical associations (PMA), including IMA, FOSGI, IAP and NNF.

c) Encourage private sector to ensure implementation of complete care cascade of EVTHS to ensure enactment of appropriate practices.

d) Sensitize the private sector on the use of injection benzathine penicillin G (BPG) for treating pregnant women identified with syphilis, promoting proper implementation of updated protocols.

e) Enhance reporting from the private sector in the HMIS and Reproductive and Child Health Management Information System (RCH-MIS) portal.

f) Strengthen coordination between NHM officers, NACP and the private sector for regular reporting from facilities providing EVTHS services in the private sector.

XV. Implementation of EVTHS interventions on the principles of human rights, HIV & AIDS (Prevention and Control) Act 2017, gender equality and community engagement

a) Ensure implementation of EVTHS interventions in accordance with the principles of human rights.

b) Implementation of HIV and AIDS (Prevention and Control) Act, 2017 to ensure protection of PLHIV and other affected populations.

c) Strengthen community engagement and promote community participation at all levels of planning and implementation of the EVTHS interventions.

d) Ensure involvement of positive networks, patient groups, key populations and civil society organizations in the entire cascade of EVTHS implementation.

XVI. Prepare strategic roadmap to guide actions towards attainment of validation of elimination of vertical transmission

a) Ensure strict adherence to the standardized criteria and validation processes outlined by WHO for the elimination of vertical transmission of HIV and Syphilis.

b) Demonstrate progress in program, laboratory, data, human rights, gender equality and community engagement areas, in addition to meeting programmatic targets.

c) Implement standardised tools for assessing progress on elimination, enabling accurate evaluation and identification of areas of improvement.

d) Prepare a comprehensive roadmap outlining specific action points and defined timelines to achieve the elimination of vertical transmission, based on the assessment outcomes.

2.3 The Four-pronged Strategy for EVTHS

Under NACP phase V, the four-pronged strategy has been redesigned to include strategies for EVTHS. The newer four Prongs of EVTHS are depicted in Figure 2.3.1.

Figure 2.3.1. Newer Four Prongs of EVTHS under NACP phase V

<table>
<tr><th>Prongs</th><th>Prong 1</th><th>Prong 2</th><th>Prong 3</th><th>Prong 4</th></tr>
<tr><td>HIV</td><td>Primary prevention of HIV, especially among women of reproductive age-group</td><td>Prevention of unintended pregnancies among WLHIV</td><td rowspan="2">Prevention of vertical transmission of HIV and Syphilis during pregnancy and childbirth</td><td rowspan="2">Provision of care and management services for infected women and their exposed/ infected children during post-natal and breastfeeding period</td></tr>
<tr><td>Syphilis</td><td colspan="2">Primary prevention of syphilis, especially among women of reproductive age group</td></tr>
<tr><td colspan="5">Partner Management</td></tr>
</table>

Prong 1: Prevention of HIV and Syphilis among women of reproductive age group constitutes a fundamental aspect of achieving EVTHS. This objective can be attained through provisioning comprehensive sexual and reproductive health services including interventions for health education towards prevention of HIV and STI/RTI. Collaborating with community structures and actively engaging with the general health system are imperative steps to increase awareness and improve access to essential prevention services.

The main beneficiaries for these services are women in reproductive age group (including adolescents). In addition, these services should be implemented amongst following vulnerable population as per the latest programmatic guidelines:

- High-risk women such as female sex workers and female injecting drug users
- Women who are considered at-risk of acquiring HIV and/or Syphillis (Box No. 1 below)
- Female spouses/partners of persons from high-risk groups and discordant couples
- Walk-in clients with self-perceived risk who have tested negative for HIV and/or Syphilis

Box No. 1 Women considered at-risk of acquiring HIV and/or Syphilis are as follows:

- Adolescent girls and young women engaged in high-risk behaviors
- Women with multiple sexual partners
- Women facing unstable housing or homelessness
- Women with a history of transactional sex, or drug use, or domestic violence
- Women living in prisons and other closed settings
- Women infected with STI/RTI
- HIV-negative partner of PLHIV

Prong 2: To prevent unintended pregnancies in WLHIV, it is essential to offer tailored counselling on Healthy Timing and Spacing of Pregnancy (HTSP) and linking them to facilities providing family planning services. HTSP is an approach of achieving healthier pregnancies and subsequent healthier outcomes.

This approach is pivotal in enhancing the health outcomes for WLHIV and their children. For WLHIV preventing unintended pregnancies, is vital to enhance their lives, protect their children and stop the transmission of HIV. Contraception provides women control over their choice for reproduction, allowing them to plan their pregnancy and practice birth spacing. This empowerment reduces unwanted pregnancies, the need for abortions, chances of pregnancy wastage and lowers the risk of vertical transmission to the baby. This prong also involves inclusion of male partner in the provisioning of HTSP services under RMNCAH+N.

Prong 3: Ensuring the prevention of vertical transmission of HIV and Syphilis requires providing pregnant women with comprehensive and stigma-free HIV testing and counselling services. Universal screening of pregnant women for HIV and Syphilis is an essential intervention towards early diagnosis of HIV and Syphilis in pregnant women. Additionally, linking these women with appropriate treatment services is critical for preventing vertical transmission. Regular monitoring and follow up of pregnant women infected with HIV and/or Syphilis along with robust counselling and support for institutional delivery are critical interventions. The availability and accessibility of screening and management services for pregnant women with HIV and/or Syphilis remains essential to keep these women under the umbrella of interventions towards EVTHS. This also includes screening of pregnant women directly coming in labour (DIL cases) for HIV and Syphilis in the labour room and management of partners.

Prong 4: Providing postnatal care, treatment and support to women infected with HIV and Syphilis, as well as their children and partners, is of utmost importance. This includes ensuring continuous access to antiretroviral therapy for managing HIV and implementing effective management strategies for women diagnosed with HIV and/or Syphilis during labour and post-natal period. The care and follow-up of HIV and/or Syphilis-exposed infants, along with appropriate management for those diagnosed with HIV and/ or congenital syphilis, are essential components of this prong. The management of partners in case of discordant couples is essential to prevent new infection in women during breast feeding period.

The integrated approach outlined in the above-mentioned prongs demonstrates a comprehensive care cascade for the Elimination of Vertical Transmission of HIV and Syphilis. By focusing on prevention, counselling, testing, treatment and support, the framework ensures a holistic and effective response. Collaborative efforts between community, community networks and the general health system are emphasized, reflecting a commitment to enhancing awareness and accessibility. This multifaceted approach holds significant promise for achieving the goal of EVTHS.

CHAPTER-3

Service Delivery Model of EVTHS

Service Delivery Model of EVTHS

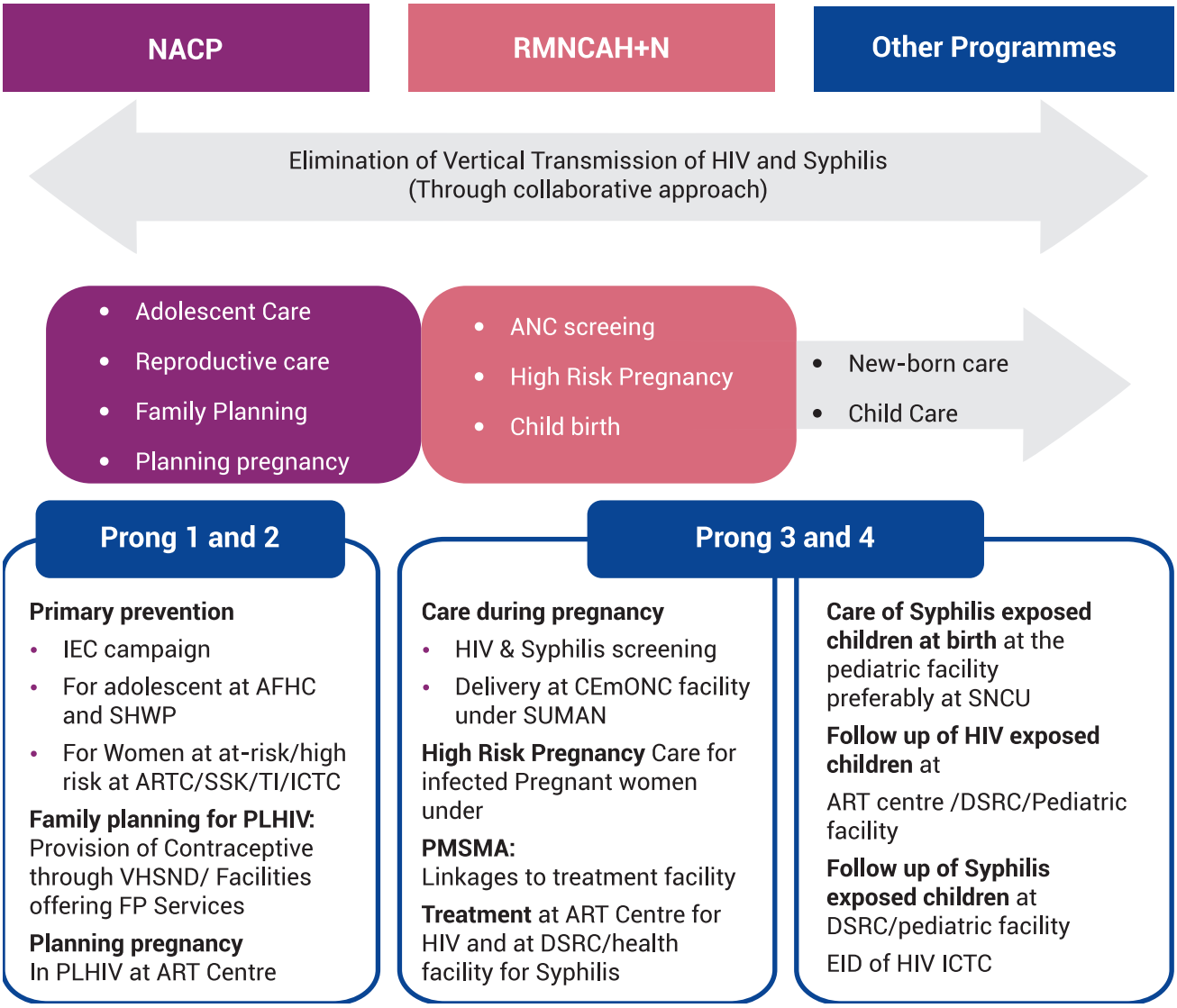
3.1 Integrated comprehensive care approach

The pregnant and breastfeeding WLHIV as well as syphilis infected pregnant women not only need prompt treatment but also need comprehensive maternal care to reduce maternal morbidity and mortality. Pregnant women living with HIV are also at increased risk of experiencing pregnancy complications and life-threatening infections such as sepsis and opportunistic infections, including TB, pneumonia and meningitis.

Similarly, the HIV and/ or Syphilis exposed children are at a higher risk of morbidity and mortality compared with non-exposed children due to higher risk. These children need comprehensive child health care such as immunization, optimal nutrition, and clinical assessment, in addition to the prophylaxis for vertical transmission and early diagnosis.

This means that HIV and Syphilis infected pregnancies need holistic care and one cannot compartmentalize the service provision. The services for prevention of vertical transmission are hence, required as a comprehensive and integrated care approach as described in Figure 3.1.1

Figure 3.1.1: Integrated care approach to EVTHS



RMNCAH+N: Reproductive, Maternal, Neonatal, Child, Adolescent Health and Nutrition

A well-structured service delivery model consisting of four major components (4 prongs) aims at promoting preventive measures, family planning, and management of infected pregnant women and exposed infants/children is the anchor for EVTHS. This model ensures a holistic approach to addressing the challenges posed by HIV and Syphilis while providing comprehensive reproductive, maternal and child care while supporting those affected. Integrated services can improve health outcomes and service delivery, and potentially lead to efficiencies.

Government of India has taken cognisance of this need and ensured appropriate integration of services. The continuum of care is provided through various health programs for strengthening service linkages and minimizing lost to follow-up.

3.2 Implementation of the Services

The EVTHS interventions designed at the national level, should further be customized and implemented at state level. However, as depicted in figure-3.2.1, the district health system should ensure final implementation of EVTHS interventions. The interventions should be implemented jointly by but not limited to, the District Reproductive and Child Health (RCH) officers, District Program Manager (DPM), or the Cluster Program Officer (CPM), with support of the Clinical services officer (CSO) and Data Monitoring and Documentation Officer (DMDO) at DISHA. This includes, and is not limited to joint review and monitoring, coordination meetings at facility levels, need based training and sensitization of Front-Line worker (FLW), and timely reporting.

At district level interventions should be provided through facility based and community-based services.

Facilities under NACP providing EVTHS services are

- Anti-retroviral (ART) centre
- HIV confirmatory Facilities
- Designated STI/RTI Clinic (DSRC)
- Sampoorna Suraksha Kendra (SSK)
- Targeted Intervention (TI)

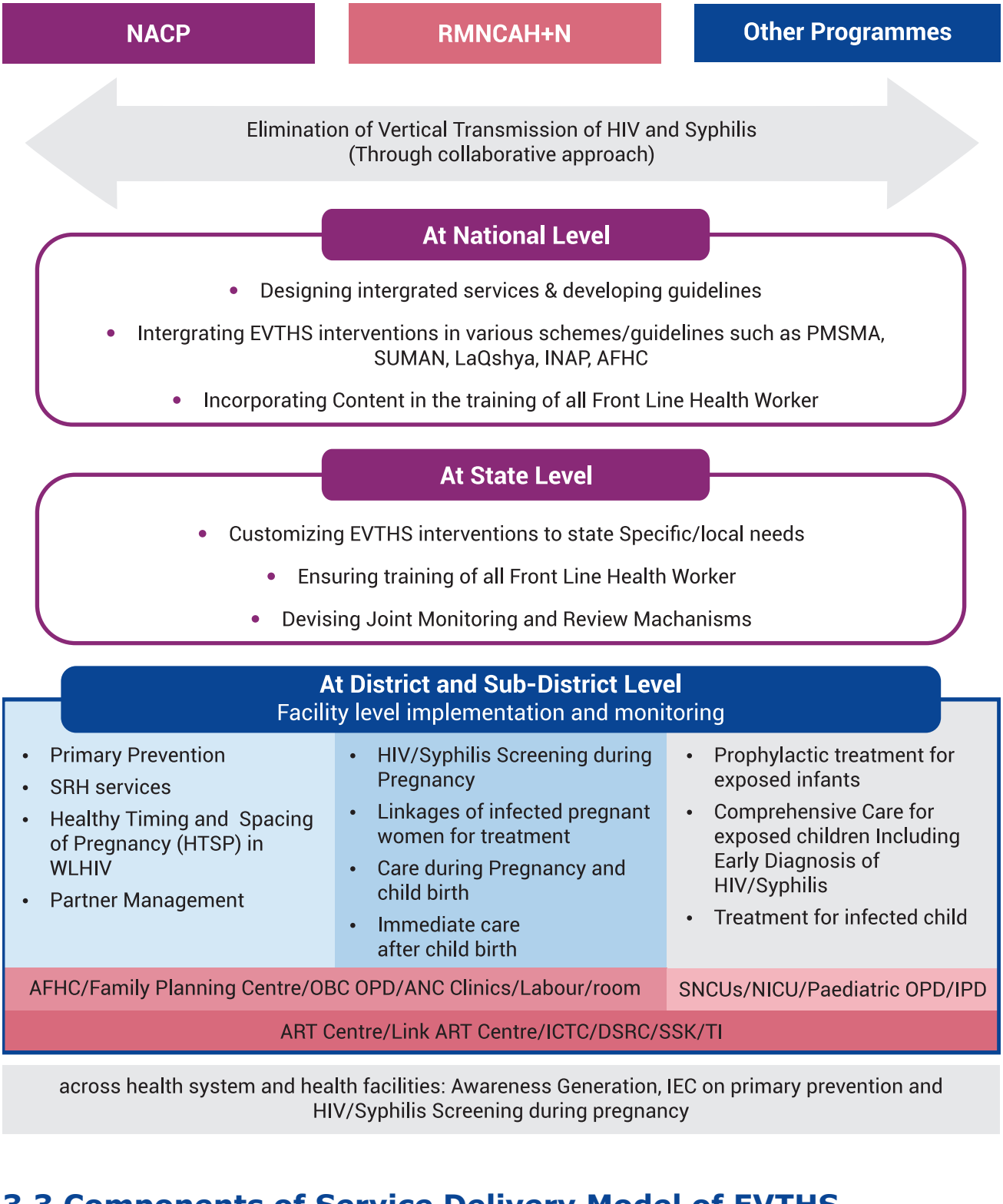
Facilities/ Schemes under NHM providing EVTHS services are

- ANC clinics/OPDs
- Special Newborn Care Unit (SNCU)
- Neonatal Intensive Care Unit (NICU) and other pediatric treatment facility
- Labour Room
- Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA)
- Village Health, Sanitation and Nutrition Day (VHSND)
- Family Planning service delivery points (OPD/Labour Room/OT/Counselling Room/ Outreach sessions
- Primary Health Centre (PHC)
- Community Health Centre (CHC)
- Health and Wellness Centres (HWC)- 'Ayushman Arogya Mandir'

Facilities under Private sectors providing EVTHS services are

- Private maternity facilities
- Private Screening and Confirmatory facilities
- ART centres in private sector, including medical colleges
- Service delivery points for Family Planning

Figure 3.2.1: Implementation module of EVTHS



3.3 Components of Service Delivery Model of EVTHS

Components of service delivery model of EVTHS focus on breaking the silos between HIV and Syphilis services under NACP and integrating them into routine maternal and child health care, leading to a more efficient and effective approach in eliminating vertical transmission. The details of Service Delivery Model are depicted in figure 3.3.1.

- **Primary Prevention:** This component involves a combination of commodity services, such as differential HIV and STI screening, as well as non-commodity services like counselling and risk reduction. Additionally, referral services are provided to engage women who are considered at-risk of acquiring HIV and/ or syphilis, ensuring they receive necessary support to remain negative and maintain their overall health.

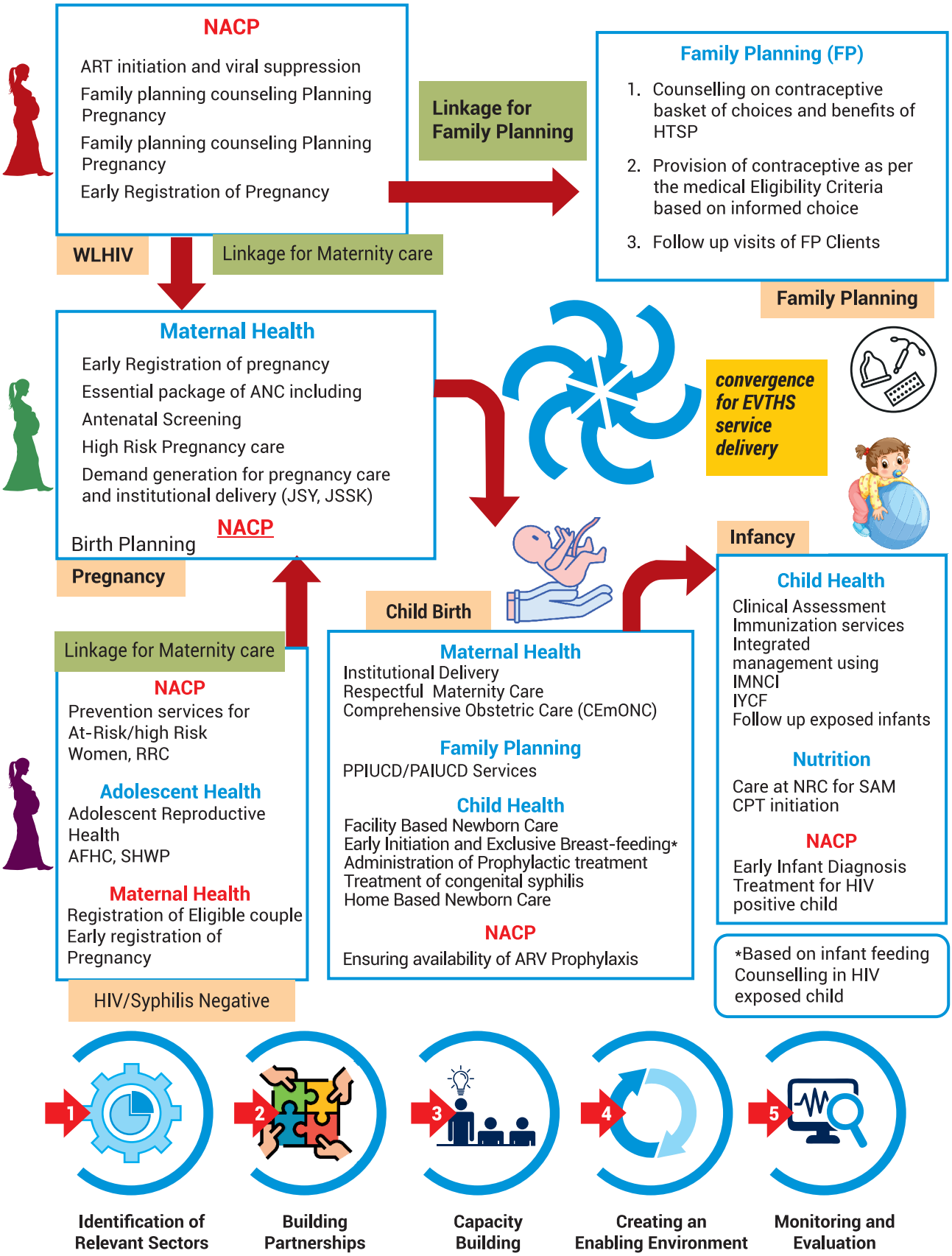
Primary prevention services for adolescent will be provided at Adolescent Friendly Health Clinics (AFHC) and for school children through School Health and Wellness Program (SHWP). Primary prevention services for women at-risk and high-risk for HIV and STI should be provided through ART centre, DSRC, TI, SSK and ICTC. Spouse/partner management should be provided at ART centre, DSRC, TI, SSK and ICTC

- **Healthy Timing and Spacing of Pregnancy in WLHIV:** Health facilities offer family planning counselling services and access to contraceptives for all women including women living with HIV. Stigma free family planning services (both spacing and limiting) should be provided at all family planning facilities for all PLHIV. Counselling on family planning and need assessment should be conducted at ART centre/Link ART centres for all WLHIV from reproductive age group.

During ANC visits, the ANC service providers such as ANM, Nurse, and Obstetricians should counsel on family planning services post-partum/post abortion and should help pregnant WLHIV and Syphilis infected pregnant women to choose appropriate family planning method.

WLHIV desirous of pregnancy are counselled regarding Healthy Timing and Spacing of Pregnancy (HTSP), when they have achieved viral suppression, as this reduces the risk of vertical transmission of HIV. After child birth or abortion, the labour room nurses and obstetricians should ensure that the selected family planning methods are provided to WLHIV and Syphilis infected pregnant women.

Figure 3.3.1: EVTHS Service Delivery Model



iii. Management of HIV and/or Syphilis Infection in Pregnant and Breastfeeding Women:

ANC services cover HIV and Syphilis screening during pregnancy. ANM/nurse should link the diagnosed infected pregnant women to treatment facilities immediately. Treatment for syphilis infected pregnant women will be offered at nearest health facility. Additionally, syphilis treatment and monitoring are available at all DSRC facilities. ART centres provide ART as well as monitor treatment (ART adherence and VL suppression) for all pregnant and breastfeeding women breastfeeding women 'infected with HIV'.

The pregnancy related care for all HIV and Syphilis infected pregnant women should be continued to be rendered through ANC clinics/OPDs or PMSMA clinics as per maternal health guidelines.

Stigma free childbirth services should be provided at Comprehensive Emergency Obstetric and Neonatal Care (CEmONC) facilities. The DSRC and ART centres should assist the infected pregnant women for birth planning including selection of delivery facility well in advance.

iv. Management of HIV and/or Syphilis-Exposed Babies:

The immediate care at birth should be provided at the labour room. The management of syphilis exposed infants is provisioned at SNCU/NICU/other paediatric treatment facilities. The HIV-exposed infants should be provided with ARV prophylaxis at the labour room.

The follow up care of exposed children for routine as well as specialized care should be provided under supervision of a medical officer (including but not limited to ARTC and DSRC doctors) and support from LT including but not limited to ICTC/ARTC counsellors. Wherever expert or specialist care is required it should be provided through referral and linkages through health system.

Components of EVTHS Service delivery is compiled in table 3.3.1

Table 3.3.1:Components of EVTHS service delivery

Care Component	Responsi-bility	Service Delivery Points	Services to be provided
Primary Prevention	NACP and NHM SACS at state level, DISHA and district RCH at district level	• Family Planning service delivery points • Adolescent Friendly Health Clinics • Health and Wellness centres • NACP facilities: ARTC, SSK, DSRC, ICTC, TI • Private Clinic/ facilities	• Awareness Generation • IPC/Counseling • Prevention and risk reduction • HIV/STI screening • Referral services for at-risk women to ensure that they stay negative and healthy

Care Component	Responsi-bility	Service Delivery Points	Services to be provided
Healthy Timing and Spacing of Pregnancy in WLHIV	NACP and NHM at state and district level	• ART Centre • Family Planning service delivery points • OBGY clinics/ OPDs • Private Clinic/ facilities	• ART initiation in all WLHIV after adequate preparedness counselling • Counseling for family planning for WLHIV and Spouse • Condom Provisioning at ART centres • Linkage and accompanied referral to Family Planning service delivery points • Access to stigma-free family planning services to prevent unintended pregnancies among WLHIV • Inclusion of WLHIV for post-partum/post abortion services of family planning • Adherence Counselling of WLHIV to achieve viral suppression • Nutritional Counselling for optimal health of the couple. • Screening and management of STI/ RTI for the couple • Linkage to OBG clinics for specialist care
HIV and Syphilis Screening During Pregnancy	NHM and NACP	• ANC clinics/ OPDs including VHSND/HWC/ labour room • ICTC	• Screen for HIV and Syphilis in the first trimester, preferably at the time of ANC registration • Provide pre and post-test counselling for HIV testing as per guideline • At-risk pregnant women, should be screened again in the third trimester and at-labour • Linkage of HIV reactive cases to ICTC for HIV confirmation and referral for treatment, after confirmation • Linkage of Syphilis reactive cases to Treatment sites after providing first dose of Injection Benzathine Penicillin

Care Component	Responsi-bility	Service Delivery Points	Services to be provided
Index Testing for HIV and Partner testing for Syphilis	NACP	• ICTC • ART centre • DSRC	• Counsel the pregnant women to disclose her status to her sexual partners • Encourage index testing (spouse/ partner and biological children) of pregnant WLHIV • Encourage partner testing for Syphilis
Care of Pregnant and Breastfeeding WLHIV	NACP and NHM	• ANC Clinics/ OPDs • ART centre • Labour room	• Routine ANC services and high-risk pregnancy care • Rapid ART initiation, Adherence counselling to achieve viral suppression for EVTHS • Counselling for safer sex practices, infant feeding options, adequate nutrition, care of nipple and breast and institutional delivery • Viral load testing at 32-36 weeks of pregnancy, to assess the HIV transmission risk for the baby • Birth planning and pre-sensitization of delivery sites for care during labour • Encourage access for existing services for high-risk pregnancies like referral transportation for institutional delivery and Stigma free delivery services

Care Component	Responsi-bility	Service Delivery Points	Services to be provided
Care of Pregnant Women with Syphilis Infection	NACP and NHM	• ANC Clinics/ OPDs • HWC/PHC/ CHC/SDH/DH • DSRC • Labour room	• Routine ANC services and high-risk pregnancy care • One dose of injection benzathine penicillin should be given all the pregnant women as soon as she screens reactive for Syphilis at the nearest treatment facility • Ensure complete treatment for all syphilis infected pregnant women (Three doses of inj. BPG) • Treatment monitoring at DSRC • Repeat serological titers preferably at least after 12 weeks of treatment/ 32nd week of pregnancy/ at the time of labour • Birth planning and pre-sensitization of delivery sites for care during labour and referral to SNCU/NICU/ other pediatric treatment facilities • Encourage access for existing services for high-risk pregnancies like referral transportation for institutional delivery and Stigma free delivery services
Care of HIV-exposed babies	NACP and NHM	• ART Centre • ICTC • Labour Room • Pediatric OPD/ treatment facilities	• Provide immediate care at birth • Provide ARV prophylaxis immediately after birth, preferably within one hour of delivery • Follow-up as High-risk babies by Pediatrician • Routine health services, including immunization, growth monitoring, clinical assessment by Medical Officer or Pediatrician • Follow-up protocol including Early Infant Diagnosis for HIV, for HIV-exposed infants up to 18 months or three months after complete cessation of breastfeeding

Care Component	Responsi-bility	Service Delivery Points	Services to be provided
Care of Syphilis-exposed babies	NACP and NHM	• ART Centre • DSRC • Labour Room • Pediatric OPD/ treatment facilities	• Provide immediate care at birth • Evaluation by pediatrician at birth and management of the Syphilis exposed infants at Pediatric Facilities • Follow up at 14 weeks and 6 months by pediatrician

3.4 Convergence for EVTHS service delivery

An integrated, inclusive and multi-sectoral approach that aims to share the ownership of HIV/AIDS issues, including its direct and indirect causes, impact and response with various stakeholders, for achievement of the EVTHS targets. The non-health sector plays a critical role in reducing vulnerability to HIV and Syphilis and mitigating the impact of these diseases on those infected and affected.

Break the silos, build synergies

NACP phase V recognizes the opportunities available within the Program as well as in other national health programs to catalyze progress on stated goals. Break the silos, build synergies will promote coordinated actions, through single window delivery systems along with functional and measurable referral and linkages, within NACP and across the national health programs and related sectors, for efficient service delivery. This will take into account the local contexts to ensure a suitable, functional and sustainable model.

The designing, implementation and monitoring of the beneficiary-centric services will meaningfully involve collaborators and leaders from the community concerned, including those from adolescent, youth and women living with HIV, ensuring full ownership and participation of the beneficiary in national HIV response. Structural interventions like community system strengthening and community-led monitoring will navigate beneficiary and community centric approaches under NACP phase V.

NACP is focused on strengthening existing partnerships with different ministries/departments and forging new partnerships with other public and private sector organizations to mainstream elimination of vertical transmission of HIV and Syphilis in India. The objective of this approach is to strengthen the multisectoral response and optimize resource utilization to maximize programme impact.

Process for Convergence in EVTHS Services by NACO:

Step 1: Identification of Relevant Stakeholder:

- Identify all relevant stakeholders including civil societies, which have a role in the EVTHS programme, including health, education, labour, social welfare and others depending on the local context.
- Conduct a mapping exercise to identify key stakeholders within each sector who can contribute to EVTHS Services.
- Prioritize stakeholders based on their relevance and potential contribution.

Step 2: Building Partnerships:

- Build partnerships with different ministries/departments, public and private sector organizations and civil society organizations to mainstream EVTHS programme in India.
- Collaborate with the partners to develop strategies for mainstreaming elimination of vertical transmission of HIV and Syphilis, in their respective sectors.
- Establish partnership mechanisms to ensure effective coordination and collaboration between different sectors.

Step 3: Capacity Building:

- Build capacities of key institutions at various levels to initiate activities on risk reduction and integration of EVTHS to mitigate the impact of HIV and Syphilis.
- Develop training programmes for different stakeholders to enhance their knowledge and skills related to EVTHS Services.
- Provide technical assistance to the partners to enable them to mainstream elimination of vertical transmission of HIV and Syphilis, in their respective sectors.

Step 4: Creating an Enabling Environment:

- Create an enabling environment through policies, programmes and communication to facilitate mainstreaming of elimination of vertical transmission of HIV and Syphilis, in India.
- Develop policies and guidelines for the partners to facilitate mainstreaming of EVTHS Services.
- Conduct advocacy and communication activities to raise awareness among different stakeholders about the importance of mainstreaming of elimination of vertical transmission of HIV and Syphilis.

Step 5: Monitoring and Evaluation:

- Develop a monitoring and evaluation framework to track the progress of mainstreaming activities in EVTHS Services.
- Establish a reporting mechanism to ensure regular reporting by the partners on the progress of mainstreaming activities. Streamline the data sharing mechanism between the stakeholders while ensuring the data confidentiality.
- Conduct periodic evaluations to assess the effectiveness of mainstreaming activities and identify areas for improvement.

NACO is actively working towards strengthening existing partnerships with different ministries and departments, while also forging new collaborations with other ministries as well as public and private sector organizations. State AIDS Control Societies (SACS) are encouraged to form state and sub-state level partnerships with government departments to maximize the reach of NACP. Additionally, engaging (Professional Medical Associations) PMAs, especially through training and sensitization supported by developmental partners, is a priority. This initiative ensures fostering a comprehensive and inclusive approach and offers window for social protection schemes for People Living with HIV (PLHIV) from different ministries.

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SECTION II: TECHNICAL AND OPERATIONAL FRAMEWORK FOR EVTHS SERVICES

CHAPTER-4

Primary Prevention and Prevention of Unintended pregnancies in WLHIV

Primary Prevention and Prevention of Unintended pregnancies in WLHIV

4.1 Primary Prevention of HIV and STI

Prong-1: Primary prevention of HIV and STI, especially among women of reproductive age group

Primary prevention refers to actions taken before the onset of a disease, aimed at eliminating the possibility of the disease ever occurring. In the context of HIV and STI, primary prevention involves specific interventions at the population and individual levels to minimize the burden of these diseases and its risk factors.

Availability and accessibility of comprehensive sexual and reproductive health services for women in reproductive age group, adolescents, and at-risk and high-risk women becomes imperative for implementing EVTHS strategies.

The following activities are recommended for effective primary prevention of HIV and STI

A. IEC (Information, Education, and Communication) Activities:

- **Focused and customized IEC material:** Develop pamphlets, posters, audio-visual content, mid-media and mass media content and social media messages in regional or local languages to promote HIV and STI prevention.
- **IEC campaigns on EVTHS:** Conduct IEC campaigns on EVTHS, to raise awareness about early testing and prevention. These campaigns should be rolled out in a mission-oriented approach.
- **EVTHS Week:** Celebrate EVTHS week on a regular basis, in close coordination with State NHM, to generate awareness specifically in priority districts, focusing on HIV and STI prevention.

B. Health Education and Counselling for SRH in school children and adolescents:

- **Training of school teachers:** Facilitate training programs for school teachers to educate them about HIV and STI prevention. This training can be conducted through Health and Wellness Ambassadors under the School Health and Wellness Program.

- **School health and Wellness Program:** is being implemented in government and government aided schools. In every school, designated "Health and Wellness Ambassadors" shall educate school children on health promotion and disease prevention information on eleven thematic areas in which HIV and STI are included.
- **Adolescent Education Program and Red Ribbon Clubs:** Engage with youth through Adolescent Education Programs and Red Ribbon Clubs, which promote awareness, education, and prevention of HIV and STI.
- **Adolescent Friendly Health Clinics:** Inform, educate, and counsel adolescents on various aspects of adolescent health, including HIV and STI. Provide referrals to health facilities, HIV testing centres, de-addiction centres, and clinics for non-communicable diseases and STI.

C. **Sexual and Reproductive health services:**

- **VHSND Day Sites:** VHSND Day programs include services targeted towards counselling all women in the reproductive age group on nutrition, food fortification, the importance of micronutrients etc. in alignment with the POSHAN Abhiyaan.
- **Counseling for Health Timing and Spacing of Pregnancy (HTSP)**: A list of newly married couples is maintained by the ASHA and the couples should be provided counselling on delaying the first pregnancy and adopting HTSP.
- **Promotion of routine gynecological care** among women in the reproductive age group. This includes encouraging regular visits to health facilities for gynecological care, nutritional care, and management of non-communicable diseases (NCDs).

The table 4.1.1 below enumerates the Primary Prevention Services for HIV and Syphilis along with their key activities and responsible stakeholder.

Table 4.1.1: Primary Prevention Services for HIV and Syphilis along with their key activities and responsible stakeholder

Services	Activities	Stake-holders
Information, Education and Communication	• Develop focused and customized IEC materials (pamphlets, posters, audio-visuals, social media messages, etc.) on the prevention of HIV and Syphilis in regional languages. • Roll out IEC campaigns on EVTHS in mission mode. • Celebrate EVTHS week to generate awareness, with a focus on priority districts. • Facilitate regular coordination meetings between SACS and RMNCAH+N.	SACS in coordination with RMNCAH+N program

Services	Activities	Stake-holders
Health Education and Counselling for SRH in school children and adolescents	1. **Adolescent Friendly Health Clinics (AFHC):** provide clinical and counselling services on: • Sexual and Reproductive Health (SRH) • Nutrition • Substance abuse • Injuries and Gender-based violence • Non-Communicable Diseases and • Mental Health 2. Peer Education Program 3. Adolescent Health Day 4. Adolescent Friendly Clubs 5. Menstrual Hygiene Scheme 6. School Health and Wellness Program: training of school teachers and children (age appropriate) on prevention of HIV and STIs facilitated through Health and Wellness Ambassadors	RMNCAH+N program, in coordination with DISHA Adolescent Friendly Health Services are delivered through trained service providers at AFHCs located at PHCs /CHCs/District Hospitals and Medical Colleges
Sexual and Reproductive health services	**VHSND Day programs** **Health Timing and Spacing of Pregnancy:** ASHA counsels couples on delaying the first pregnancy and adopting HTSP **Women in the reproductive age group** should be encouraged to establish and maintain routine gynaecological care, nutritional care, and management of NCDs through regular visits to health facilities.	RMNCAH+N program in coordination with SACS/ DISHA

4.2 Prevention Services for at-risk and high-risk women

At-risk and high-risk women face unique challenges in accessing and adhering to prevention and treatment services. These populations bear a disproportionate burden of HIV and STI infection and are at greater risk of transmitting the virus to their children.

Identifying at-risk women of reproductive age groups and ensuring the availability of prevention services are pivotal components of the EVTHS interventions.

Several interventions can be implemented as Preventive Services for at-risk and high-risk women. The high-risk women should receive these services through Targeted intervention (TI) projects and the Link Worker Scheme (LWS). The at-risk women would receive these services through the Sampoorna Suraksha Kendra/ICTC/DSRC.

Towards this end, the following customized services exist under NACP for high-risk and at-risk groups including women of reproductive age and pregnant women.

Customized Services under NACP:

- **Targeted Intervention projects:** Tailored programs, including peer education, outreach, and support groups, for groups at higher risk of HIV infection, like sex workers, transgender women and injection drug users.
- **HCTS Confirmatory Facilities:** Dedicated centres for confirmatory HIV testing after a preliminary positive result, ensuring accuracy and timely diagnosis.
- **Designated STI/RTI Clinics (DSRCs):** Safe spaces offering STI screening and treatment, counselling , referrals, and social support services for individuals, including at-risk women.
- **Opioid Substitution Therapy (OST) Centres:** Facilities providing medication and support to individuals struggling with opioid dependence, reducing their risk of HIV infection through unsafe injection practices.
- **Sampoorna Suraksha Kendra (SSK):** Provides comprehensive package of prevention services to at-risk HIV-negative individuals as per their needs
- **Targeted Outreach and Education:**
    - Raising awareness about HIV and Syphilis prevention through community events, workshops, and media campaigns specifically targeted towards HRGs and at-risk populations.
    - Providing information about available services, including HIV testing, counseling, and treatment options.
    - Empowering individuals with knowledge and skills to protect themselves and their loved ones from HIV infection.
- **Confidential HIV/STI Counseling and Testing:**
    - Offering free and confidential HIV and syphilis testing services in a supportive and enabling environment.
    - Providing pre and post-test counseling to address anxieties, answer questions, and explain test results.
    - Linking individuals diagnosed with HIV and STIs to appropriate treatment and care services.
- **Access to Essential Prevention Services:**
    - Providing condoms and lubricants to promote safer sexual practices.
    - Educating individuals about risk reduction strategies and harm reduction practices.
    - Referral and Linkages:
        - Connecting individuals to other essential services like TB, NCD and hepatitis prevention and testing services.
        - Facilitating access to mental health, NCD and psychosocial support services.
        - Providing referrals for legal aid and advocacy services, if needed.
- **Continuous Support and Follow-up Care:**
    - Scheduling regular follow-up appointments to monitor health status and adherence to treatment plans.

- Offering ongoing counseling and support to address any challenges or concerns related to HIV and AIDS or other health issues.
- Advocating for access to healthcare and social services without discrimination

Advocacy for HRG Rights:

- Raising awareness about the rights of HRGs, including access to health care, education and employment.
- Working with policymakers and service providers to ensure HRGs receive fair and respectful treatment.
- Empowering HRGs to advocate for themselves and their communities.

Once pregnancy is confirmed, in these populations, they should be referred for the ANC services under the general health system for the routine maternal and child health interventions.

4.3 Health Timing and Spacing of Pregnancy (HTSP) in WLHIV

Prong 2: Prevention of unintended pregnancies among women living with HIV

HTSP is an approach for achieving healthier pregnancies and outcomes. This is achieved by using appropriate contraceptive methods and planning the pregnancy, appropriately.

WLHIV should ideally plan her pregnancy, after achieving adequate ART adherence and sustained viral suppression. WLHIV should preferably achieve undetectable viral load to minimise the risk of transmission to the child.

ART initiation in newly diagnosed WLHIV

All newly diagnosed HIV infected women in reproductive age group need to be initiated on lifelong ART, after counselling for drug adherence and safer sex practices.

Dolutegravir (DTG) is a highly potent integrase inhibitor, which achieves faster viral suppression and is very effective in prevention of vertical transmission of HIV. DTG is effective for HIV 1, HIV 2, HIV 1 & 2 infections and is also used in women exposed to single dose Nevirapine in past and PLHIV coinfected with TB or Hepatitis B and C. It is available in the program as a tablet with a fixed drug combination, TLD containing three drugs (Tenofovir (300 mg) + Lamivudine (300 mg) + Dolutegravir (50 mg)), and prescribed as a single pill taken once a day as per patient's convenience.

Results of the Botswana Tsepamo Study on neural tube defects by ARV and HIV exposure

The Tsepamo study, a large observational study of birth outcomes that started in 2014 in Botswana. In August 2018, the WHO Advisory Committee on Safety of Medical Products set up a subcommittee on DTG to review all available evidence. Prevalence difference of neural tube defects (NTDs) by ARV and HIV Exposure Categories till April 2020, in study had declined to 0.19%. Conclusion was that the prevalence of NTDs among infants born to women on DTG at conception has declined to 0.11% and does not substantially differ from other exposure groups.

(Source: Update on neural tube defects with antiretroviral exposure in the Tsepamo Study, Botswana; available at: https://programme.aids2022.org/Abstract/Abstract/?abstractid=12759)

Program recommends that all HIV infected women of childbearing age or potential, should be provided appropriate information and counselling on the immense benefits as well as minimal risk related to

use of DTG, in order to make an informed choice about DTG use. Linkages to contraceptive services is essential in women in reproductive age group, who consent to initiation on TLD regimen.

Women of childbearing potential who do not wish to take DTG-based ART after adequate and optimal counselling, will be initiated on an Efavirenz based ART. In situations where Efavirenz is contraindicated (e.g. in women with HIV-2/ HIV-1&2/ prior NNRTI exposure), these women will be initiated on a Protease Inhibitor based ART regimen. For further details, on ART initiation and monitoring for ARV adverse reactions, refer to section-2.2, of the National guidelines for HIV care and Treatment, 2021.

Healthy Timing and Spacing of Pregnancy (HTSP)

For women living with HIV, preventing unintended pregnancies is vital to enhance their lives, protect their children and prevent transmission of HIV. Contraception provides women control over their reproductive choices, allowing them to delay childbirth, space pregnancies, and avoid risky pregnancy. This empowerment reduces the need for abortions and lowers the risk of vertical transmission.

Educating all WLHIV on available methods of contraception methods is an essential strategy under EVTHS. It is essential to assess the eligible couples for their reproductive health, risk of STI, and motivation to practice tailored methods for family planning and HIV and STI prevention. The responsibility for providing comprehensive counselling and referral linkages for these services lie with the ART centre, specifically the counsellors and ART Medical Officers (MO).

The ART centre counselor may develop a line list of PLHIV in the reproductive age group based on the data from SOCH. This list will help in identifying eligible persons who require family planning services.

The following activities can be undertaken:

- **IEC (Information, Education, and Communication)**

Educational Posters and Brochures: ART Centres should display educational posters and distribute informative brochures. These materials will cover topics such as family planning, safer conception techniques and sexual and reproductive health.

- **Counselling**
  - Counselling on family planning: During follow-up visits at the ART centre provide counselling on family planning options. The counselling session can be documented in the patient record.
  - Planning pregnancy: WLHIV who desire pregnancy, should be provided counselling on planning their pregnancy, when they have achieved viral suppression or undetectable viral load results to reduce risks of vertical transmission. Counselling for available conception care services, includes discussion on optimal timing for attempting conception, managing HIV during pregnancy and reducing the risk of vertical transmission.
  - Assessment and linkage to facilities offering Family Planning (FP) services: The couple should be assessed for their family planning needs and accordingly the counsellor should facilitate their referral and linkage to appropriate facilities offering FP services. The counselor should provide comprehensive counselling to WLHIV on the following important aspects:

    a) **Effective methods of contraception:** The counselor should educate WLHIV about various effective methods of contraception to prevent unintended pregnancies and the importance of dual protection, which involves using condoms along with other contraceptive methods to reduce the risk of both HIV transmission and pregnancy.

WLHIV with contraceptive needs should be linked to family planning services, including permanent FP methods, for males and females, to ensure they have access to appropriate choices.

b) **Healthy Timing and Spacing of Pregnancy:** The staff at all NACP facilities should assist WLHIV in making informed decisions regarding timing of pregnancy and contraception methods. Women with advanced HIV clinical stage should receive special assistance in selecting suitable contraceptive options based on their health condition.

Three key messages about HTSP that should be conveyed are:

1) First pregnancy should be planned only after the age of 20 years, in order to avoid unfavourable consequences of teenage pregnancies.

2) After a live birth, next pregnancy should be planned only after 2 years or later to keep adequate interval between two births (ideal spacing between two births is 3–5 years).

3) After a miscarriage or abortion, next pregnancy should be planned only after 6 months or later to avoid chances of an abortion again.

For further reading, refer to Reference Manual for Integrated RMNCAH+N counselling, MOH, GOI, September, 2021; available at https://nhm.gov.in/images/pdf/programmes/family-planing/guidelines/RMNCAH+N_Manual_on_Counseling_2021.pdf

c) **Risks and Protection:** WLHIV should be informed regarding the risks of HIV transmission to an uninfected partner during unprotected intercourse, particularly when attempting to conceive. Additionally, they should be educated on the risks of transmitting HIV to their child as well as the benefits of ART (treatment as prevention) and Antiretroviral prophylaxis for their child to significantly reduce the risk of vertical transmission.

d) **Family-Centric Approach:** The counselor should encourage involvement of spouses and other family members in the decision-making process. Shifting from a "client-centric" to a "family-centric" approach ensures that decisions about family planning and HIV management are collectively made, promoting a supportive and understanding environment to ensure viral suppression and treatment retention.

Referral and Linkages for Family Planning Services: All eligible WLHIV should be counselled on all available family planning methods during their visit to ARTC/Link ARTC. They should be assisted in making informed decisions regarding planning for pregnancy and childbirth by the staff at ART centre. WLHIV with unmet family planning needs should be promptly referred to health facility offering family planning services on a priority basis.

The Medical Officer at the ART Centre will diligently record all necessary details related to Sexual and Reproductive Health (SRH), obstetric and gynaecological history and family planning status in the patient's clinical records. A coordination process should be established with the Family Planning service delivery points, to address the unmet family planning needs of WLHIV. District Integrated Strategy for HIV and AIDS (DISHA) can facilitate this coordination and delivery of appropriate services.

Methods of Contraception

A range of contraceptives, for spacing and limiting children, are available under the National Family Planning Programme (NFPP). No contraceptive method is 100 percent effective and this needs to be clearly explained during counselling. The table 4.3.1, enumerates the types of Contraception for different needs/reproductive intent.

Table 4.3.1: Types of Contraception for different needs/reproductive intent

Why is Contraception Needed?	Contraceptive Options
For delaying the first child	• Condoms • Oral contraceptive pills (Mala N, Chhaya) • Intra Uterine Contraceptive Devices (IUCD 380A & 375) • Injectable contraceptive MPA (Antara Programme) • Emergency contraceptive pills (Ezy Pill, not to be used routinely)
For healthy spacing between two pregnancies	• Condoms • Oral contraceptive pills - (Chhaya, Mala N) Mala-N pills - not to be given until the breastfed baby is 6 months old • Intra Uterine Contraceptive Devices (IUCD 380A & 375) • Injectable contraceptive MPA (Antara Programme)
For limiting family size*	• Male Sterilization (Conventional/ Non Scalpel Vasectomy) • Female Steriliazation (Minilap tubectomy/ Laproscopic tubal occlusion) • Long acting reversible methods • Intra Uterine Contraceptive Device (IUCD 380A & 375) • Injectable contraceptive MPA (Antara Programme) *Oral pills & condoms can also be used to limit the family size; however, the client should be counseled about the importance of correct & consistent use of the method as incorrect or inconsistent use may lead to failure.

Source- Reference Manual for Integrated RMNCAH+N counselling, MOH, GOI, September, 2021; available at https://nhm.gov.in/images/pdf/programmes/family-planing/guidelines/RMNCAH+N_Manual_on_Counseling_2021.pdf

Family Planning for WLHIV

Asymptomatic WLHIV who are adherent on ART can safely use available forms of contraception. However, it is crucial to prevent cross-infection with HIV and other STIs. Therefore, dual protection, which involves correct and consistent use of condom in addition to other effective method of contraception, is essential to prevent unplanned pregnancy, as well as HIV and STIs.

The Category 1 of the medical eligibility criteria for contraceptive use (MEC) allows use of all hormonal contraceptive methods and intrauterine devices (IUDs) for women at high-risk of HIV. Refer to *Annexure-1 for details on Medical Eligibility Criteria (MEC) Categories for Contraceptive Use: Guidelines for Interpretation and Application in Clinical Practice.*

Women at high-risk of HIV can use all methods of contraception without any restrictions in the absence of any other medical or physiological contraindications. Condoms (both male and female) are currently the only available dual protection method for preventing both STIs (including HIV) and unintended pregnancy and counseling on the benefits of dual method – use of condoms with another form of

contraception – helps the client make informed choices regarding the prevention of HIV, other STIs and unwanted pregnancy. The considerations for use of available methods of contraception among PLHIV are highlighted in table 4.3.2.

Table 4.3.2: Considerations for PLHIV on available methods of contraception

No.	Method	Considerations for PLHIV
1.	**Intrauterine device (IUD): copper-bearing IUD (Cu-IUD)**	• WLHIV can safely undergo an IUD insertion if they have mild or no clinical HIV disease (irrespective of their status of ART). • WLHIV with advanced or severe clinical disease should not undergo IUD insertion. • New HIV infection in women (with IUD) does not warrant removal of IUD. • A WLHIV who develops advanced or severe clinical disease can keep IUD but should be closely monitored for pelvic inflammatory disease. • Women who are at high-risk for gonorrhea and/or chlamydia infections or have gonorrhea, chlamydia, purulent cervicitis, or pelvic inflammatory disease should not undergo IUD insertion.
2.	**Hormonal methods**	This applies for all methods present under National Family Planning Program including Combined Oral Pills-Mala-N; Injectable Contraceptives, MPA (Antara - Intramuscular/Subcutaneous), Subdermal Contraceptive Implant (single rod), Emergency Contraceptive Pill- Ezy Pill. • Safe and suitable for WLHIV, whether or not on antiretroviral therapy • Atazanavir Interaction: When co-administered with Atazanavir, oral contraceptives should contain at least 35 mcg of ethinyl estradiol
3.	**Female Sterilization**	• Safe and suitable for WLHIV, whether or not on antiretroviral therapy • The procedure may need to be delayed in clients with purulent cervicitis, chlamydia, or gonorrhea or PID or HIV-related illness. • The client may be advised to use other modern contraceptive method till the delay period.
4.	**Vasectomy**	• Safe and suitable for clients living with HIV, whether or not on antiretroviral therapy • The procedure may need to be delayed if the client has active sexually transmitted infection. • The client may be advised to use other modern contraceptive method till the delay period.

The table 4.3.3 presents the criteria for initiation of Family Planning Methods as per WHO adapted GOI MEC Wheel 2022.

Table 4.3.3: Initiation of Family Planning Methods as per WHO adapted GOI MEC Wheel (2022)

	Combined Pills & Combined Injectables*	Centchroman Pills	Progesterone Only Pills*	DMPA & NET EN*	Implants	Copper IUCD	LNG IUD*
HIV/AIDS	1[G]	1	1[G]	1[G]	1[G]	2-3[H]	2-3[H]
STI/RTI- Purulent Discharge	1	1	1	1	1	4[E]	4[E]
STI/RTI- Non-Purulent Discharge& Individual with high-risk	1	1	1	1	1	2	2

G- If on ART, it's MEC 2, except ritonavir – boosted ARVs, where it is MEC 3 category

H- If not receiving ART and not clinically well, Cu IUCD and LNG-IUD is MEC 3 category

E- Current PID and Current STI (Purulent discharge): Cu IUCD and LNG-IUD is MEC 4 category: if she develops these conditions while using Cu IUCD and LNG-IUD, give treatment and continue with the de

By carefully considering these factors and providing accurate information, health care providers can support WLHIV in making informed decisions about contraception, ensuring their SRH needs are met while minimizing the risk of HIV transmission and other STIs. The available methods for family planning under National Family Planning Program (NFPP) are described in table 4.3.4.

Table 4.3.4: Methods of Contraception under National Family Planning Program (NFPP)

Spacing Methods
• IUCD 380A and Cu IUCD 375
• Injectable Contraceptive MPA (Antara)
• Combined Oral Contraceptive (Mala-N)
• Centchroman (Chhaya)
• Subdermal contraceptive Implant (Single Rod)
• Condoms (Nirodh)
Limiting Methods
• Female Sterilization: Laparoscopic, Minilap
• Male Sterilization: No Scalpel Vasectomy, Conventional Vasectomy
Emergency Contraception
➢ Emergency Contraceptive pills (Ezypills)

Pregnancy Planning

Pregnancy Planning is a critical component of primary health services for all women in their reproductive age group. It's primary goal is to ensure that every pregnancy is planned and occurs at the most

opportune time, taking into consideration optimal maternal health. Additionally, Pregnancy Planning, significantly reduces the risk of HIV transmission to uninfected partners and children. In addition, it is crucial for WLHIV to be adherent to antiretroviral therapy (ART) and achieve viral suppression/ undetectable viral count, before planning a pregnancy. This ensures the best possible health outcomes for both the mother and her baby.

Access to Pregnancy Planning is essential to decrease unintended pregnancies, optimize maternal health and offer safer options for conception and contraception. Pregnancy Planning plays a vital role in promoting the health and well-being of WLHIV who desire pregnancy, as well as keep their partners HIV-negative. WLHIV who has completed her family, should be encouraged to use contraceptives or opt for permanent methods of contraception.

The responsibility for providing Pregnancy Planning care lies with the ART centre. The following activities can be undertaken:

- **IEC (Information, Education, and Communication)**

Educational Posters and Brochures: ART Centre will display educational posters and distribute informative brochures, at easily accessible areas. These materials should be in regional languages, and cover topics such as Pregnancy Planning, the importance of viral suppression, safer conception techniques and family planning options.

- **Counselling:**
  - Viral load suppression and ART adherence: Provide counselling on the importance of achieving viral load suppression in the HIV-positive partner before planning pregnancy. The need for optimal adherence to antiretroviral therapy (ART) to achieve and maintain viral suppression, should be reinforced.
  - Optimal health of the couple: Ensuring that both partners are in optimal health condition before attempting conception is essential. Underlying health issues, such as anemia or malnutrition, or drug abuse need to addressed.
  - Education regarding risks of transmission of HIV, available infant feeding options, potential effects of HIV and ART during pregnancy is essential. Early detection of pregnancy and initiating prenatal care promptly, are critical factors to prevent vertical transmission of HIV.
  - Tailoring prevention strategies based on fertility intentions, including testing, disclosure, condom promotion, ART and PrEP use, if eligible.
  - Providing prophylaxis for opportunistic infections (OI), if indicated and management of OI, if required.
  - Screening and management of STIs/RTIs: Both client and partners should be screened for STI/RTI. If any infections are detected, appropriate treatment and counselling should be provided to minimize the risk of transmission and optimize reproductive health.
  - Linkage to maternal health services: The counselor should facilitate linkage of the couple to maternal health services for Pregnancy Planning and conception care.

Pregnancy Planning for WLHIV

Pregnancy Planning for a pregnant woman with HIV includes a series of important steps aimed at optimizing maternal health and ensuring a successful pregnancy outcome:

a) **Establishing and maintaining routine gynaecological care:** Regular gynaecological check-

ups are essential for women planning to conceive. These visits help identify and manage any underlying gynaecological conditions that may affect pregnancy, such as cervical abnormalities or uterine issues. Regular care also includes screening for STI/RTI to ensure their prompt detection and treatment.

b) **Achieving normal BMI prior to pregnancy:** Achieving a healthy body mass index (BMI) before pregnancy is crucial for maternal and foetal well-being. Women should aim to maintain a normal BMI by following a balanced diet and engaging in regular physical activity. An appropriate BMI reduces the risk of complications during pregnancy and promotes the overall health of the mother and the baby.

c) **Preventing and managing Anaemia:** Adequate screening for anemia and its appropriate management through iron-folic acid supplementation and dietary improvements are essential Pregnancy Planning measures.

d) **Monitoring and managing non-communicable diseases and other chronic illnesses:** WLHIV on ART, should be regularly monitored for adherence to antiretroviral therapy (ART) and presence of non-communicable diseases or other chronic illnesses. If any of these are detected, then referral for appropriate management should be facilitated by the counsellor.

e) **Micronutrient supplementation:** Adequate intake of folic acid and essential micronutrients before pregnancy is vital to prevent neural tube defects and support the healthy development of the foetus.

f) **Lifestyle modifications:** Encouraging healthy lifestyle habits, such as avoiding smoking, alcohol and recreational drugs, is important for women planning to conceive. These lifestyle changes contribute to better maternal health and reduce potential risks to the developing baby.

For HIV discordant couples who desire to have children, there are several approaches available to reduce the risk of transmission of HIV from one partner to the other during attempts to conceive.

4.4 Pregnancy Planning for spouses of HIV infected Men

Involvement of Male Partner

The involvement of male partner is pivotal in achieving universal access to comprehensive reproductive health services. By actively engaging men, we can increase the rate of institutional deliveries and the adoption of family planning methods by couples. Moreover, male participation has shown positive associations with improved pregnancy outcomes, benefiting both women and infants.

Ensuring that every pregnancy is desired and planned is a shared responsibility of the couple. When male partner actively participate in pregnancy planning, there is a notable enhancement in reproductive health outcomes and improved health behaviors among both partners. This involvement further facilitates better preparation for fatherhood, leading to healthier pregnancies and better parenting experiences. The screening and management of STI/RTI among male partners is equally important to prevent transmission of infections and enhance pregnancy outcomes. This collaborative approach between men and women fosters a supportive and inclusive environment for family planning and reproductive health decision-making.

Considerations for HIV concordant couple (Both are HIV infected/ HIV-positive couple)

a) When an HIV-positive couple is considering pregnancy, it is essential to ensure that both partners are adherent on-ART, virally suppressed and free from STI/RTI.

b) The risk of HIV superinfection or infection with a resistant virus is negligible when both partners are on ART and virally suppressed. This underscores the importance of achieving and maintaining viral suppression to ensure the health and well-being of both partners and to minimize the risk of transmission during conception and throughout their relationship.

Considerations in case of HIV-discordant couple

For HIV discordant couples who desire to have children, there are several approaches available to reduce the risk of transmission of HIV from one partner to the other during attempts of conception.

a) The HIV-positive partner should be counselled and monitored for adherence to ART and the need to achieve sustained viral suppression.

b) The couple can be counselled for considering PrEP (pre-exposure prophylaxis) for the negative partner to further reduce the risk of transmission. This is crucial in reducing the risk of sexual transmission of HIV to the HIV-negative partner.

For further details on PrEP, please refer to National Guidelines for Pre-Exposure Prophylaxis 2021, available at: https://naco.gov.in/sites/default/files/National_Technical_Guidelines_(Web).pdf

Special Scenarios

Additional guidance might be required in the following scenarios:

- If the partner/spouse living with HIV has not achieved sustained viral suppression or their status of viral suppression is unknown, OR
- If concerns exist that the partner/spouse with HIV might not be adherent to ART during the periconceptional period.

In these circumstances, the following guidance can be provided to the couple:

- The partner with HIV should receive step-up adherence counselling (wherever needed) for achieving and further sustaining viral suppression. The partner with HIV should be informed of the importance of viral suppression in safer conception.
- The couple should be counselled on available alternatives for safer conception. The clinicians should educate HIV discordant couples about the potential risks and benefits of all available alternatives for safer conception.
- PrEP may be initiated for safer conception.
- The clinicians should discuss the comprehensive information related to the potential risks and benefits of PrEP for conception, so that an informed decision can be made.

If the couple accepts the option to use PrEP for safer conception, the clinician must ensure that:

- The HIV-positive partner is on ART and virally suppressed with VL of <1000 copies/ml or viral load is undetectable (TND).
- PrEP is initiated at least 20 days ahead of unprotected sex (When PrEP is taken by the HIV-negative female partner).
- PrEP should not be discontinued immediately after conception and should be continued by the HIV-negative partner for 28 days after the last unprotected sexual encounter. Unprotected sexual encounters should be ceased after conception.
- The most fertile period may be advised to the couple to increase the chances of conception. It should be suggested to consider attempts for unprotected sex (without condom) to coincide

with ovulation (peak fertility) so as to reduce the risk for HIV transmission and increase the chances of conception.

- Where female partner/spouse is living with HIV, home insemination can be a safer alternative to unprotected sexual intercourse for conception, providing a way for HIV discordant couples to pursue pregnancy while still maintaining preventive measures against HIV transmission. This option may be discussed with the treating obstetrician and pursued with adequate supervision.

Please Note: PrEP is not provided under the National Program.

However, it can be provided by a trained physician at an individual basis following the National Technical Guidelines of Pre-exposure Prophylaxis, NACO. *For further details please refer to National Guidelines for Pre-Exposure Prophylaxis 2021, available at: https://naco.gov.in/sites/default/files/National_Technical_Guidelines_(Web).pdf*

Assisted reproductive technologies

Assisted Reproductive Technologies offer viable options for HIV affected couples who desire to have children while minimizing the risk of HIV transmission between partners. These technologies involve medical interventions that assist with conception and pregnancy and have been used to facilitate safe conception for HIV discordant couples.

- When a WLHIV is in a relationship with an HIV-negative partner and wants to conceive, assisted insemination during the periovulatory period with semen from the male partner is a suitable option. This process involves carefully timed insemination to coincide with the woman's ovulation, maximizing the chances of successful conception while eliminating the risk of HIV transmission to the male partner.
- In the case when a male living with HIV is in a relationship with an HIV-negative partner who wishes to conceive, using donor sperm from an HIV-negative man is an alternative for conception. This approach ensures that there is no risk of HIV transmission to the partner.

In the past, semen preparation techniques like "sperm washing" followed by testing the sample for HIV RNA were used to facilitate safe conception for HIV discordant couples. However, with the advent of highly effective antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP) which significantly reduce the risk of transmission of HIV, these techniques are no longer routinely recommended. The role and efficacy of semen preparation techniques in the current context are uncertain considering their cost and technical requirements. As a result, their use is now limited, especially considering the availability of other safer and more effective methods.

It is essential for HIV discordant couples to consult with health care providers who are experienced in reproductive medicine and HIV care to determine the most suitable assisted reproductive technology based on their specific health needs and circumstances. While these techniques can be valuable in cases of male infertility or for couples using donor sperm or a surrogate parent, each case requires personalized evaluation and consideration of the available options. The goal is to ensure safe conception while minimizing the risk of transmission of HIV, supporting the couple in achieving their desired family planning goals.

Please Note: These services are not provided under the National Programme. The patient can be explained about these techniques and can be referred to centre of excellence, tertiary care hospitals (including medical colleges) or private sector (if the patient desires to access these services).

CHAPTER-5

HIV and Syphilis Screening and Diagnosis during Pregnancy

HIV and Syphilis Screening and Diagnosis during Pregnancy

The screening of HIV and Syphilis during pregnancy should preferably be done using HIV and Syphilis dual rapid diagnostic testing (Dual RDT) kits. However, when Dual RDT is not available, separate PoC test kits for HIV with Rapid Plasma Reagin (RPR) or Venereal disease research laboratory (VDRL) test for Syphilis can be used.

The responsibility of conducting these tests lies with facilities providing ANC services such as VHSND/ HWC/ Screening sites and labour rooms with the support from nearest HCTS confirmatory facilities.

It is crucial to ensure that proper screening and treatment protocols are in place and followed rigorously to protect the health of both the mother and the child. Pregnant women who test positive for HIV or Syphilis should receive immediate and appropriate treatment and linkages to prevent vertical transmission of HIV.

5.1 Screening for HIV and Syphilis during Pregnancy

HIV screening and confirmation are two distinct processes. HIV screening involves initial testing to detect the presence of HIV antibodies or HIV antigens in a person's blood using rapid diagnostic kits which provide quick results, often within 20-30 minutes along with brief group/individual counselling sessions. HIV confirmation is a follow-up process that involves conducting additional tests to rule out false positive results from screening tests and provide a definitive diagnosis.

HIV and Syphilis screening services are available across various public and private facilities as well as provided through outreach services such as community-based screening. The Dual RDT strategy for HIV and Syphilis has been introduced in the programme and elucidated under the NACP phase V strategy to improve efficiency and coverage for both HIV and Syphilis screening for pregnant women.

For pregnant women, NHM will provide Dual RDT kits for field level testing. The screened HIV reactive cases will be linked to the nearest confirmatory ICTC where the services for confirmation of HIV diagnosis are provided. The screened reactive Syphilis cases will be linked to nearest treatment facility for appropriate management.

Screening protocol for HIV and Syphilis in pregnant women should include the following activities:

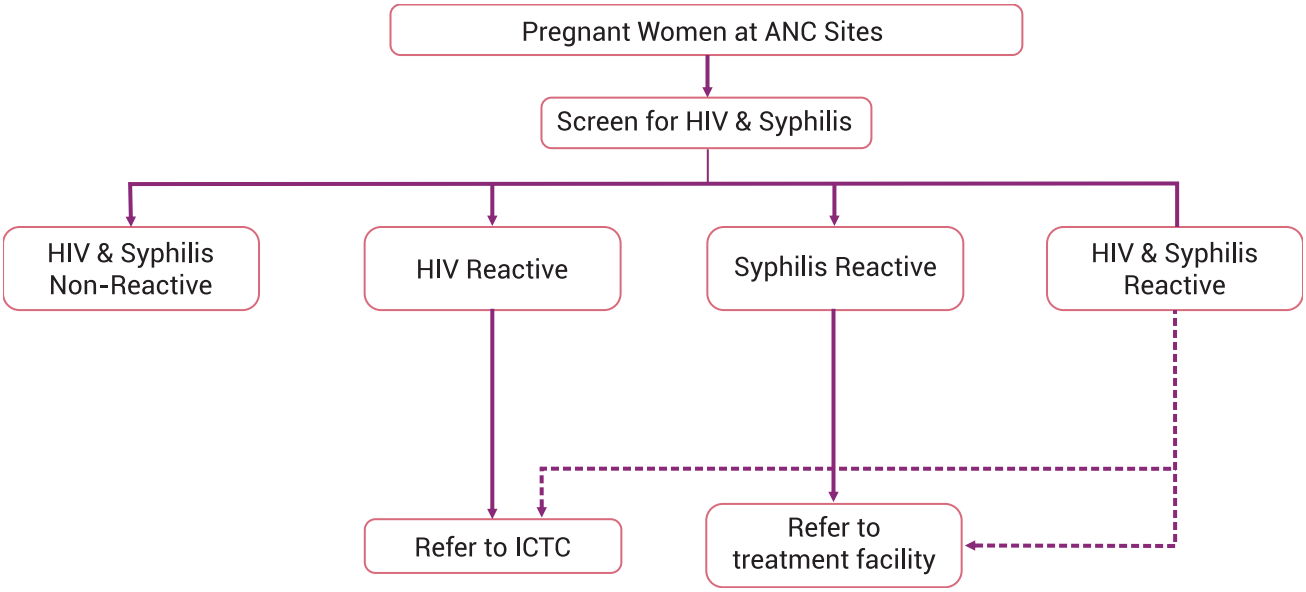
- Screen all pregnant women for HIV and Syphilis in the first trimester preferably at the first ANC visit.
- Ensure availability of HIV and Syphilis screening kits at facilities providing ANC services such as VHSND/ HWC/ PHC/ CHC/ FRU and labour room.
- Obtain informed consent and provide pre and post-test counseling, for HIV testing as per guidelines.
- All pregnant women reporting direct-in-labour, with unknown HIV and Syphilis status must be screened in the labour room by labour room nurse, and if, screened reactive, should be referred to ICTC for HIV confirmation. If HIV infection is confirmed, pregnant women shall be linked to ART centre for subsequent care and treatment.
- Inventory management to be done including cold chain management throughout the supply chain process.
- Reporting of HIV and Syphilis screening in HMIS/ RCH portal-ANMOL/ SOCH. This will be ensured by nurses and data entry operators, who so ever is available and is in charge for the work.

Repeat testing criteria for HIV and Syphilis

- For pregnant women who are at-risk/ high-risk for HIV and/or Syphilis infection, the screening should be repeated in third trimester and at-labour.
- The additional criteria for repeat syphilis screening are mentioned below:
    - Pregnant women with a history of repeated abortions, stillbirths or past history of delivery of premature babies or neonatal deaths.
    - Testing at the time of delivery in cases where the partner of syphilis reactive pregnant women was not tested/managed.
    - The screening should also be repeated among pregnant women who live in areas with high prevalence of Syphilis among pregnant women (>1% sero-positivity)

The figure 5.1.1 depicts the flowchart for Screening of Pregnant Women for HIV and Syphilis at screening sites.

Figure 5.1.1: Screening of Pregnant women for HIV and Syphilis at screening sites



5.2 Linkages of HIV reactive and Syphilis reactive cases

Linkage of HIV reactive cases

If any pregnant woman is found reactive for HIV, then the ANM/Nurse should write on the MCP card of the pregnant women, "**Refer to ICTC**" and link the pregnant woman to ICTC for confirmation.

The ANM should also share details with the linked In-charge PHC MO. This will ensure proper management of the pregnant women's HIV infection and reducing the risk of vertical transmission. If confirmed positive for HIV, then pregnant women should be linked to nearest ART Centre for rapid ART initiation. This should be ensured by ANM caring for the pregnant women or by the counsellor of the confirmatory facility. *(Refer to the National HIV Counselling and Testing Services Guidelines, 2024)*

Linkages of Syphilis reactive cases

If any pregnant woman is screened reactive for Syphilis, then the ANM should write on the MCP card of the pregnant women, "**Reactive for Syphilis**" and refer the pregnant woman to nearest PHC/treatment facility. She must also share details with the linked In-charge PHC MO.

All the pregnant women screened reactive for Syphilis, should be given at-least one dose of injection benzathine penicillin at the nearest treatment facility (including DSRC). Thereafter, all syphilis reactive pregnant women should be linked to confirmatory sites for RPR/ VDRL testing. All women screened reactive with RPR/VDRL should be provided with complete treatment with 3 doses of injection benzathine penicillin at the nearest treatment facility (including the DSRC). (Refer to the National Technical Guidelines on STI and RTI, 2024.)

Follow up of all Reactive cases (HIV and/or Syphilis)

- All pregnant women referred for confirmation at ICTC should be ensured for linkages and the confirmation of HIV. PWLHIV referred for other HIV services, including ART services, should be tracked to ensure that they avail the services and have been registered at the respective centres.
- All the pregnant women screened reactive for Syphilis should be given the first dose of Injection Benzathine Penicillin, at the nearest treatment facility and should be followed up for complete treatment. The treatment response should be monitored after 3 months/ 3rd trimester/ at-labour (whichever is earlier), of completion of treatment at DSRC/treatment facility.

The referral and linkage process for Pregnant women who screened reactive for HIV and/or Syphilis is depicted in table 5.2.1

Table 5.2.1: Referrals & Linkages for Pregnant women who screened reactive for HIV and/or Syphilis

No.	Result of Screening		Referral Action
	HIV	Syphilis	
1.	Reactive	Reactive	Refer to ICTC (HIV reactive cases) Refer to MO-PHC/CHC or DSRC (Syphilis reactive cases) and ensure institutional delivery
2.	Reactive	Non-Reactive	Refer to ICTC and ensure institutional delivery
3.	Non-Reactive	Reactive	Refer to MO-PHC/CHC or DSRC and ensure institutional delivery
4.	Non-Reactive	Non-Reactive	No referral → re-testing of at-risk women and ensure routine maternal and child care as per the standard practices.

Ref: Standard Operation Procedures for HIV & Syphilis Screening at VHSND, MH division, MOH,FW)

5.3 Confirmation of HIV and Syphilis diagnosis

Confirmation of HIV diagnosis

All HIV reactive cases need to be referred for confirmation at HCTS confirmatory facility immediately, preferably within one working day.

All reactive cases referred from screening sites should be fast tracked for HIV confirmation. At confirmatory facility, three test kits of different principles should be positive in sequence before a diagnosis of HIV can be established.

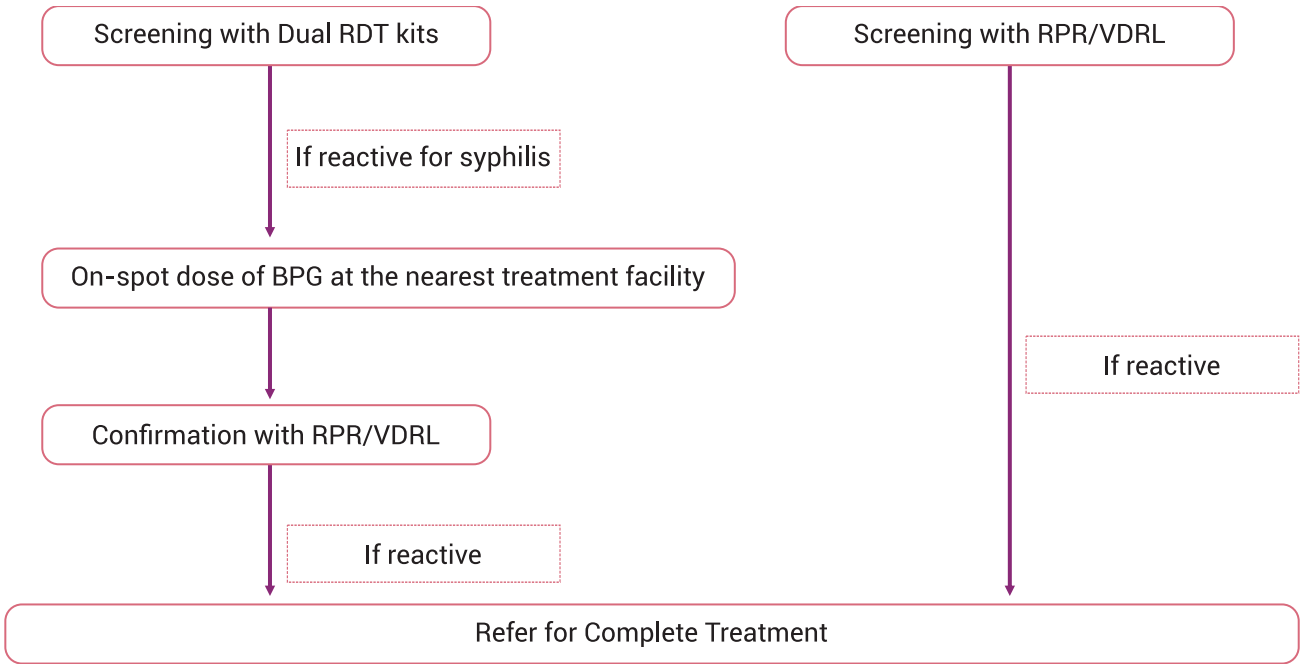
The pregnant women diagnosed as HIV-positive, should be linked to ART centre immediately, preferably within one working day.

For more details on HIV testing and diagnosis, refer to the National HIV Counselling and Testing Services (HCTS) Guidelines, 2024.

Confirmation of Syphilis diagnosis

When the screening test is a PoC treponemal test or dual RDT kit, the second test for confirmation of Syphilis is RPR/VDRL. The pregnant women screened reactive through Dual RDT should be referred to facilities with availability of RPR/VDRL testing (including ICTC) for confirmation. When the screening test is RPR/ VDRL, the second test for confirmation is TPHA/TPPA. However, the availability of confirmatory testing in either of the conditions is not a criterion to provide on-spot dose of Injection Benzathine Penicillin G (BPG) or providing further management. Moreover, the confirmation through TPHA/TPPA is not mandatory to manage a pregnant women screened reactive for syphilis using RPR/ VDRL. The operational algorithm for Syphilis screening and linkage for pregnant women is mentioned in figure 5.3.1 below.

Figure 5.3.1: Algorithm for Syphilis screening and linkage for pregnant women



5.4 Testing for HIV and Syphilis

Index testing for HIV:

Index testing for HIV is an important component of the EVTHS program. In the context of EVTHS, index testing involves identifying and testing, the sexual and/or needle sharing contacts and the biological children (less than 19 years of age), of HIV infected pregnant women. The purpose of index testing for EVTHS is to identify and diagnose new HIV infections among the contacts and biological children (less than 19 years of age) of PWLHIV, and to link them to appropriate prevention, treatment and care services.

When a pregnant woman is diagnosed with HIV, she is encouraged to disclose her status to her sexual and needle sharing contacts and encourage them to get tested. If the partner is willing to get tested, health care providers shall offer HIV counselling and testing services to them. This approach helps to identify new HIV infections and link partners to treatment and care services, including antiretroviral therapy (ART) to reduce the risk of transmission of HIV. For further reading, refer to the National HIV Counselling and Testing Guidelines, 2024.

Partner Testing for Syphilis

Partners of pregnant women who are screened reactive for Syphilis should be evaluated clinically and serologically for confirmation and the stage of infection and treated accordingly to prevent re-infection to the pregnant women. Responsibility for partner testing for syphilis lies with the DSRC counsellor or ANM.

The dual RDT kits can be used for screening of spouses and partners of HIV and/or Syphilis sero reactive pregnant women.

CHAPTER-6

Management of HIV/ Syphilis infection in pregnant women

Management of HIV/ Syphilis infection in pregnant women

6.1 Optimizing Pregnancy Outcomes

Pregnancy is a crucial period that requires specialized care to optimize outcomes for both mother and child. Pregnant women with HIV and/or Syphilis are considered to have high-risk pregnancies and therefore, should be provided with care components enlisted under 'Extended PMSMA (Pradhan Mantri Surakshit Matritva Abhiyan) for high-risk pregnancy tracking'.

- **HIV and Syphilis screening**: as a package of high-risk pregnancy identification, it is the responsibility of the village ASHA to mobilize all the pregnant women in her village to attend the nearest PMSMA clinic and undergo high-risk screening, including 'HIV and Syphilis screening' by a doctor/ obstetrician.
- **Management as High-risk Pregnancies (HRP)**: HIV and Syphilis infection in pregnant women detected at PMSMA clinics must be counselled, treated, and a line-listing to be maintained by the facility and the respective ANM & ASHA. Once a pregnant woman is categorized as an HRP, it is the responsibility of the respective ASHA/ANM to ensure 3 additional ANC visits for that HRP by a Doctor/Obstetrician. For each of these follow up ANC visits with the Doctor/ Obstetrician, ASHA shall accompany the high-risk pregnant woman to the clinic. These follow up visits may be conducted either in the subsequent PMSMA session or at the nearest health care facility. Visit for syphilis treatment at health facility/DSRC will be part of the 3 additional ANC visits. Similarly, visit for ART centre for ART initiation and VL testing at 32-36 weeks will also be part of the three additional ANC visits.
- **Institutional Delivery**: It is mandatory that all identified high-risk pregnancies must be linked with nearest First Referral Units (FRU) for ensuring safe delivery after completion of pregnancy and prompt management of complications, if any. Free transport for referral to the FRU at the time of delivery is to be ensured by the ASHA under JSSK.

During onsite monitoring by the District Quality Assurance Committee (DQAC) for PMSMA activities, the prompt linkages for HIV and Syphilis treatment and outcome and status of mother and child at 45th day after delivery for these cases may be assessed. *(reference: https://www.nhm.gov.in/New_*

Update-2022-23/MH/GUIDELINES-%20MH/Guidance_Note-Extended_PMSMA_for_tracking_HRPs.pdf)

- **Outreach and Patient tracking by Care Support Centres**: There should be separate prioritized tracking of both WLHIV in reproductive age group as part of prong 2 and Pregnant WLHIV on ART, to track adherence, viral load suppression and ARV prophylaxis prescriptions prior to birth of their infants. Outreach and patient tracking of pregnant women newly initiated on ART or those who missed pill pick up date or are due for viral load testing, will be supported by Care Support Centres.

All pregnant women who test positive for syphilis should be followed up by a health care worker (ASHA/ANM under NHM facilities through extended PMSMA and counsellor under NACP facilities) at the closest facility.

6.2 Management of HIV in pregnant women

Vertical transmission of HIV can be prevented through successful antiretroviral therapy (ART) to pregnant women, by achieving sustained viral suppression and provisioning of appropriate prophylaxis and interventions for the HIV-exposed babies.

If taken as prescribed, ART reduces the amount of HIV in the body (viral load) to a very low level. This is called viral suppression. This state of suppressed viral load prevents weakening of immune system. Adherent ART can cause the HIV viral count to become so less, that it cannot be detected in the test (reported as target not detected). The HIV virus has actually migrated from the blood, and is resting in various reservoirs, such as brain, lymph nodes, bones, spleen etc. This is known **an undetectable viral load**. This helps in keeping WLHIV healthy as well as prevent transmission to their sexual partners and children (through vertical transmission). This concept is known as Undetectable = Untransmittable or U=U.

This prevention method is very effective as long as WLHIV takes ART without missing doses and the HIV viral load remains undetectable. This is referred to as **treatment as prevention (TasP).**

After screening and diagnosing pregnant women living with HIV, it is crucial to ensure they are linked for optimal HIV care, support and treatment. One of the key objectives of NACP is to provide care, support and treatment to all PLHIV and ensure lifelong retention and sustained viral load suppression.

NACP aims to facilitate sustainable and patient centric service delivery through a three-tier structure for delivery of care, support and treatment services to all PLHIV. This service delivery model for HIV care and treatment comprises Anti-retroviral Therapy centres (ART centres), Centres of Excellence and Link ART centre (LAC).

The ART centres are established mainly in the medicine departments of medical colleges and district hospitals. However, some ART centres are functioning in the sub-district and block hospitals also, mainly in high prevalence states. The centres are set up based on prevalence of HIV in the district/region, capacity of the facility to deliver ART related services. In addition to government sector, NACP is also engaging with private sector for setting up of ART centres. *(National Operational Guidelines for ART Services, 2021)*

Link ART Centres (LAC) and LAC Plus Centre (LAC plus), a strategy which was rolled out in 2008, is a differentiated service delivery model for decentralized ART services near the patient's residence rolled out in 2008. These sites could be ICTC, community health centres, primary health centres,

opioid substitution therapy centres; care and support centres and targeted intervention sites as well as other community level sites at NGOs/ CBOs/ CSOs. The goal of this model is to make the treatment services easily accessible to PLHIV and promote adherence by addressing the barriers associated with inconvenience due to frequent visits, long travel distance and cost to the patients. These centres are linked to a nodal ART centre and function as its outreach unit. The main functions of LACs include monitoring PLHIV on ART, drug refill to patients on ART, treatment of minor OIs, identification and management of adverse effects and reinforce adherence on every visit.

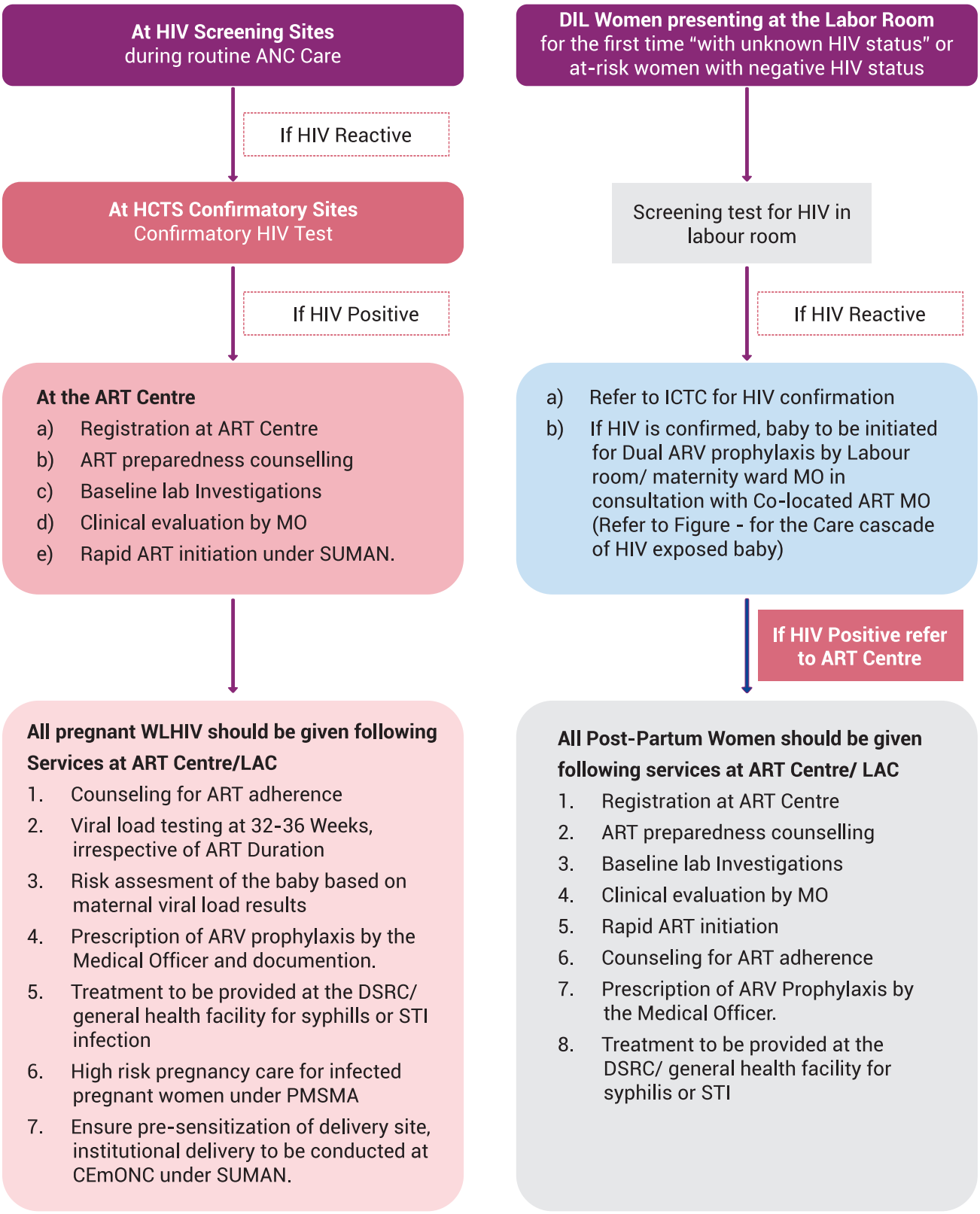
To commence HIV care services, PWLHIV should be linked to ART centres. At the ART centre, they will undergo comprehensive clinical and laboratory evaluation to assess their baseline HIV status. Additionally, they will be treated for any pre-existing opportunistic infections, provided treatment preparedness counselling and receive rapid ART initiation, preferably on the same day, unless contraindicated.

ART prevents vertical transmission of HIV by

- Reducing the maternal viral load
- Loading the foetus with Anti-retroviral drugs that prevent the transmitted virions from replicating
- Improving overall health of mother

The figure 6.2.1 describes the Care cascade for pregnant women living with HIV.

Figure 6.2.1: Care cascade for pregnant women living with HIV



General Considerations for Newly diagnosed Pregnant WLHIV

1. **Adequate preparation and informed consent for ART:** Pregnant WLHIV should be adequately counselled about HIV care and ART services before initiation of treatment. Informed consent should be obtained before commencing ART, after providing information on lifelong treatment, drug adherence and need for viral suppression to prevent vertical transmission of HIV. In addition, they need to be counselled regarding adverse drug reactions, and the importance of positive prevention and safer sex methods. Further, PWLHIV need to be repeatedly counselled on ART adherence throughout the pregnancy and breastfeeding period, to reduce the risk of HIV transmission to the baby. Adequate counselling should be done for care of breast and nipples, for mother who opt for breastfeeding. Counselling PWLHIV should be a team effort by the ART staff, led by the ART Medical Officer, to ensure long-term retention and viral load suppression.
2. **Caregiver support:** Pregnant WLHIV should have a caregiver identified to provide adequate support. Caregivers must be counselled and trained to support treatment adherence, follow-up visits and shared decision-making.
3. **Cotrimoxazole Preventive Therapy (CPT):** All pregnant WLHIV with WHO clinical stages 3 and 4 or those with CD4 less than 350 cells/mm3 should be put on CPT.
4. **Tuberculosis screening and preventive therapy:** All pregnant WLHIV should be screened for TB using the 4S -screening tool (current cough, fever, night sweats, and weight loss). Those without TB should be started on Tuberculosis Preventive Therapy (TPT) in addition to ART. Those PWLHIV diagnosed with Tuberculosis should be initiated on ATT as per current national guidelines.
5. **Opportunistic infections (OIs):** ART should not be started in the presence of an active OI. OIs should generally be treated or stabilized before commencing ART.

For further reading refer to Chapter-2.2 and 2.5 of National Guidelines on HIV Care and Treatment 2021; available at https://www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment%202021.pdf

The table 6.2.1 enumerates the Counselling messages for pregnant WLHIV to reduce risk of vertical transmission of HIV.

Table 6.2.1: Counselling messages for pregnant WLHIV to reduce risk of vertical transmission of HIV

1.	Explain the advantages of ART for her health and to prevent transmission of HIV to her baby and need for starting ART immediately
2.	Adherence to ART during pregnancy, labour, entire breast-feeding period and life-long
3.	Safer sex practices to avoid fresh HIV and STI infection, throughout pregnancy and breastfeeding
4.	Counsel for regular ANC visits
5.	Ante-natal counselling for selecting feeding option by parents
6.	Care of nipples and breasts
7.	Nutritional counselling aimed at taking 'a balanced diet'
8.	Iron, folic acid and calcium supplements to be advised throughout pregnancy and breast-feeding period
9.	Viral load testing at 32-36 weeks of gestation to decide the risk of HIV transmission
10.	Institutional delivery and birth planning, for interventions during childbirth and timely initiation of ARV prophylaxis for the baby
11.	ARV prophylaxis to be started for the infant immediately after birth
12.	Provide information and counselling that her baby will be under follow up, till HIV infection is excluded, i.e., 18 months or 3 months after stopping of breastfeeding

Counselling for drug-drug interaction of DTG: DTG has interactions with few anticonvulsants, metformin, antacids, multi-vitamins, iron, calcium, etc. It is important to educate and counsel the pregnant WLHIV regarding these and support them in fixing the timing of the ART and the supplements prescribed in pregnancy.

The important drug-drug interactions with DTG, and the suggested management is depicted in table 6.2.2.

Table 6.2.2: Important drug-drug interactions with DTG, and the suggested management

Key drug interaction	Suggested management
Amodiaquine	Use an alternative antimalarial agent
Carbamazepine	Use DTG twice daily or substitute with an alternative anticonvulsant agent
Phenytoin and phenobarbital	Use an alternative anticonvulsant agent
Dofetilide	Use an alternative antiarrhythmic agent
Metformin (DTG increases the drug levels of metformin)	Limit daily dose of metformin to 1000mg when used with DTG & monitor glycemic control
Polyvalent cation products containing Al, Ca, Fe, Mg and Zn (eg: antacids, multivitamins & supplements)	Use DTG, 2 hours before or 6 hours after polyvalent cations containing product
Rifampicin	Use DTG twice daily or substitute with rifabutin

Source: Table-2.2.6, Chapter-2.2, National Guidelines for HIV care and treatment, 2021.

ART Initiation

- All pregnant women coming to the ART centre shall be seen as priority
- Dolutegravir (DTG) based ART regimens will be offered to all newly diagnosed pregnant women, **irrespective of the duration of pregnancy**
- Same day /rapid ART initiation is recommended for all HIV-positive pregnant and breastfeeding women after preparedness counselling
- ART initiation should preferably be done at ART centres. If the pregnant WLHIV is unable to travel to the ART Centre, she may be followed up at LAC Plus centres. ART initiation may be supervised by the Medical Officer of the Nodal ART centre after taking requisite informed consent.

  (For further reading on ART initiation at LAC Plus, refer to the National Operational Guidelines for ART Services, 2021)
- Currently, the preferred ART regimen for pregnant and breastfeeding women living with HIV is TLD (Tenofovir/Lamivudine/Dolutegravir), according to national guidelines.
- It is the responsibility of the NACP counsellor at ART centre, to telephonically contact the pregnant WLHIV within two weeks of ART initiation to inquire about drug adherence and any adverse events. If any of the baseline lab investigation are abnormal, such clients should be called back to the ART Centre as soon as possible, within two weeks of ART initiation.
- WLHIV who are under HIV care at the ART centre, and have now become pregnant, need to be linked to the collocated ICTC, for line-listing and provisioning of EVTHS Services. A coordination system should be set up between the ICTC and collocated ART centre, to monitor the provision of EVTHS services.
- Women who become pregnant while taking DTG based regimen should be counselled regarding drug adherence and U=U, and DTG should be continued.
- All women who are pregnant and not on DTG based regimen should be shifted to DTG based regimen, as soon as possible, unless DTG is contraindicated. Sample for viral load testing should be drawn before transition to the DTG-based regimen.
- The services for pregnant women should be prioritized, including fast-tracking of lab investigation results, ART dispensation and medical follow-ups.

Refer to Annexure-2 for A Guide to ART Drug Safety during Pregnancy and Annexure-3 for Comorbidities in Pregnant Women with HIV: Implications for Antenatal Care.

Advanced HIV disease management

For PLHIV or CLHIV, aged 5 years and above, advanced HIV disease is characterized by a CD4 cell count <200 cells/mm3 or the presence of WHO stage 3 or 4 events. Advanced HIV disease is linked to a higher risk of Opportunistic Infections (OIs), Immune Reconstitution Inflammatory Syndrome (IRIS), incomplete immune reconstitution, and an increased risk of AIDS-related and non-AIDS-related comorbidities. People living with HIV (PLHIV) with advanced HIV disease require more frequent monitoring, which can lead to a significant psychosocial impact and economic burden for both PLHIV and the health care system.

During each visit to the ART centre, pregnant WLHIV should be evaluated for the presence of advanced HIV disease. Appropriate screening for OIs, particularly Tuberculosis and Cryptococcal meningitis, should be carried out during follow-up visits, and OI prophylaxis should be advised wherever indicated.

In general, the care package for pregnant and breastfeeding women with advanced HIV disease is the same as for non-pregnant WLHIV. For more details, refer to Section 2.3: Advanced Disease Management in PLHIV in the National Guidelines for HIV Care and Treatment 2021.

Follow-up and monitoring after ART initiation

Regular follow-up and monitoring are crucial for patients initiated on ART to assess clinical progress, monitor their well-being, viral suppression and identify adverse drug reactions.

ART monitoring comprises clinical and laboratory monitoring, including adherence to ART. At every visit, the client should be assessed for clinical progress, ARV side effects and treatment adherence. Clinical and laboratory evaluations are carried out at specified intervals for patients on ART.

The parameters to be monitored during follow-up visits are summarized in table 6.2.3. For further information on follow-up and monitoring, please refer to Section 2.2.9 of the National Guidelines for HIV Care and Treatment 2021.

Table 6.2.3: Monitoring and follow-up schedule for WLHIV on ART

Monitoring Tool	When to Monitor
Body Weight	Every visit
Treatment adherence	Every visit
Clinical monitoring and T-staging	Every visit
4-symptom TB screening	Every visit
Screening for common NCD; Hypertension, Diabetes Mellitus, mental health	Every 6 months or symptom directed
Laboratory evaluation based on ART regimen	Every 6 months or symptom directed
CD4 count	CD4 testing must be done every 6 months
Viral load	• Routine VL testing: at 6 months after ART initiation, at 12 months after ART initiation, and then every 12 months* • For newly diagnosed PWLHIV: At 6 months after ART initiation, at 32-26 weeks of pregnancy, at 12 months after ART initiation, and then every 12 months • For WLHIV already on treatment and now pregnant: at 32-36 weeks of pregnancy, in addition to routine VL testing
* For patients on second/third-line ART, Plasma Viral Load testing to be done every 6 months	

Note: Viral load testing is performed for HIV-1 infections. Patients with HIV-2 should be monitored for treatment response by CD4 count trends and clinical monitoring.

PLHIV with HIV-1 and 2 combined infections, will be monitored with both VL and CD4 monitoring. The table 6.2.4 depicts the Laboratory monitoring of the individual ARV drugs.

Table 6.2.4: Laboratory monitoring of individual ARV drugs

For all patients on ART, we need to do CD4 count, Hb, TLC, DLC, ALT (SGPT), and serum creatinine. Once every six months								
Tests for monitoring patients on ART (Follow-up tests): Drug-specific tests frequency as below								
Monitoring ARV drug in the regimen	Monitoring test	Baseline	15th Day	First month	Third month	Sixth month	Then every6 months	At 12 months
On Tenofovir-based ART	Serum creatinine	Yes	-	-	-	-	Yes	-
	Urine for Protein	Yes	-	-	-	-	Yes	-
On Zidovudine-based ART	CBC	Yes	Yes	Yes	Yes	Yes	Yes	-
Efavirenz-containing ART	Lipid Profile	Yes	-	-	-	-	-	Yes
Atazanavir-containing ART	LFT Lipid Profile	Yes	-	-	-	-	Yes	-
Lopinavir-containing ART	Lipid Profile and Blood Sugar	Yes	-	-	-	-	Yes	-
Dolutegravir-containing ART	ALT (SGPT) & Blood Sugar	Yes	-	-	-	-	Yes	-

ART: Special considerations in pregnancy

Adherence to ART results in clinical and immunological improvement as well as viral suppression. However, in the first three months of treatment, certain OIs and/or IRIS and/or early adverse drug reactions such as drug hypersensitivity may occur. For more information on ARVs and toxicities, please refer to Chapter 2.6 of the National Guidelines for HIV Care and Treatment 2021. *For details on the safety of ART drugs during pregnancy, please refer to Annexure 2.*

Nausea and Vomiting: Nausea and vomiting are common symptoms during the early stages of pregnancy, typically resolving by the second trimester. Women taking ART may also experience these symptoms, and if necessary, should adjust their pill timing. It is important to rule out organic causes, such as lactic acidosis, hepatitis and pancreatitis, which may be complications of ART, before diagnosing hyperemesis in HIV-positive women on ART. Safe antiemetics may be used during pregnancy, and there are no known interactions between these medications and antiretrovirals. *Refer to Annexure 3 for Antenatal Care implications in Pregnant WLHIV with comorbidities.*

Monitoring of pregnant WLHIV by regular entry in EVTHS card is essential, and separate cards should be maintained for each pregnancy.

The figure-6.2.2 depicts the EVTHS card, and responsibility of entry in the card is of the ART Medical Officer, with support from ART Staff Nurse.

Figure 6.2.2: EVTHS Card (section-11 of the Patient Treatment Card)

Section-11: PREGNANT WOMEN

Obstetric History

- LMP: D D M M Y Y Y Y EDD: D D M M Y Y Y Y
- ☐ Gravide ☐ Para
- Institute/Place selected for the delivery: ☐ Govt ☐ Private ☐ Home
- Name of the institution planned for delivery .....

Details Viral Load Testing (32-36 weeks) .....

- Viral Load testing done at 32-36 weeks: ☐ Yes ☐ No ☐ Not Applicable
- Viral Load testing: D D M M Y Y Y Y Result: .....
- Category of baby based on Viral Load Testing:(☑ Tick the appropriate)

☐ a) Low Risk ⟶ Single Prophylaxis ☐ b) High Risk ⟶ Dual Prophylaxis

Delivery Details

- Status of pregnant women at the registration of EVTHS

☐ Already on ART ☐ Newly diagnosed PLHIV ☐ Direct in labor ☐ Post delivery

- Date of Delivery: D D M M Y Y Y Y
- Mode of Delivery: ☐ Normal ☐ Cesarean ☐ Assisted
- Place of Delivery: ☐ Govt ☐ Private ☐ Home
- Name of the institution where delivered: : .....
- Pregnancy Outcome: (☑ Tick the appropriate)

☐ a) Live birth single ☐ b) Live birth twin ☐ c) MTP

☐ d) Still birth ☐ e) Abortion

HIV EXPOSED INFANT

Birth Details:

- Date of birth: D D M M Y Y Y Y
- Birth weight: .....Kgs
- Selected Infant feeding Option* (☑ Tick the appropriate)

☐ a) EBF ☐ b) ERF ☐ c) Mixed

* To reassess feeding practice at 6 weeks for high-risk infans

- CPT initiation Date: D D M M Y Y Y Y (Ensure CPT initiation at 6 weeks of age)
- Any other details: .....

.....

ARV prophylaxis

- Date starting ARV prophylaxis: D D M M Y Y Y Y Date completion: D D M M Y Y Y Y
- Name of ARV Drug: (☑ Tick the appropriate)

a) Nevirapine - Initiated: (☐ Yes/ ☐ No) Completed: (☐ Yes/ ☐ No)

b) Zidovudine - Initiated: (☐ Yes/ ☐ No) Completed: (☐ Yes/ ☐ No)

c) Any Other - Initiated: (☐ Yes/ ☐ No) Completed: (☐ Yes/ ☐ No)

- During of Prophylaxis: (☑ Tick the appropriate)

☐ 6 weeks ☐ 12 weeks ▸ Date of cessation of Breast Feeding: D D M M Y Y Y Y

Routine Viral Load Monitoring

Within the first few weeks of starting antiretroviral therapy (ART), the plasma viral load should begin to decrease, and regular plasma viral load tests should be conducted to monitor the response to treatment. Patients on first line ART should undergo plasma viral load testing at 6 and 12 months after initiating treatment, and then annually. Patients on second or third line ART should undergo viral load testing every 6 months after initiating treatment.

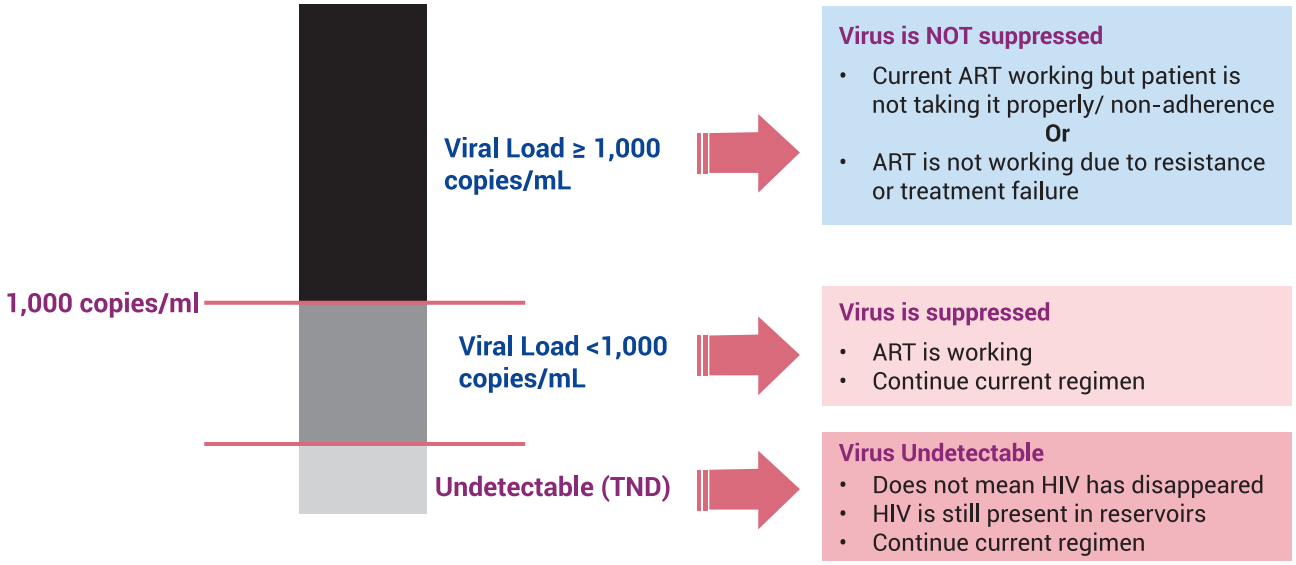
The scheduled dates for routine viral load testing should be recorded in the ART Patient Booklet, ART Treatment Card, and MCH card of the pregnant woman by the ARTC Medical Officer, Nurse, or Counsellor. Refer to Annexure-4 for the ART Patient Booklet, Annexure-5 for the ART Treatment Card and Annexure-6 for HIV-1 Viral Load Sample Collection, Processing, Storage, Packaging and Transportation at ART centre for Pregnant Women.

Interpretation of Plasma Viral Load Testing Results:

Under the program a viral load result of less than 1000 copies/ml, is taken to be viral suppression and the same ART regimen should be continued. The next viral load testing should be done according to guidelines.

The three clinical scenarios for viral load results are depicted in the figure 6.2.3 below.

Figure 6.2.3: Clinical Case Scenarios for Viral Load Results



- A pregnant WLHIV with a plasma viral load result equal to or more than 1000 copies/ml, should undergo three sessions of step-up adherence counselling for three months. It is preferred that all counselling sessions are done by the same counsellor to ensure consistency, continuity and proper documentation of issue resolution. These sessions can be conducted when she visits ART centre for pill pick up. *(For overview of step-up adherence counselling sessions, refer to Table 2.7.2, in the National Guidelines for HIV Care and Treatment, 2021)*
- Repeat viral load testing should be performed once treatment adherence is over 95% for three consecutive months.
- If the repeat plasma viral load is less than 1000 copies/ml, patients should continue on the same ART regimen.

- If the repeat plasma viral load is equal to or greater than 1000 copies/ml, then these patients should be referred electronically to the State AIDS Clinical Expert Panel (e-SACEP) for further management.

Treatment failure

Treatment failure is defined as the occurrence of antiviral resistance to the current ART regimen. This can be determined by using one of three criteria:

- **Virological failure**: Detected through routine plasma viral load testing, where a detectable plasma viral load ≥1000 copies/ml are observed at least 6 months after initiating ART, with >95% adherence to treatment for each of the last 3 months. It is crucial to ensure proper pre-workup and timely referral to SACEP for further evaluation of such patients following the SACEP guidelines.
- **Immunological failure**: Identified through CD4 testing.
- **Clinical failure**: Observed through clinical monitoring.

For further reading on management of treatment failure, refer to Chapter-2.7, of the National Guidelines for HIV Care and Treatment, 2021.

Viral Load Testing at 32 to 36 weeks of Pregnancy in WLHIV

Appropriate and adherent maternal ART reduces the HIV viral load to suppressed levels within a few months of treatment. The level of viral load during last trimester of pregnancy is a key risk factor for HIV transmission during labour, delivery and breastfeeding. It is recommended that HIV risk categorization for the infants should be done based on viral load suppression in HIV-positive pregnant women. Therefore, viral load testing of all HIV-positive pregnant women should be done during 32 to 36 weeks of pregnancy (regardless of duration of ART).

In the event that VL testing is performed as a routine VL test (6 months after treatment initiation or 12 months after the last test) and the date of VL testing falls within the pregnancy period before 32 weeks, the ART MO may make a decision based on their clinical discretion by evaluating ART adherence history and previous viral load test results of that pregnant woman on case to-case basis.

The following measures should be taken with regard to viral load testing:

- During the first visit, the ARTC Counsellor should counsel the mother on the importance of the additional viral load (VL) testing and schedule the test. The test date should be recorded in the Green Book, White Card, and MCH Card by the Counsellor.
- The data manager at each ART centre should generate a list of all HIV-positive pregnant women due for the 32-36 weeks viral load test.
- The Counsellor should contact the pregnant women at least 15 days before the VL test due date.
- The test report, the HIV risk categorization and drugs for infant ARV prophylaxis should be noted down in the ART Patient Book by the Medical Officer.
- Appropriate counselling should be offered to explain the interpretation of the VL results and infant ARV prophylaxis drug.

The HIV-exposed infants are categorized as low-risk or high-risk, and their prophylaxis options are given in table 6.2.5.

Table 6.2.5: HIV Risk assessment of infants born to WLHIV and the Infant ARV Prophylaxis options

HIV Risk status	Options for ARV Prophylaxis
Low-risk infants: • Infants born to mothers with suppressed viral load (<1000 copies/ml) done any time after 32 weeks of pregnancy up to delivery	**1. Syrup Nevirapine** or **2. Syrup Zidovudine#** (in situations where Nevirapine will not be effective, as mentioned below): • Infant born to a mother with confirmed HIV-2 or HIV-1 and HIV-2 combined infections • Infant born to a mother, who had received single dose of Nevirapine during earlier pregnancy or delivery • Infant born to a mother who is on PI-based ART regimen due to treatment failure **Duration of ARV prophylaxis:** From birth till 6 weeks of age
High-risk infants: • Infants born to HIV-positive mother not on ART • Maternal viral load not done after 32 weeks of pregnancy till delivery • Maternal viral load not suppressed between 32 weeks of pregnancy till delivery • Mother newly identified HIV-positive in post-natal period, within 6 weeks of delivery	**Options for dual prophylaxis:** Syrup Nevirapine + Syrup Zidovudine## **Duration of Dual ARV Prophylaxis:** • In case of Exclusive Replacement Feeding (ERF): From birth till 6 weeks of age • In case of Exclusive Breastfeeding (EBF): From birth till 12 weeks of age
# When Zidovudine syrup is not available, syrup Lopinavir/ritonavir should be used after 14 days of birth **##** When Zidovudine syrup is not available, syrup Nevirapine should be used for first 14 days after birth and then add syrup Lopinavir/ritonavir after 14 days of birth till 6 weeks in case of Exclusive Replacement Feeding or 12 weeks in case of Exclusive Breast Feeding. **##** Another alternative that may be used in this situation is AZT+3TC+NVP (ZLN) paediatric formulation	
In exceptional scenarios and for high-risk Infants born to HIV-2 positive mothers or **for high-risk Infants** born to mothers, who had received single dose of Nevirapine during earlier pregnancy or delivery, **opinion of SACEP should be sought**	

Source: Table-2.5.4, Chapter-2.5, National Guidelines for HIV Care and Treatment, 2021

For dosage of Infant ARV prophylaxis (syrup nevirapine, syrup zidovudine and syrup lopinavir/ritonavir) refer to Annexure-7

Duration of ARV Prophylaxis:

- A minimum of 6 weeks of ARV prophylaxis is given in all HIV-exposed infants to cover the peri-natal exposure to HIV virus during labour and delivery.
- In infants who are being breastfed and also categorized high-risk for transmission of HIV, duration of ARV Prophylaxis has to be extended to 12 weeks.
- Explanation:
    - o Mother is not virally suppressed to achieve optimal HIV viral suppression in breast milk
    - o Extended prophylaxis reduces risk of HIV transmission due to breast feeding
    - o Beyond 12 weeks, maternal ART causes enough viral suppression to make breast milk relatively safe
- Infants on Exclusive Replacement Feeding do not require extended ARV prophylaxis.

Summary of Risk Categorization based on maternal viral load is described in table 6.2.6

Table 6.2.6: Summary of Risk Categorization based on maternal viral load

Scenario	Risk status
Infants born to HIV-positive mother not on ART	**High-Risk**
Maternal viral load not done between 32 weeks of pregnancy till delivery or viral load result not available	**High-Risk**
Unsuppressed maternal viral load between 32 weeks to pregnancy (viral load ≥ 1000 copies/ml)	**High-Risk**
Mother newly identified as HIV-positive within 6 weeks of delivery (including direct in labour diagnosed cases)	**High-Risk**
Infants born to mothers with suppressed viral load at 32-36 week of pregnancy (TND or viral load < 1000 copies/ml)	**Low-Risk**

Summary of Interventions to reduce risk of HIV during pregnancy and during childbirth are compiled in table 6.2.7 and table 6.2.8 respectively

Table 6.2.7: Summary of Interventions to reduce risk of HIV during pregnancy

Summary of Interventions to reduce risk of HIV during pregnancy
• Provide information about HIV to ALL pregnant women. • Antenatal visits are opportunity for providing counselling on EVTHS. • Counsel for safer sex practices to reduce risk of fresh HIV and STI infections. • Prevention of vertical transmission through adherent maternal ART. • Referral for Viral load between 32 and 36 weeks of pregnancy to determine the ARV prophylaxis for the baby based on HIV risk. • Counselling for institutional delivery so that interventions for EVTHS can be undertaken. • Ante-natal counselling on infant feeding practices and ARV prophylaxis for the baby.

Table 6.2.8: Summary of Interventions to reduce risk of HIV during childbirth

Summary of Interventions to reduce risk of HIV during childbirth
Under the cover of Maternal ART, the care given to pregnant WLHIV and their babies is similar to the care given to uninfected mothers and their babies. Safe delivery techniques should be followed for pregnant WLHIV during labour and childbirth, as described below: • Standard Workplace Precautions to be adhered to. • Minimize vaginal examinations and use aseptic techniques. • Avoid prolonged labour; consider oxytocin to shorten labour. • Avoid artificial rupture of membranes. • Use non-invasive foetal monitoring and avoid invasive procedures. • Support perineum and avoid routine episiotomy. • Avoid instrumental delivery as much as possible, unless indicated. Considerations in Mode of Delivery: In India, normal vaginal delivery is considered unless the woman has obstetric indications for a Caesarean section (like foetal distress, obstructed labour)

Source: Chapter-2.5, National guidelines for HIV Care and Treatment, 2021

6.3 Management of Syphilis in pregnant women

Treatment Considerations:

- Benzathine Penicillin G (BPG) is the only known effective antimicrobial for treating syphilis infection in pregnancy and preventing congenital syphilis. This is a safe drug and evidence suggests that anaphylaxis due to the drug is extremely rare.
- A single dose of BPG is sufficient to prevent infection to the foetus, regardless of the stage of syphilis. However, complete treatment as per the stage of infection is necessary for the complete management of sero-reactive pregnant women.
- No proven alternatives to penicillin are available for the treatment of syphilis among pregnant women.
- The use of tetracycline and doxycycline for management of syphilis should be avoided in the second and third trimesters of pregnancy.
- Erythromycin and azithromycin should not be used as these drugs neither reliably cures maternal syphilis infection nor treats an infected fetus.
- Data is insufficient to recommend ceftriaxone or other cephalosporins for the treatment of maternal infection and prevention of congenital syphilis.

Treatment Protocols:

- The "Test & Treat" policy for syphilis should be followed under the National Programme, and at least one dose (on-spot dose) of injection BPG should be given to all pregnant women screened positive/reactive for syphilis (when screening was conducted using Dual RDT, PoC test Syphilis or RPR/VDRL kits). This may also result in overtreatment of false positive cases and cases with

primary/secondary/early latent syphilis. However, this is justified in the context of pregnant women to achieve the programmatic goal of eliminating vertical transmission of syphilis in India.

- All pregnant women screened reactive for syphilis should be provided with an on-spot dose of 2.4 million IU of Injection Benzathine Penicillin G This may result in over-treatment due to false positive results in the screening. However, the benefit of preventing congenital syphilis outweighs the risk of over-treatment.
- All pregnant women screened or confirmed positive by RPR/VDRL should receive complete treatment with injection BPG administered as three doses of 2.4 million units IM each at one-week interval.
- If the last dose of injection benzathine penicillin G is administered less than 30 days before delivery, the treatment is considered to be 'inadequate' to prevent the vertical transmission of syphilis.
- The treatment providers should rule out the history of a severe allergy to Benzathine Penicillin through oral history taking. A skin test should be conducted to rule out the possibility of anaphylaxis. An emergency tray should be available at all facilities providing treatment. *Details of Penicillin anaphylaxis management are provided in Annexure 8.*
- Pregnant women presenting with manifestations of neurosyphilis, ocular syphilis and oto-syphilis should be referred to a tertiary care centre for further management. *Refer to Annexure 9 for management of neurosyphilis, ocular syphilis, and oto-syphilis*

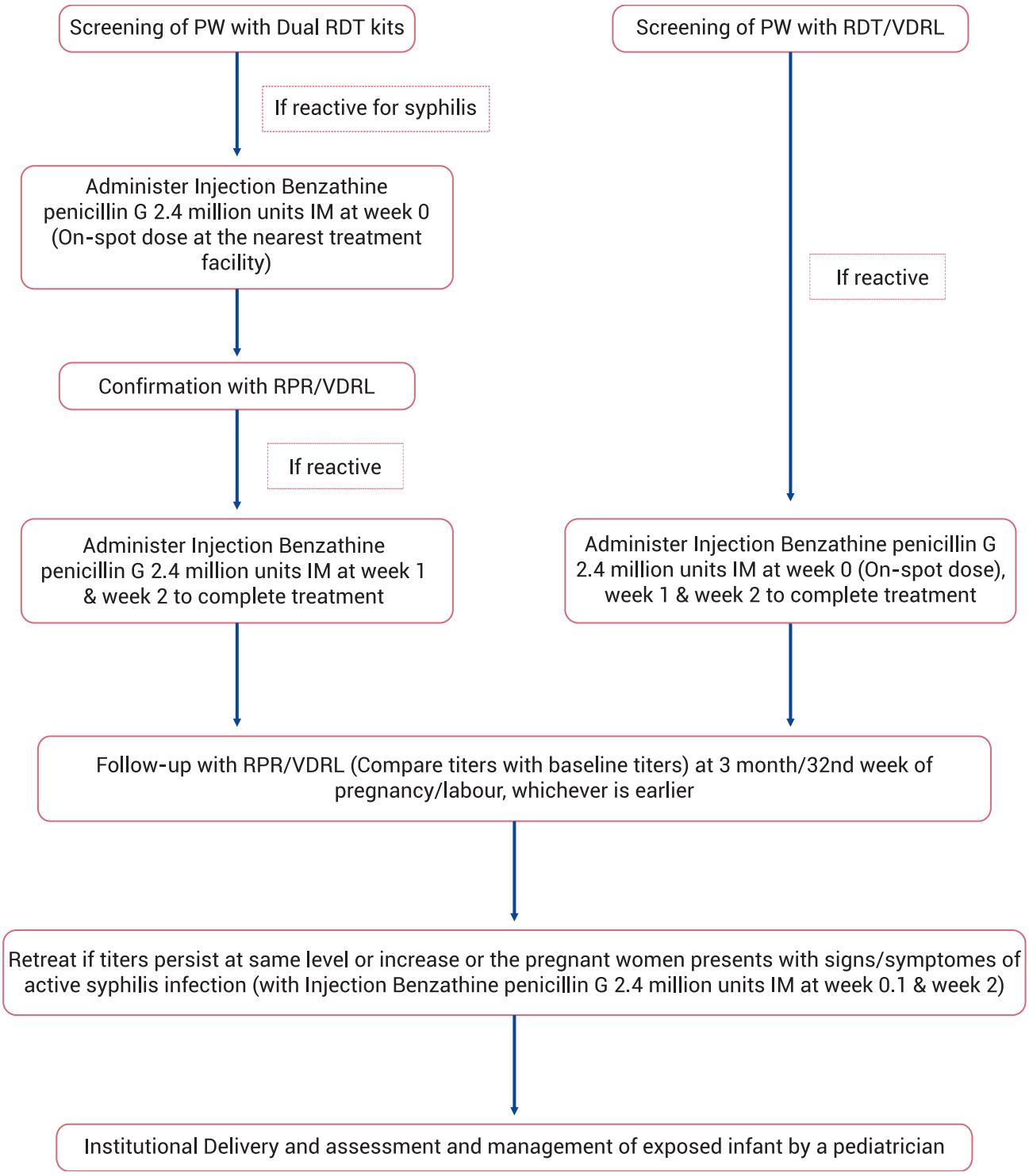
Summary of the important points for treatment of Syphilis in pregnant women are described in table 6.3.1

Table 6.3.1: Summary of important points for treatment of Syphilis in pregnant women

Treatment of Syphilis in pregnant women: Important points
• Screened reactive for syphilis: on-spot dose of 2.4 million units of Injection Benzathine Penicillin G (BPG), IM stat after test dose
• Screened reactive or confirmed positive by RPR/VDRL: Three doses of injection BPG, 2.4 million units, given IM once a week, after test dose
• Doxycycline use for management of syphilis should be avoided in pregnancy
• Erythromycin and azithromycin should not be used as neither reliably cures maternal infection nor prevents vertical transmission
• Syphilis infected pregnant women, who have penicillin allergy should be referred to tertiary centres for desensitization and further treatment with Injection Benzathine Penicillin
• Pregnant women with signs of neurosyphilis, ocular syphilis and oto-syphilis should be referred to a tertiary care centre

Care Cascade for Syphilis infected pregnant mother is depicted in figure 6.3.1

Figure 6.3.1: Care cascade for Syphilis infected pregnant mother



Monitoring the Response to Treatment for Maternal Syphilis

To monitor the treatment response for maternal syphilis, it is important to compare the titre values of RPR/VDRL tests with the baseline value obtained at the time of confirmation of the infection. It is crucial to use the same non-treponemal test (either RPR or VDRL) from the same manufacturer and perform the test at the same laboratory to ensure consistency in the results for comparing the titres values.

A fourfold reduction in titres, equivalent to a change of two dilutions (e.g., from 1:16 to 1:4), indicates successful treatment. Titres should not be repeated before 8 weeks of completion of treatment but preferably after 12 weeks of treatment, at the 32nd week of pregnancy, or at the time of labour (whichever is earlier).

If the titre value at 12 weeks is decreasing compared to the baseline titre values, and there is no clinical evidence of syphilis, no further treatment is needed. However, if the titre values persist at the same level or increase after 12 weeks, treatment failure or re-infection can be suspected and complete treatment should be given according to the treatment protocol.

It is important to note that for syphilis diagnosed and treated after 24 weeks of gestation, achieving a fourfold decrease in titres may not be possible, although this does not necessarily indicate treatment failure. Regular monitoring of the treatment response is essential to ensure the best possible outcome for both the mother and foetus.

All pregnant women who test positive/reactive for syphilis should be followed up by a health care worker (ASHA/ANM under NHM facilities through extended PMSMA and counsellor/outreach workers under NACP facilities) at the closest facility. The assigned health care worker will ensure the completion of treatment, monitoring of treatment response, and facilitate referral for institutional delivery and subsequent follow-up.

All syphilis infected women will be monitored and their clinical and treatment parameters will be entered in the EVTHS Syphilis Card. This document is foldable card, that captures screening, management and follow-up details of pregnant women/ DIL cases who screened reactive for syphilis. The responsibility of maintaining these cards lies with DSRC Counsellor/HCW at NHM facility. A copy of this card will be carried by the pregnant women at each follow-up visit and also for institutional delivery. The same card captures the details for follow-up/ management of syphilis-exposed babies. Figure-6.3.2. depicts the front page of the EVTHS Syphilis card. The complete card is available as Annexure-10

Figure 6.3.2: Front page of the EVTHS Syphilis Card

EVTHS Card - Syphilis			
Pregnant Woman's Card			
(to be completed for all pregnant women screened reactive for Syphilis)			
Name	:	**PID No./ Mobile Number & DSRC**	:
Age	:	**Case**	: Pregnant Women/ DIL
Gravida	:	**Parity**	:
LMP	:	**EDD**	:
Details on Syphilis Screening			
Type of test with date of screening	: RPR/VDRL/Dual RDT/ TPHA/ Others (Please Name)		
Whether test for confirmation conducted	: Yes/No	**If yes, test used & results**	:
RPR/ VDRL Titres	: (Mention baseline titres)		
Treatment Details			
Injection Benzathine Penicillin	1st Dose (Yes/No)	**Date of treatment**	:
	2nd Dose (Yes/No/NA)	**Date of treatment**	:
	3rd Dose (Yes/No/NA)	**Date of treatment**	:
Treatment Monitoring (Yes/No)			
If yes, date of monitoring	:	**RPR/VDRL Titres**	:
Outcome	: Treatment Failure/ Successful	**If failure, then Retreatment**	: Yes/No/NA (Date)
Partner Screening and Management	: Yes/No	**Provide details**	:
Details on Delivery			
Pregnancy Outcome	: Abortion/MTP/Still Birth/Live Birth	**Date of delivery (NA if Abortion or MTP)**	:
RPR/VDRL Titres (at delivery/ childbirth)	Yes/No	**RPR/VDRL Titres**	:

The pregnant women should be sensitized for ensuring institutional delivery at a facility with availability of paediatrician. Birth planning and pre-sensitization of site for delivery becomes an essential activity and should be facilitated by the DSRC Counsellor/ responsible HCW at the NHM facility.

The facility should be sensitized for ensuring implementation of protocols mandated under these guidelines. The table 6.3.2 describes the Operational aspect of screening and management of Syphilis in pregnant women.

Table 6.3.2 Operations for Screening and Management of Syphilis in Pregnant Women

Site	Facility	Screening Test	Management (if screened reactive)
Screening Site	Sub-centre, HWCs, VHSND & PMSMA sites	Dual RDT kits	Refer to nearest treatment facility for on-spot treatment → refer for confirmation with RPR/VDRL at the confirmatory sites → if reactive → complete treatment → follow-up → Institutional Delivery
	PHC, CHC	Dual RDT kits	Provide on-spot dose of BPG (if available) or refer to the nearest treatment facility for on-spot treatment → refer for confirmation with RPR/VDRL at the confirmatory sites → complete treatment → follow-up → Institutional Delivery
Confirmatory Site	PHC, CHC, ICTC	RPR/VDRL	Provide complete treatment with 3 doses of BPG or refer to the nearest treatment facility for complete treatment → Follow-up → Institutional Delivery
	SDH, DH & DSRC	RPR/ VDRL	Provide complete treatment with 3 doses of BPG or refer to the nearest treatment facility for complete treatment → Follow-up → Institutional Delivery

6.4 Management of women coming directly in labour

When pregnant women present directly in labour with unknown HIV and Syphilis status or are at -risk, the following interventions should be implemented:

Considerations for HIV screening in labour room

- Labour room nurse will offer bedside counselling and HIV screening test.
- If the woman consents, screen for HIV, with the Point-of-care (POC) test kit - 'Whole Blood Finger Prick Test'(WBFPT) or Dual RDT kits in delivery room or labour ward.
- If result is screened reactive for HIV, the labour room nurse should inform the ICTC counsellor and laboratory technician for further confirmation of HIV status as per guidelines.
- If the HIV positive status is confirmed at the HCTS confirmatory site, the woman should be referred to ART centre for evaluation and ART initiation as per national guidelines.

Risk Assessment of infant of WLHIV reporting directly in labour or of women identified as HIV positive postnatally, within 6 weeks of delivery, are categorized as High-Risk for HIV transmission. The following should be offered to such mother-baby pairs:

- Start Dual ARV Prophylaxis at baby's first encounter with health services
  - o Can be started even if more than 72 hours have passed since birth
  - o Should be continued for minimum 6 weeks, regardless of feeding option selected
- Extend the duration of ARV prophylaxis to 12 weeks, if the mother is breast feeding
- Mother should be linked to ART services and initiated on ART, at the earliest.

Considerations for syphilis screening in the labour room

The following pregnant women who come directly to the labour room (DIL) should be screened for syphilis:

- Those with no history of ANC visits.
- Those with no documentation of syphilis screening during pregnancy.
- At-risk pregnant women.

Direct-in-labour cases can be screened for syphilis using available screening kits as per the facility, such as RPR/VDRL or Dual RDT kits/ POC syphilis test kit.

If the screening reveals a positive result, the woman will receive complete treatment based on the stage of syphilis after delivery. The first dose of injection BPG may be administered during the hospital stay after delivery. If BPG is not available, the woman may be referred to the DSRC for further management after delivery. The syphilis-exposed infant will be referred to a paediatrician for further assessment and appropriate management. The exposed infant will be followed up as per the protocols presented in next chapters.

The specific considerations for care of pregnant women with HIV and Syphilis co-infection, are summarized in the table 6.4.1.

Table 6.4.1: Care of pregnant women with HIV and Syphilis co-infection

Care of pregnant women with HIV and Syphilis co-infection
• Co-infection with HIV and Syphilis can have detrimental effects on the health of both the pregnant woman and the developing foetus. • Placental inflammation from congenital syphilis infection might increase the risk for perinatal transmission of HIV. • Though rare, unusual responses for treponemal and non-treponemal tests might be observed: o Higher/ fluctuated post-treatment serological titers than expected o False negative serological test results and delayed appearance of sero-reactivity • Treatment must be considered in all pregnant women with HIV infection, when the clinical findings are suggestive of syphilis, but serological titers are non-reactive, or their interpretation is unclear. • Pregnant women with HIV infection and primary or secondary syphilis should be evaluated clinically and serologically for possible treatment failure every three months (up to 24 months) after therapy.

6.5 Standard Workplace Precautions in Labour Rooms

As per Ministry of Health and Family Welfare (MOHFW), National Guidelines for Infection Prevention and Control in Healthcare Facilities, Jan 2020, standard workplace precautions are work practices that are applied to all patients receiving care in health facilities, regardless of their diagnosis or presumed infectious status. The aim of taking standard precautions is to minimize the risk of transmission of infectious agents in all situations.

Standard workplace precautions are taken to:

- Minimize risk of transmission of infectious agents between Health Care Workers (HCWs) and patients, and from patient to patient.
- To be followed for all patients, irrespective of their infection status.
- To avoid contact with blood, body fluids, secretions and excretions regardless of whether contaminated grossly with blood or not.

The key components of Infection Prevention and Control in health facilities are hand hygiene, Personal Protective Equipment (PPE), respiratory hygiene and cough etiquette, prevention of injuries from sharps and safe handling of patient-care equipment.

As part of EVTHS services, it is crucial to ensure the implementation of Standard Workplace Precautions and proper Biomedical Waste Management during all activities in health care facilities to protect health care providers and prevent the spread of infection from patient to patient. Further, it becomes essential to ensure that all health care workers are trained and effectively implement these standard workplace precautions.

The details on Cleaning and Disinfection of Labor Rooms, are given in Annexure-11.

For further reading, refer to the following national guidelines:

- *Guidelines for Standardization of Labour rooms at Delivery Points; Maternal Health Division, MOH & FW, GOI, April, 2016. Available at: https://nhm.gov.in/images/pdf/programmes/maternal-health/guidelines/Labor_Room%20Guideline.pdf*
- *'LAQSHYA', Labour Room Quality Improvement Initiative, National Health Mission, MOH & FW, GOI,2017. Available at: https://nhm.gov.in/New_Updates_2018/NHM_Components/RMNCH_MH_Guidelines/LaQshya-Guidelines.pdf*

Biomedical Waste management:

Biomedical waste is the waste that is generated during examination, immunization, investigations, diagnosis and treatment such as bandages or surgical sponges; which includes blood, blood products (fresh or dried blood) or other body fluids. There are three kinds of waste generally found in health facilities: general waste, medical waste and hazardous chemical waste. It is important to dispose all kinds of waste properly, since improper disposal of medical and hazardous chemical waste poses the most immediate health risk to the community.

There are four components for BMW management plan: Segregation; Disinfection; Proper Storage before Transportation; and Safe Disposal.

1. Most waste (e.g. paper, trash, food, boxes) at health centres and hospitals is not contaminated and poses no risk of infection to people who handle it. Some waste, however, is contaminated and, if not disposed properly, can cause infection.
2. Contaminated waste must therefore be disposed separately from non-contaminated waste.
3. Segregation at source in color-coded waste bins, as per the guideline, is hence essential.
4. Each facility must have housekeeping and waste management protocols depending upon the caseload, waste generated, available human resource, and facility of waste disposal.
5. Staff in the facility must be aware of infection prevention practices and protocols.

6. General/non-contaminated waste should be put in black bin.

Segregation should be done at the source, using colour coded, leak-proof bags/ containers. Figure-6.5.1 depicts the segregation of hospital waste into colour coded bags or containers

Figure 6.5.1: Segregation of Hospital waste into colour coded bags or containers

Source: https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Pictorial_guide_covid.pdf

For further reading, about Biomedical Waste Management, refer to Annexure VIII of the National Guidelines for Infection Prevention and Control in Healthcare Facilities, NCDC, DGHS, MOH&FW, Jan 2020. Available at: https://www.mohfw.gov.in/pdf/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf

CHAPTER-7

Management of Babies exposed to HIV and/ or Syphilis infection

Management of Babies exposed to HIV and/ or Syphilis infection

7.1 Management of HIV-exposed babies

The term "**HIV-exposed babies**" is used to refer to the babies born to mothers infected with HIV, until HIV infection can be reliably excluded or confirmed in them.

HIV viral loads are higher in infants as compared to adults and persist till 2 years of life. Hence, HIV disease progresses very rapidly in infants and young children, especially in the first few months of life, often leading to death. Without care and treatment, about one third of infants living with HIV will die in their first year of life and almost 50% of children by the second year of life.

Regardless of their own HIV status, HIV-exposed babies are at a high-risk of malnutrition, growth failure, developmental delay and repeated infectious diseases-related morbidity by common as well as unusual organisms.

Thus, it is very important to follow-up all HIV-exposed babies with a structured plan to minimize risk of HIV transmission, ensure timely detection and management of HIV infection and to give optimal comprehensive care to improve their overall outcome. (For further details, refer to Section-3.1, National Guidelines on HIV Care and Treatment, 2021).

The main components of care for HIV-exposed babies include the following:

I. Immediate care at birth
II. ARV prophylaxis
III. Infant feeding advice
IV. Cotrimoxazole preventive therapy (CPT)
V. Clinical assessment/evaluation by Paediatrician
VI. Early infant diagnosis (EID)

VII. Counselling

VIII. Clinical assessment/evaluation by Paediatrician

IX. Access to follow-up care for Immunization, Vitamin-A supplementation, Growth and Development, etc. at the general health facilities, as high-risk babies.

Responsibility: The responsibility for the care of HIV-exposed babies is the joint responsibility of NACP and the general Health system. HIV-exposed babies will be followed up as high-risk babies by Paediatrician.

Prescription of Infant ARV Prophylaxis:

All pregnant WLHIV should undergo a viral load test between 32-36 weeks of pregnancy. The viral load result will determine the drugs to be prescribed as infant ARV prophylaxis. It is desirable that the drug prescription for infant ARV prophylaxis be recorded in the mother's ART booklet, at the ART centres, which should be then carried to the labour room. ARV prophylaxis based on the birth weight of child will be initiated by Medical Officer of OT/Labour Room. Dosage chart for ARV Prophylaxis is detailed in Annexure-10 should be utilized for initiating the ARV prophylaxis. If needed, a consultation with MO of co-located ART centre, may be initiated for ARV Prophylaxis prescription.

Dispensation of Drugs for ARV prophylaxis

The infant ARV prophylaxis drugs will be dispensed from the nearest ICTC (HIV confirmatory facility)/ ART centre.

Care during labour and delivery for pregnant WLHIV:

Pregnancy in WLHIV is considered as a high-risk pregnancy and their deliveries should be planned. It is expected that delivery of WLHIV will be conducted at CEmONC facilities where services for specialist obstetric care and newborn management are available.

The labour room staff (MO labour Room, labour room In-charge, labour room nurse, etc.) is responsible for providing immediate care at birth, offering appropriate feeding options and ensuring the timely initiation of infant ARV prophylaxis. Thereafter, the mother-baby pair will be followed up at the ART centre and ICTC, with leveraging support from the health systems for routine services and paediatric consultations.

It is essential to build collaborations between NACP and health systems to provide all necessary components of care to HIV-exposed babies.

Activities for Optimal Care

The following activities are essential for the optimal care of HIV-exposed babies:

1. Provision of immediate care during childbirth as per guidelines.
2. Infant ARV Prophylaxis: drugs for ARV prophylaxis should be administered to the babies, preferably within the first hour after birth, based on the prescription written by the ART medical officer in the mother's ART Booklet (Green Book) or prescribed by the treating Obstetrician and recorded in the ANC card or the Labour room doctor.
3. NACP counsellor will ensure that infant receives ARV prophylaxis within 72 hours of delivery. ARV prophylaxis can be started beyond 72 hours after birth, though its efficacy in preventing perinatal HIV transmission will be lower. Monitoring the drug adherence for infant ARV prophylaxis

becomes essential and would need to be assessed during the complete duration of therapy, i.e. for 6 week or 12 weeks as per the prescription.

4. For infants whose mothers are identified HIV-positive during labour, the labour room nurse will coordinate with the nearest ICTC to confirm the HIV diagnosis and mobilize the drugs for infant ARV prophylaxis to the labour room. On confirmation of HIV infection in the mother, the NACP counsellor at ICTC will ensure that her baby receives the ARV prophylaxis within 72 hours of delivery.

5. Initiation of appropriate infant feeding practices within the first hour after birth is essential. This activity will be based on the counselling provided during the ANC period. For infants whose mothers are identified during labour, the labour room nurse will counsel the parents on the infant feeding options and initiate feeding accordingly.

6. All HIV-exposed infants should undergo evaluation and clinical assessment by the paediatrician, at birth and during each follow-up visit. Counselor at ICTC may provide accompanied referral or a referral slip for the HIV-exposed babies, to ensure routine follow up visits for immunization, growth monitoring and clinical assessment by paediatrician under the health system.

7. All HIV-exposed babies should receive care as 'high-risk babies' for immunization, growth and development monitoring and reiterated nutritional advice on infant feeding, through the routine health system similar to the care given to babies who have not been exposed to HIV infection.

8. All HIV-exposed babies should be followed up at the linked HIV confirmatory facilities at 6 week, 6 months, 12 months and 18 months for EID services. If the HIV-exposed child remains on breastfeeding beyond 18 months, EID services should be offered 6 monthly during the breastfeeding period. The last EID testing to be done at 3 months after complete cessation of breastfeeding. This opportunity should be utilized to provide clinical evaluation by a paediatrician in the same health facility, through accompanied referral by the counsellor of the confirmatory facility.

9. All HIV-exposed babies should be initiated on Cotrimoxazole Preventive therapy (CPT) at 6 weeks, and this therapy too needs to be assessed for drug adherence. CPT should be stopped once HIV infection is excluded in the exposed child.

10. All HIV-exposed babies detected as HIV-positive through EID protocol, should be immediately referred to ART centre for ART initiation. In cases where the baby cannot be taken to the ART centre, care can be provided at a Link ART Centre Plus (LAC Plus), supervised by the ART Medical Officer (MO). In situations where accessing a Linked ART Centre is not feasible, the ART MO may collaborate with the nearest health facility, preferably one with a trained Medical Officer or use teleconsultation to ensure the provision of essential HIV care.

11. The final testing for HIV diagnosis in exposed babies will be performed at 18 months or after 3 months of complete cessation of breastfeeding, whichever is later. Regular follow-up of HIV-exposed babies is essential until the HIV infection is confirmed or excluded.

12. Babies of mothers with HIV-Syphilis co-infection should also be referred to a paediatrician for evaluation and management of syphilis infection, as per guidelines.

13. ART centre staff should reiterate to the mother regarding regular follow-up of her child, whenever the mother comes for ART pill pick up. ART medical officer will be responsible for the medical care of the mother. Follow-up details of HIV-exposed baby, including the EID results, will be regularly updated in the EVTHS section of the mother's Patient Treatment Card (Annexure-5). However, the HIV-exposed baby will be registered at the co-located ICTC to enable proper tracking of service delivery and maintenance of records. This is crucial for comprehensive care of HIV-exposed babies.

14. Mother's ART pill pick-up or viral load testing appointment should be aligned with her child's follow-up visits as per protocol for EID and other services such as immunization, etc. This streamlined approach will ensure robust service delivery to mother-baby pair in a single visit, while reducing missed opportunities. Detailed counselling for the mothers and other family members for regular follow-up of mother-baby pair becomes essential.

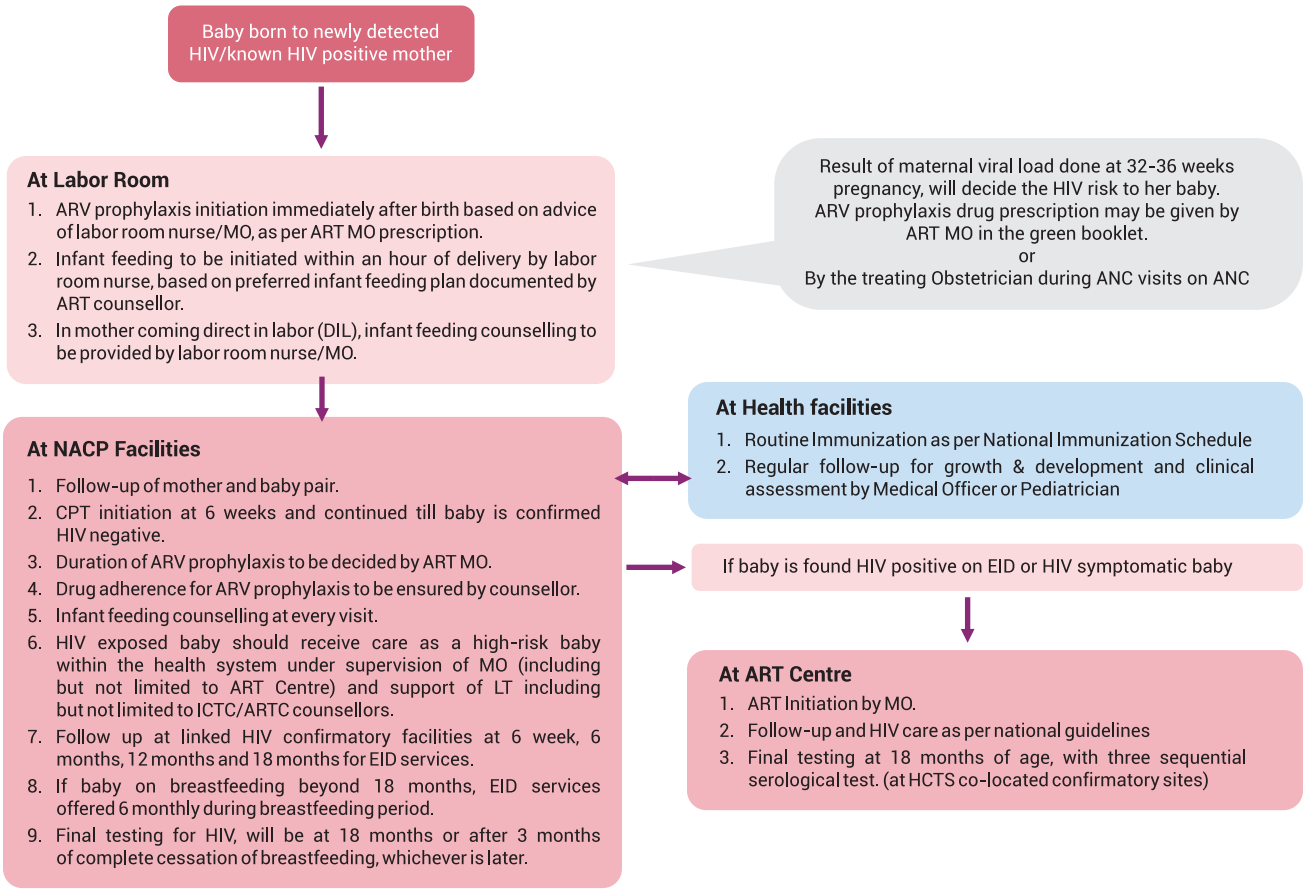
15. At any time, the HIV-exposed baby develops an episode of illness, or is detected with growth faltering, he/she should be evaluated preferably by a paediatrician or a Medical Officer (MO) trained in care of HIV-exposed children under the health system.

16. At every visit mother or the caregiver should be provided robust counselling on regular follow-up, drug adherence, EID services and age-appropriate infant feeding advice, etc.

7.2 Care cascade for HIV-exposed Babies

The figure 7.2.1 describes in detail the Cascade of care for HIV-exposed babies.

Figure 7.2.1 Cascade of Care for HIV-Exposed Babies



Immediate care at birth for HIV-exposed Infant

Care for HIV-exposed infants should adhere to the "Navjaat Shishu Suraksha Karyakram" (NSSK) guidelines. *For further reading, refer Navjaat Shishu Suraksha Karyakram, (NSSK) Resource Manual, Child Health Division, MOH, F&W, GOI, 2020; available at: https://nhm.gov.in/images/pdf/programmes/child-health/guidelines/NSSK/NSSK-Resource-Manual.pdf*

Management of HIV-exposed neonates at birth is no different from the management recommended

for babies not exposed to HIV infection. Additional recommendations for immediate care at birth for HIV-exposed babies are as follows:

- Suctioning at birth for the newborn should only be performed if the liquor is meconium stained. If suctioning is required, the suction pressure should be kept below 100 mm Hg, or a bulb suction should be used.
- It is important to wipe and clean the baby's mouth and nostrils as soon as the head is delivered. The HIV-exposed infants should be handled with gloves until all blood and maternal secretions have been washed off.
- Delayed umbilical cord clamping (not earlier than 1 minute after birth) is recommended for improved maternal and infant health and nutrition outcomes.
- Milking of the cord should be avoided. Always cover the cord with gloved hands and gauze before cutting the cord to avoid blood splattering. Initiate feeding within the first hour of birth according to the preferred and informed choice of the parents.
- The most critical factor influencing the risk of mother to child transmission of HIV is maternal viral load suppression and the linked single or dual ARV prophylaxis to the infant. Thus, the recommended management of HIV exposed neonate at birth is no different from the management recommended for HIV unexposed infants.

Infant ARV Prophylaxis

The HIV-exposed infant should be given prophylactic ARV drugs to reduce the risk of HIV transmission during perinatal period and breastfeeding period. The HIV-exposed infants are categorized as low-risk or high-risk for HIV transmission, based on their mothers' viral load result performed between 32-36 weeks of pregnancy.

Risk Categorization of HIV-exposed babies, based on the maternal viral load is summarized in table 7.2.1

Table 7.2.1: Risk Categorization of HIV-exposed babies based on maternal viral load

Scenario	Risk status
Infants born to HIV-positive mother not on ART	**High-Risk**
Maternal viral load not done between 32 weeks of pregnancy till delivery or viral load result not available at the time of delivery	**High-Risk**
Unsuppressed maternal viral load between 32 weeks to 36 weeks of pregnancy (viral load ≥ 1000 copies/ml)	**High-Risk**
Mother newly identified as HIV-positive within 6 weeks of delivery (including direct in labour diagnosed cases)	**High-Risk**
Infants born to mothers with suppressed viral load at 32-36 weeks of pregnancy (TND or viral load < 1000 copies/ml)	**Low-Risk**

According to the risk categorization, the drugs for infant ARV prophylaxis are prescribed. Dual drug ARV prophylaxis is prescribed for infants who are at high-risk for HIV transmission and a single drug ARV prophylaxis is prescribed for infants who are at low-risk for HIV transmission.

HIV Risk assessment of infants born to HIV infected mothers and the Infant ARV Prophylaxis options are discussed in table 7.2.2.

Table 7.2.2: HIV Risk assessment of infants born to HIV infected mothers and the Infant ARV Prophylaxis options

HIV Risk status	Options for ARV Prophylaxis
Low-risk infants: • Infants born to mothers with suppressed viral load (<1000 copies/ml) done any time after 32 weeks of pregnancy up to delivery	**Syrup Nevirapine** or **Syrup Zidovudine#** (in situations where Nevirapine will not be effective, as mentioned below): • Infant born to a mother with confirmed HIV-2 or HIV-1 and HIV-2 combined infections • Infant born to a mother, who had received single dose of Nevirapine during earlier pregnancy or delivery • Infant born to a mother who is on PI-based ART regimen due to treatment failure **Duration of ARV prophylaxis**: From birth till 6 weeks of age
High-risk infants: • Infants born to HIV-positive mother not on ART • Maternal viral load not done after 32 weeks of pregnancy till delivery • Maternal viral load not suppressed between 32 weeks of pregnancy till delivery • Mother newly identified HIV-positive in post-natal period, within 6 weeks of delivery	**Options for dual prophylaxis:** Syrup Nevirapine + Syrup Zidovudine**##** **Duration of Dual ARV Prophylaxis:** • In case of Exclusive Replacement Feeding (ERF): From birth till 6 weeks of age • In case of Exclusive Breastfeeding (EBF): From birth till 12 weeks of age
# When Zidovudine syrup is not available, syrup Lopinavir/ritonavir should be used after 14 days of birth **##** When Zidovudine syrup is not available, syrup Nevirapine should be used for first 14 days after birth and then add syrup Lopinavir/ritonavir after 14 days of birth till 6 weeks in case of Exclusive Replacement Feeding or 12 weeks in case of Exclusive Breast Feeding. **##** Another alternative that may be used in this situation is AZT+3TC+NVP (ZLN) paediatric formulation	
In exceptional scenarios and for high-risk Infants born to HIV-2 positive mothers or **for high-risk Infants** born to mothers, who had received single dose of Nevirapine during earlier pregnancy or delivery, **opinion of SACEP should be sought**	

Source: Table 2.5.4, Chapter-2.5, National Guidelines for HIV Care and Treatment, 2021

For dosage of Infant ARV prophylaxis (syrup nevirapine, syrup zidovudine and syrup lopinavir/ritonavir) refer to Annexure-7

Duration of ARV Prophylaxis:

- A minimum of 6 weeks of ARV prophylaxis is advised for all HIV-exposed infants to cover the peri-natal exposure to HIV virus during labour and delivery

- In infants who are being breastfed and are also categorized High-risk for HIV transmission, duration of ARV Prophylaxis has to be extended to 12 weeks
- Explanation:
    - Mother is not virally suppressed to achieve optimal HIV viral suppression in breast milk
    - Extended prophylaxis reduces risk of HIV transmission due to breast feeding
    - Beyond 12 weeks, maternal ART causes enough viral suppression to make breast milk relatively safe
- Infants on Exclusive Replacement Feeding don't need extended ARV prophylaxis

Duration of Infant ARV Prophylaxis is described in table 7.2.3

Table 7.2.3: Duration of Infant ARV Prophylaxis

Type of Infant	Type of feeding option	Duration of ARV Prophylaxis
Infant with low-risk for HIV transmission	Exclusive Breast feeding (EBF)	6 weeks, regardless of feeding option
	Exclusive Replacement feeding (ERF)	
Infant with high-risk for HIV transmission	Exclusive Breast feeding (EBF)	12 weeks
	Exclusive Replacement feeding (ERF)	6 weeks

ARV Prophylaxis for babies born to women presenting directly-in-labour

Once HIV infection is confirmed in women presenting directly-in-labour, their babies should be advised Dual Infant ARV Prophylaxis. These babies will be considered as high-risk for vertical transmission of HIV. The medical officer of the labour room / ward/ OT shall determine the appropriate dosage of dual ARV prophylaxis based on the infant's birth weight. Dual-drug prophylaxis, which consists of Nevirapine and Zidovudine, should be started immediately after delivery, within 72 hours of birth, for the drugs to be effective. If the ARV prophylaxis drugs are not available in the labour room, the nearest ART centre or HCTS confirmation site should be contacted to mobilize the drugs as soon as possible. The medical officer of the labour room / ward/ OT may telephonically consult the Medical Officer of co-located ART centre, regarding the dosage of the two drugs for ARV prophylaxis.

The HCTS counsellor or staff nurse should offer infant feeding counselling to the parents. If the mother is breastfeeding the baby, the duration of the prophylaxis should be increased to 12 weeks. If the baby is on exclusive replacement feeding, then 6 weeks of prophylaxis is sufficient.

Infant feeding

National infant feeding recommendations for HIV-exposed babies

Breastfeeding provides the infant all the required nutrients and immunological factors that help to protect against common infections. However, it does carry a risk of transmission of HIV infection from HIV infected mothers to their infants. Use of concomitant maternal ART not only decreases the maternal viral load, but also the transmission of HIV to the baby through placenta and breast milk. Hence, maternal ART provides an effective pre-exposure prophylaxis to the infant, preventing replication of any transmitted virions. Thus, the chances of HIV transmission to the foetus and the infant are greatly reduced, and breastfeeding is rendered safe, under the cover of adherent ART. Breastfeeding

with concurrent ARV intervention offers HIV-exposed babies the greatest chance of HIV-free survival. In concurrence with the current WHO guidelines, breastfeeding is the recommended feeding strategy for HIV-exposed babies in India.

It is recommended that **Exclusive breastfeeding (EBF)** be provided to all HIV-exposed babies for first 6 months of life and at 6 months of age, these babies should be offered complementary foods along with breast milk.

Though given the fact that breastfeeding still carries some risk of HIV transmission, however slight it may be, individual pregnant women should be informed about alternative infant-feeding options and their advantages and disadvantages as compared to breastfeeding.

Exclusive Replacement Feeding (ERF) is not a viable public health strategy in India and other developing nations for HIV-exposed infants, due to the increased chances of non–HIV related morbidity and mortality negating the benefits of reduced HIV transmission. Thus, it cannot be recommended and promoted as the optimal infant-feeding strategy for HIV infected mothers in India.

The benefits and risks of Exclusive Breastfeeding (EBF) and Exclusive Replacement Feeding (ERF) have been discussed in table 7.2.4.

Table 7.2.4: Comparison of Benefits and Risks of Exclusive Breastfeeding (EBF) and Exclusive Replacement Feeding (ERF)

	Exclusive breastfeeding (EBF)	Exclusive Replacement feeding (ERF)
Benefits	• Breast milk contains all the nutrients the baby needs in the first six months. • Breast milk is easy to digest. • Breast milk protects the baby from diarrhoea, pneumonia, and other infections. • Breast milk is readily available and does not require preparation. • Breastfeeding helps in developing mother-infant bonding. • Exclusive breastfeeding helps the mother to recover from childbirth early. • Exclusive breastfeeding protects the mother from getting pregnant again too soon	• No risk of HIV transmission through feeding • Other family members may be involved in feeding when mothers need help.
Risks / Demerits	• Risk of acquiring HIV infection as long as the baby is breastfed	• The expense of obtaining appropriate milk, water, fuel, the added task of cleaning utensils • Babies are at higher risk of contracting diarrhoea, pneumonia, and other infections. • The mother may be questioned about not breastfeeding her baby

Source: Table 3.1.4, Chapter-3.1, National Guidelines for HIV Care and Treatment, 2021

Current national guidelines for infant feeding in HIV-exposed infants, under six months of age, recommend the following:

- Exclusive breastfeeding for the first six months of life. In a situation where the mother is practising mixed feeding, health care workers (HCWs) and counsellors should motivate her to exclusively breastfeed.
- When exclusive breastfeeding is not possible for any reason (i.e., maternal death, sickness, twins), mothers and HCWs can be reassured that maternal ART reduces the risk of postnatal HIV transmission in the context of mixed feeding as well.
- Beyond six months of age, breastfeeding should continue while complementary feeds are gradually introduced.
- Breastfeeding should only be discontinued once a nutritionally adequate and safe diet without breast milk can be provided to the child.
- Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or beyond, similar to the general population, while receiving full support for ART adherence.
- If the HIV-positive mother plans to return to work, health care workers can reassure her that a shorter duration of breastfeeding of less than 12 months is better than never initiating breastfeeding at all.
- Exclusive replacement feeding may be considered only in situations where breastfeeding cannot be done (such as maternal sickness/death or twins) or upon individual mother's choice, provided all six criteria for replacement feeding are met. The six criteria for assessing suitability for replacement feeding are discussed in the table 7.2.5.

Table 7.2.5: The SIX criteria to assess suitability for replacement feeding

WLHIV should give replacement feeding to their infants only when ALL the following conditions are met:	
1.	Safe water and sanitation are assured at the household level and in the community
2.	The mother or any other caregiver can reliably afford to provide sufficient and sustained replacement feeding (milk), to support the normal growth and development of the infant
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
5.	The family is supportive of this practice.
6.	The mother or caregiver can access healthcare that offers comprehensive child health services.

Source: Table 3.1.5, Chapter-3.1, National Guidelines for HIV Care and Treatment, 2021

Counselling parents for choosing a feeding option

A discussion with the parents should take place well before delivery regarding choice of infant feeding strategy. While clearly recommending EBF as the feeding option of choice, the counsellor should provide the family information about risk of HIV transmission associated with breastfeeding as well as stressing good adherence to ART as a tool for minimizing it. Benefits and risks of replacement feeding should also be provided, and family situation assessed using six criteria for replacement feeding as mentioned above. Since each mother is different from the others in terms of education, financial situation and social support; counselling as well as the final decision regarding feeding option needs to be customized as per everyone's unique need. Most importantly, the counsellor must support the family in executing the chosen feeding option in a correct manner.

Counselling mothers who decide to breastfeed infants

Mothers who decide to breastfeed their infants should be counselled to give breastfeeds as often as the child wants, day and night, at least eight times in 24 hours. The mother should be advised to continue breastfeeding if the child is sick. She should not give any other food, fluids or water to her infant during the first 6 months of life. Counselling should also include steps for appropriate breast care. The counsellor should stress upon the importance of breastfeeding exclusively, since even a small amount of mixed feeding makes a child vulnerable to gastrointestinal and other infections.

Mothers need to counselled about the steps for correct attachment of the baby's lips to the breast and the correct way to breastfeed. In addition, they need to be informed that appearance of sore nipples or breast engorgement, or oral ulcers in baby needs to be addressed immediately by a visit to nearest health facility. In context with adherent ART and maternal viral suppression, the management of these conditions remains the same as in uninfected mothers.

Counselling and Support for Exclusive Replacement Feeding:

a) Explain the types of replacement feeding options available and help parents choose an appropriate option for their circumstances.

b) Discuss and demonstrate the amount to be fed.

The options of Replacement Feeding include unmodified animal milk or pre-packed processed toned milk (containing 3% fat, 3.1% protein and providing 58 Kcal/100 ml) or suitable infant formula reconstituted as per recommendation of the manufacturer. Although animal milk is not ideally suited to meet the complete nutritional requirements of an infant below 6 months, it is easily available, economical and culturally acceptable. Infants receiving animal milk should additionally receive multivitamin and iron supplementation.

Mothers who decide to give ERF to their infants need to be counselled about the hygienic way to prepare feeds and about the amount of feeding the child will need at different ages. They should wash their hands with soap and water before preparing the feed and use clean utensils. The child should be fed using katori (bowl) and spoon or paladai. Bottle feeding should be strictly avoided since it carries a higher risk of causing gastro-intestinal infections.

Mixed feeding

It was earlier recommended that giving an infant a combination of breastfeeding and replacement feeding is to be avoided since an artificially fed or breastfed child is at less risk of acquiring HIV than the child who receives mixed feeding. Use of animal milk/formula feed increases the chance of causing inflammation of gut mucosa due to allergy and infections, making it easier for the HIV in breast milk to gain access and cause HIV infection in the infant. However, current evidence suggests that in continued presence of maternal ART, mixed feeding is also rendered safe and may be preferred over no breastfeeding at all.

Although EBF is still recommended during first 6 months, practising mixed feeding is not a reason to stop breast-feeding in the presence of ARV drugs. Thus, with ongoing maternal ART during pregnancy and lactation, there remains no difference in the feeding guidelines related to feeding of HIV-exposed versus unexposed infants. *(Source- Chapter-3.1, National Guidelines for HIV Care and Treatment, 2021)*

Cotrimoxazole Preventive Therapy (CPT) for HIV-Exposed Infants and Children

Cotrimoxazole Preventive Therapy (CPT) is an effective strategy to reduce morbidity and mortality in HIV-exposed infants and children. It provides protection against various infections, including pneumocystis jiroveci, malaria, and few bacterial diseases. Guidance on the use of CPT in HIV-exposed infants and children are detailed as below.

Timing and Dosage: National guidelines recommend initiating CPT for all HIV-exposed infants and children from 6 weeks of age, at the first immunization visit or anytime afterward. The Medical Officer (MO) at the ART centre or Paediatrician/MO at the health facility, will prescribe a one-month supply of Cotrimoxazole, with repeat prescriptions done monthly and continued until HIV infection is excluded. The recommended dosage of Cotrimoxazole is 5mg/kg of Trimethoprim per day, given once daily in syrup form. In situations where the HIV-exposed child develops an allergic reaction to CPT, he/she should be referred to a paediatrician at the nearest health facility.

During home visits and outreach:

- ORW, ANM, ASHA, or counsellor should check if the infant is receiving CPT and ensure adequate drug stock at home. If not, cotrimoxazole supplies should be replenished from the health facility with a prescription from the MO.
- Remind parents/caregivers to collect Cotrimoxazole supply monthly from the health facility and reinforce adherence to CPT.

Additional Information: For more details related to CPT, please refer to Chapter 2.9 (Prevention of Opportunistic Infections) in the National Guidelines for HIV Care and Treatment, 2021.

Clinical Assessment and Evaluations for HIV-Exposed Babies

HIV-exposed babies are at a higher risk of acquiring infections and more likely to develop severe complications. Therefore, it is crucial to keep these babies under close growth and development monitoring and protect them against vaccine-preventable diseases by administering all recommended childhood immunizations.

Regular clinical evaluations for HIV-exposed infants and children are crucial for early identification of symptomatic HIV infection and opportunistic infections. It is essential to elicit relevant history from the mother/caregiver to gather information about the child's health, including feeding patterns, recent illnesses, medication use, hospitalizations and developmental milestones.

Common signs and symptoms suggestive of paediatric HIV infection include:

- Persistent Oral thrush
- Recurrent pneumonia
- Persistent diarrhoea
- Enlarged lymph nodes
- Recurrent ear infections
- Parotid gland enlargement
- Malnutrition, and failure to thrive
- Unexplained hepatosplenomegaly

At every visit, a comprehensive head to toe physical and thereafter a systemic examination should be performed by the Paediatrician to look for signs of HIV infection, growth and development delays, signs of vitamin deficiencies, malnutrition and opportunistic infections.

Early Infant Diagnosis (EID)

Early Infant Diagnosis (EID) is an important laboratory test performed at 6 weeks, 6 months, 12 months and 18 months of age and three months after cessation of breastfeeding, to detect mother to child transmission of HIV and timely initiation of anti-retroviral therapy for the babies found HIV positive.

The standard tool for HIV-1 infection used for adults has limited utility in new-borns and infants due to the transplacental transfer of maternal antibodies from mother to child during pregnancy and childbirth. Research indicates that maternal antibodies are present in an infant and child up to 18 months after birth. Clinical diagnosis of HIV-1 infection in exposed infants is not possible; hence laboratory diagnosis is mandatory. Since the standard antibody tests cannot differentiate between maternal and infant antibodies, the use of HIV-1 Antibody Detection Rapid Test and Enzyme-Linked Immunosorbent Assay (ELISA) until 18 months of age is not advised. To address this issue, an algorithm for Early Infant Diagnosis (EID) by detection of Total Nucleic Acid (TNA) Particles of HIV 1 in blood has been developed by the National AIDS Control Organization (NACO). The EID algorithm has been explained in the lab EID guidelines. *For further details, refer to Laboratory Technical Guidelines on Early Infant Diagnosis for HIV-Exposed Infants, November-2023.*

The scope of EID testing algorithm addresses the following:

- Eligibility criteria for the test
- Age of infant/child and type of test to be performed
- Number of tests required for definitive diagnosis
- Interpretation and follow-up when reported as:
    - HIV-1 Detected
    - HIV-1 Not Detected
    - Sero-discordant*
    - Indeterminate
- Testing requirements in breastfeeding infants
- Eligibility criteria for the initiation of ART in HIV-1 positive infants

(*Approach to sero-discordant reports at 18 months of age or 3 months after cessation of breastfeeding, whichever is later)

1. Early Infant Diagnosis in National AIDS and STD Control Program

Under NACP, an algorithm for EID testing has been developed by the National AIDS Control Organization (NACO), wherein Polymerase Chain Reaction (PCR) is used for the qualitative detection of Total Nucleic Acid (TNA) for EID. Early diagnosis of HIV-1 allows health care providers the scope for timely decision-making to offer optimal care and initiate ART for infants and children. Presently, TNA PCR is performed on DBS samples. Published data have confirmed survival benefits for infants who were started on ART as early as possible *(Reference: Laboratory Technical Guidelines on Early Infant Diagnosis for HIV-Exposed Infants, November-2023)*

2. Objectives of the EID Testing Program

- Diagnosis of HIV-1 infection in infants and children, less than 18 months of age, by qualitative PCR and integrating positive cases into the NACP's care, support, and treatment program.
- Infant HIV-1 PCR testing algorithm to be universally accessed and implemented on every HIV-1 exposed infant and child less than 18 months of age.
- Exposed and infected infants and children less than 18 months of age to be linked to appropriate referral, care, and treatment services.

3. Eligibility

The following categories of infants and children less than 18 months of age are eligible for HIV-1 PCR testing:

- HIV-1 exposed infants and children (born to HIV-1 positive mother)
- Infants and children with signs and symptoms of HIV
- Infants and children not accompanied by mother/ mother not traceable.

Reference: Laboratory Technical Guidelines on Early Infant Diagnosis for HIV-Exposed Infants, November-2023

Key Points for Early infant diagnosis of HIV

Key points for EID have been summarized in table 7.2.6

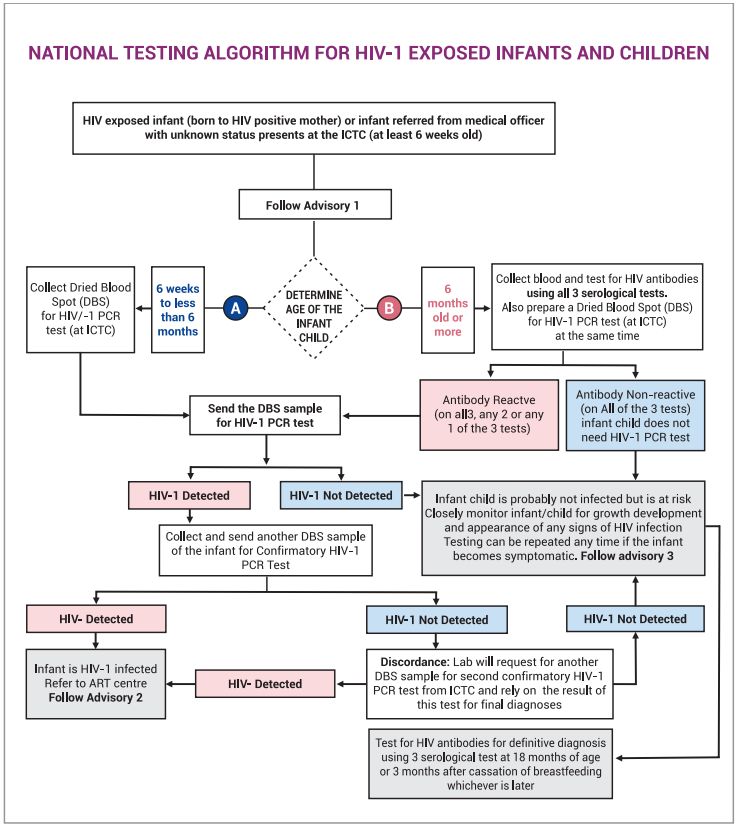
Table 7.2.6: Key Points for Early infant diagnosis of HIV

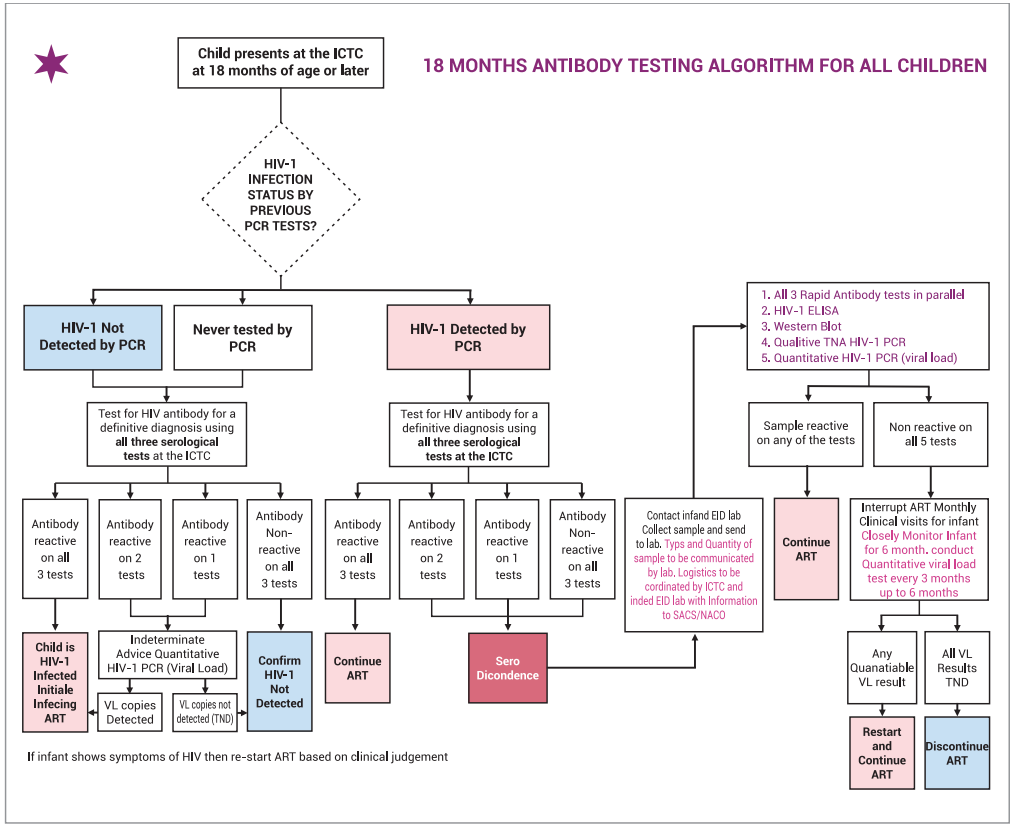
1.	All HIV-exposed babies should be followed up at the linked HIV confirmatory facilities at 6 week, 6 months, 12 months and 18 months for EID services.
2.	If the HIV-exposed child remains on breastfeeding beyond 18 months, EID services should be offered 6 monthly during the breastfeeding period with the last testing at 3 months after complete cessation of breastfeeding.
3.	All HIV-exposed babies detected HIV-positive through EID protocol, should be immediately referred to ART centre for ART initiation.
4.	In cases where the baby cannot be taken to the ART centre, care can be provided at a Link Plus ART Centre, supervised by the ART Medical Officer (MO). In situations where accessing a Linked ART Centre is not feasible, the ART MO may collaborate with the nearest health facility, preferably one with a trained Medical Officer, or use teleconsultation to ensure the provision of essential HIV care.
5.	The final testing for HIV diagnosis in exposed babies will be performed at 18 months or after 3 months of complete cessation of breastfeeding, whichever is later.
6.	Regular follow-up of HIV-exposed babies is essential until the HIV infection is confirmed or excluded.

For further reading, refer to Laboratory Technical Guidelines on Early Infant Diagnosis for HIV- Exposed Infants, November 2023.

The National Algorithm for laboratory diagnosis of HIV-1 in exposed infants and children is depicted in figure 7.2.2.

Figure 7.2.2 National Algorithm for Laboratory Diagnosis of HIV-1 in Exposed Infants and Children.





EID ADVISORIES

Universal advisory:

- Counsel mother to maintain strict adherence to art
- Initiate ARV prophylaxis as per latest HIV risk assessment of infants born to HIV-infected mother as per National Guidelines for HIV Care and Treatment.
- CPT to be initiated for all HIV exposed babies from 6 weeks of age and continued until proven HIV negative on all three serological tests at 18 months of age or later
- Continue babies on exclusive breastfeeding till 8 months of age and add complementary food after 6 months of age
- For babies on Exclusive Replacement feeding. continue the same and add complementary food after 6 month of age
- Babies diagnosed HIV positive to be linked immediately to ART centre for ART initiation and CPT should be continued until 5 Years of age
- In cases of Serological- Discordance at 18 Months continue ART and follow algorithm for management of babies with Sero-discordance at 18 months

Advisory 1:

- Initiate ARV prophylaxis as per latest HIV risk assessment of infants born to HIV-infected mother as per National Guidelines for HIV Care and Treatment.
- Start Cotrimoxazole Prophylaxis, if not already started
- Encourage exclusive breastfeeding for all babies till 6 months of age
- If age more than 6 months, start complementary feeding along with breast milk

Advisory 2:

- Continue Cotrimoxazole till 5 yrs age
- Manage OI, If any present
- Initiate appropriate ART based on the latest National ART Technical Guidelines, regardless of Cd4% or count
- Initiate complementary feeding after 6 month of age. Encourage breastfeeding till 24 months or beyond
- Test for HIV antibodies for definitive diagnosis using all three serological tests at 18 months of age or 3 months after cessation of breastfeeding, whichever is later.

Advisory 3:

- Repeat testing from (B) at 6 months and 12 months of age or 3 months after cessation of breast feeding whichever is earlier
- If signs and symptoms of HIV in develop follow the testing algorithm from (A) again if child less than 6 months and from (B) again if more than 6 months
- Continue CPT until proven negative by all three antibody tests at 18 months of age or later
- If breastfed. encourage breastfeeding till 24 months or beyond
- Counsel mother to maintain Strict adherence to ART
- Test for HIV antibody, for definitive diagnosis using all 3 Serological tests at 18 months of age or 3 months after cessation of breast feeding whichever later. ★

Presumptive Diagnosis of HIV Infection in Infants with Suggestive Symptoms in the Absence of Virologic Testing

Diagnosing HIV infection in infants with suggestive symptoms is crucial for timely ART initiation. However, in some cases, virologic testing may not be available and a presumptive diagnosis may be required. This approach is outlined in the National Guidelines for HIV Care and Treatment, 2021. In this context, it is important to understand the criteria for presumptive diagnosis and the exceptional scenarios where virological testing may be performed on priority.

- If an infant aged <18 months has symptoms suggestive of HIV infection and there is no virologic testing available, a presumptive diagnosis can be made by following the criteria outlined. (Refer to Annexure-12).
- In exceptional scenarios where the infant is very sick and EID results are delayed, the baby's sample may be sent for viral load testing after seeking an opinion from e-SACEP on priority.
- Children with confirmed virological results may be started on ART, and the EID laboratory should fast-track the TNA-PCR results.

It is important to note that virological testing in sick infants should be in addition to sending the DBS sample for TNA-PCR-HIV. A virological test result of Target Not Detected does not exclude HIV infection and confirmation is needed through TNA-PCR-HIV results.

Diagnosing HIV Infection in Infants with Suggestive Symptoms

Diagnosing HIV infection in infants with suggestive symptoms is a crucial step in providing early and appropriate management of the disease. The national guidelines for testing strategies provide a framework for diagnosing HIV infection in infants based on clinical symptoms, maternal HIV status and sequential testing procedures. Adhering to these guidelines can help ensure early detection and treatment of HIV in infants, which can improve their health outcomes and reduce the risk of transmission to others. In this section, we will discuss the national guidelines for testing strategies for diagnosing HIV infection in infants with suggestive symptoms.

1) Symptomatic infants aged less than 6 months:
   - ➢ Conduct a rapid serological test for the mother's HIV status.
   - ➢ If the mother is positive, conduct HIV-TNA-PCR testing for the child.
   - ➢ If the mother's status is unknown or unavailable, conduct serological testing of the child alongside HIV-TNA-PCR testing.
   - ➢ A positive serological test for HIV in the child should be followed up with Qualitative HIV-TNA-PCR testing.

2) Symptomatic children aged 6 to 18 months:
   - ➢ Conduct a rapid serological test for HIV, irrespective of the mother's availability.
   - ➢ Take a simultaneous DBS sample for NAAT.
   - ➢ A positive serological test for HIV in the child should be followed up with Qualitative HIV-TNA-PCR testing.

3) Symptomatic children aged >18 months:
   - ➢ Follow the current protocol for testing as for older children and adults using rapid antibody tests.

It is important to adhere to the national guidelines for testing strategies when diagnosing HIV infection in infants with suggestive symptoms. Early detection and appropriate treatment can improve the health outcomes of infants living with HIV.

For further reading on Early Infant Diagnosis of HIV refer to Laboratory Technical Guidelines on Early Infant Diagnosis for HIV- Exposed Infants, November 2023.

Counselling Messages for Parents/Caregivers of HIV-Exposed Infants/ Children regarding EID Testing: Importance and Timing.

Early detection and timely management of HIV infection in infants and children is crucial for their health. Therefore, counselling parents or caregivers about the timing of HIV testing for their infant is essential. This counselling should start during the antenatal period and should be emphasized by staff at all health facilities where pregnant WLHIV are being followed up, including ART centres, health centres, antenatal clinics and maternity wards etc. The goal of counselling is to empower parents or caregivers to make informed decisions about their child's health and well-being. It is essential to create a safe and supportive environment during counselling to ensure that parents or caregivers feel comfortable asking questions and expressing concerns.

Follow-up services for HIV-exposed babies at the General Health system

These children should be flagged as high-risk babies and referred accordingly for regular assessment at the nearest health facility by Medical Officer/Paediatrician. These visits should coincide with the routine visits to health system for immunization/ health issues/growth monitoring, etc. These visits require close coordination between staff engaged in NACP and immunization services and the MO/ Paediatrician of the health facility.

Regular follow-up care of HIV-exposed babies will continue till 18 months of age or three months after complete cessation of breastfeeding, whichever is later.

Immunization and Vitamin A Supplementation

HIV-exposed babies should be immunized according to the routine national immunization schedule with a few exceptions detailed below. It is important to give all the recommended vaccines at the correct age, as delay may not only increase susceptibility of the child to illness, but also decrease the immune response to the vaccine as the child's immune status deteriorates.

- All asymptomatic HIV-exposed babies are to be given all the vaccines in the National Immunization Program, as per the State Program.
- Vitamin A supplementation as per the national immunization schedule
- Avoid BCG in symptomatic HIV infected babies.
- Live vaccines to be avoided:
    - in severely immunocompromised (CD4 <15 %) and
    - symptomatic infants and children
- Rotavirus vaccine should be given in HIV-exposed infants due to their risk for diarrhoea
- Inactivated Japanese Encephalitis (JE) vaccine is safe for use in HIV infected babies

For further reading refer to the Chapter 3.1, of the National Guidelines for HIV Care and Treatment, 2021.

Immunization Schedule for HIV-exposed babies

The table 7.2.7 gives details of the Immunization Schedule for HIV-exposed babies.

Table 7.2.7: Immunization Schedule for HIV-exposed babies

Visit	Birth	6 Weeks	10 Weeks	14 Weeks	9 m	15 m	18 m
Immunization & Vitamin A supplements*	BCG OPV-0 Hep B Birth Dose	OPV-1 RVV-1 fIPV-1 Pentavalent-1 PCV-1	OPV-2 RVV-2 Pentavalent-2	OPV-3 RVV-3 fIPV2 Pentavalent-3 PCV-2	fIPV-3 MCV-1 Vit A JE-1** PCV Booster	MCV -2	DPT-B1 OPV-B JE-2** Vit A
Follow-up will continue till final testing for HIV infection which will be done at 18 months or 3 months after stopping breastfeeding, whichever is later. Note: *5-6 years – DPT-B2, 10 years – Td, 16 years -Td * For babies with HIV infection confirmed by early Virological testing, BCG/OPV vaccination should be delayed until ART has been started and the infant confirmed to be immunologically stable (CD4 >25%) #. (# Guidance issued by Routine Immunization Division, MOH&FW) ** Only in JE endemic districts							

Reference: https://main.mohfw.gov.in/sites/default/files/National%20AEFI%20Surveillance%20and%20Response%20Operational%20Guidelines%202024.pdf

Growth and Development Monitoring for HIV-Exposed Infants and Children

- Growth monitoring of HIV-exposed infant will be similar to HIV-unexposed infants.
- Regular monitoring of weight-for-age and length-for-age parameters is essential to detect malnutrition at an early stage
- If the child's growth curve is flattening, one should intensify the assessment of HIV-related features and screen for treatable causes, e.g., nutritional deficiency, chronic infections such as respiratory, gastrointestinal and urinary tract infections and TB.
- Developmental milestones help in assessing development or maturation of the brain of an infant/ child. They refer to abilities that children are expected to possess at different ages. Delayed development or loss of milestones after attaining them may be the first sign of HIV infection suggesting HIV encephalopathy, if other common causes are ruled out.
- It is recommended that growth and development assessments, along with clinical monitoring, be conducted by Paediatrician or medical officer within the general health system.

For further information, please refer to Chapter-3.6 in the National Guidelines for HIV Care and Treatment 2021.

Follow-up Plan for HIV-Exposed Infants and Children

HIV-exposed infants and children are a vulnerable group that require special attention and care irrespective of their status. A structured follow-up plan is crucial to identify early symptoms of HIV and ensure comprehensive care for these children.

Follow-up Activities:

1) These visits should coincide with the routine visits to health system for immunization/ health issues/growth monitoring, etc. These visits require close coordination between staff engaged in NACP and Immunization services and the MO/Paediatrician of the health facility.

2) Whenever WLHIV comes to ART centre to access her ART treatment, the opportunity will be used to counsel her regarding infant feeding practices and enquire about the health of HIV-exposed baby. The mother-baby pair will be followed up at ART centre and the collocated ICTC, at 6 weeks, 6 months, 12 months, 18 months and three months after complete cessation of breast feeding, whichever is later.

3) The follow-up details of the HIV-exposed baby will be regularly updated in the mothers EVTHS card. Refer Annexure-5.

4) The HIV-exposed baby will be linked to the ICTC to access the EID services. The baby will carry a copy of the mother's EVTHS card maintained at ART centre.

5) All visits to Paediatrician will be facilitated by the ICTC counsellor. The baby will carry a referral format along with the copy of the updated Section-11 of mothers EVTHS card. Refer to Annexure-12 for the referral format.

6) At any time, the HIV-exposed baby is detected to be infected with HIV, antiretroviral therapy (ART) should be initiated at the ART Centre without delay.

7) At any time, the babies develop acute illness, they should be referred as High-risk babies to a paediatrician or Medical Officer (MO) trained for the care of HIV. The same should apply for HIV-exposed babies with growth faltering or having suggestive symptoms of paediatric HIV infection.

8) At every visit, mother or caregiver should be counselled regarding early infant diagnosis (EID), age-appropriate infant feeding, and regular follow-up and to report to nearest hospital whenever the baby falls sick.

The table 7.2.8 outlines the follow-up protocol for HIV-exposed babies.

Table 7.2.8: Follow-up protocol for HIV-exposed Babies

Visit	Birth	6 Weeks	10 Weeks	14 Weeks	6 months	9 months	12 months	15 months	18# months
Cotrimoxazole Preventive Therapy		Start from 6 weeks (or first immunization visit) for all HIV-exposed infants and children. Stop cotrimoxazole for those tested to as HIV un-infected							
Counselling for Infant feeding	√	√	√	√	√	√	√	√	√
Growth monitoring	√	√	√	√	√	√	√	√	√

Visit	Birth	6 Weeks	10 Weeks	14 Weeks	6 months	9 months	12 months	15 months	18# months
Developmental assessment	√	√	√	√	√	√	√	√	√
Immunization & Vitamin A supplements*	BCG OPV-0 HEP B Birth Dose	OPV-1 RVV-1 FIPV-1 Pentavalent-1 PCV-1	OPV-2 RVV-2 Pentavalent-2	OPV-3 RVV-3 fIPV-2 Pentavalent-3 PCV-2	-	fIPV-3 MCV-1 Vit A JE-1** PCV Booster	-	MCV-2	DPT-B1 OPV-B JE-2** Vit A
Clinical assessment	√	√	√	√	√	√	√	√	√
HIV testing (√- if required)		√			√		√		√
Maternal Health & ART adherence	√	√	√	√	√	√	√	√	√

 # Follow-up will continue till final testing for HIV infection, which will be done at 18 months or 3 months after complete cessation of breastfeeding, whichever is later.

Note: *5-6 years - DPT-B2, 10 years - Td, 16 years -Td

*Some of the exposed babies will be diagnosed with HIV infection - For babies with HIV infection confirmed by early Virological testing, BCG/OPV vaccination should be delayed until ART has been started and the infant is confirmed to be immunologically stable (CD4 >25%).

** Only in JE endemic districts

The roles and responsibilities of health care workers (HCWs) in caring for HIV-exposed babies, is described in the table 7.2.9.

Table 7.2.9: Roles and responsibilities of healthcare workers (HCWs) in caring for HIV-exposed Babies.

S. No	Services to be provided	Focal persons
1.	Immediate care at birth	• Labour Room Nurse/MO
2.	Provision of ARV prophylaxis, to the HIV-exposed baby, immediately after birth, within 72 hours, preferably within first hour of birth	• Pediatrician/ MO/ Staff Nurse (Consultation may be held with collocated ART Medical officer for prescription of drugs)
3.	Routine health services, including immunization, growth and development monitoring, clinical assessment of HIV-exposed baby	• Follow-up as High-risk babies by Pediatrician under general health systems • Referral by NACP Counsellor

S. No	Services to be provided	Focal persons
4.	Counselling mother regarding ART Adherence to achieve viral suppression, infant feeding practices, care of nipple and breast, EID services, regular follow-up of baby by Pediatrician, to report to nearest health centre incase baby fall sick	NACP Counsellor/ART Staff Nurse/ ART MO
5.	Ensure regular follow-up as per protocol including EID for HIV, for HIV-exposed infants up to 18 months or three months after complete cessation of breastfeeding	NACP Counsellor

7.3 Management of Syphilis-Exposed Babies

This document uses the term "syphilis-exposed babies" to refer to infants born to pregnant women infected with syphilis until congenital syphilis infection can be reliably excluded or confirmed. Congenital syphilis is a serious but preventable disease that can be eliminated through effective screening of pregnant women and adequate and appropriate treatment of infected women.

Clinical Manifestations of Congenital Syphilis

Congenital syphilis is often asymptomatic in about 50% of infants, especially in the first week after birth. Clinical symptoms may appear in the first month, but they can be delayed up to two years after birth. The early and late clinical manifestations of congenital syphilis (7) are described in table-7.3.1.

Early congenital syphilis clinical manifestations might include rhinitis ("snuffles"), hepatosplenomegaly, skin rash with desquamation, chorioretinitis, pigmentary chorioretinopathy (salt and pepper type), interstitial keratitis, glaucoma, cataract, optic neuritis, periostitis, and cortical demineralization of metaphysis and diaphysis areas of long bones, anaemia, and thrombocytopenia. Some clinical signs consistent with congenital syphilis, such as hydrops and hepatosplenomegaly, might be detected by ultrasound during pregnancy.

The clinical manifestations of Congenital Syphilis are described in Table 7.3.1.

Table 7.3.1: Clinical Manifestations of Congenital Syphilis

Age of child	Clinical Signs and Symptoms of Congenital Syphilis
Early manifestations of Congenital Syphilis	▪ Rhinitis ("snuffles") ▪ Hepatosplenomegaly ▪ Skin rash - maculopapular, papulosquamous, or vesiculobullous with skin desquamation ▪ Eyes: chorioretinitis, interstitial keratitis, glaucoma, cataract, optic neuritis, periostitis ▪ Bones: cortical demineralization of metaphysis and diaphysis areas of long bones ▪ Hematological: anemia, and thrombocytopenia

Late manifestations of Congenital Syphilis	Additional clinical manifestations: ▪ Frontal bossing ▪ Saddle nose ▪ Saber Shins ▪ Cluttons' joints ▪ Hutchinson's teeth, Mulberry molars ▪ Neurological deafness ▪ Optic neuritis

Source: CDC Birth Defects Surveillance toolkit; can be accessed at following link *https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/quick-reference-handbook/congenital-syphilis.html#:~:text=Clinical%20manifestations%20of%20early%20congenital,periostitis%20and%20cortical%20demineralization%20of*)

Untreated infants can progress to late congenital syphilis, resulting in numerous additional clinical manifestations, including, but not limited to saddle nose due to cartilage destruction, frontal bossing due to periostitis, tibial thickening (saber shins), joint swelling (Cluttons joints), perforation of the hard palate, abnormal tooth development (Hutchinson's teeth, mulberry molars), interstitial keratitis, neurologic deafness and optic atrophy.

Infants might be born without clinical signs but can go on to develop late-stage manifestations of untreated congenital syphilis that include developmental delay, neurologic manifestations and physical signs of late congenital syphilis.

Clinical Case Definition for Congenital Syphilis

Clinical case definitions for congenital syphilis are provided in the table 7.3.2.

Table 7.3.2: Case Definitions for Congenital Syphilis

Suspected Case of Congenital Syphilis	**A fetal death beyond 20 weeks of gestation or >500 g weight (including stillbirth*) or a live baby born to a syphilis sero-reactive mother who was inadequately** treated for the stage of infection.**
Confirmed Case	▪ A live baby born to a syphilis sero-reactive mother with an RPR/ VDRL quantitative titer four-fold higher than the mother's titre. Or ▪ A child within the first two years of life with clinical evidence*** of syphilis and syphilis-reactive serology irrespective of mother's serology.
A baby who dies after 28 weeks of pregnancy, but before or during birth. ****Treatment completed less than 30 days before delivery with penicillin regimen or treatment with a non-penicillin regimen is considered as 'inadequate'.*** *****Clinical Evidence of Syphilis: At least two of the following: Swelling of Joints, Snuffles, Bullous Skin Lesions, Hepatosplenomegaly, Jaundice, Anaemia, Radiological Changes in long bones***	

(***Adapted from***: *National Strategy and Operational guidelines towards Elimination of Congenital Syphilis, WHO & NACO, 2015; available at following link: http://www.naco.gov.in/sites/default/files/Elimination%20of%20Congenital%20Syphilis%20Book%20%282%29%20%281%29.pdf*)

7.4 Care cascade for Syphilis-exposed infants/children

The care of infants and children exposed to syphilis involves several key components to ensure their health and well-being. In this section, we will discuss the four main components of care for Syphilis-exposed infants/children:

I. Immediate Care at Birth

II. Clinical Assessment/Evaluation at Birth

III. Management of Syphilis-exposed Infants/Children

IV. Follow-up

The detailed descriptions are mentioned in the sections below.

Immediate Care at Birth

Care for Syphilis-exposed infants should adhere to the facility-based guidelines for newborn care. Management of Syphilis-exposed neonates at birth is no different from the management recommended for unexposed infants.

Clinical Assessment/Evaluation at Birth

All syphilis-exposed babies, after birth, should be referred to the nearest Special Newborn Care Unit (SNCU), Neonatal Intensive Care Unit (NICU), or paediatric treatment facility at a Medical College, District Hospital, or Sub-district Hospital for management. The paediatrician at the facility will perform a thorough assessment for the Syphilis-exposed children as given below.

- Clinical assessment of the newborn/ infant for signs/symptoms of congenital syphilis
- Serological investigation using RPR/VDRL titers at birth, with comparison to maternal titers. Both samples should be tested with the same type of kit and in the same laboratory.
- Determination and provision of further management for syphilis-exposed infants, as per the results of RPR/VDRL.
- Assessment for signs of complications related to prematurity and low birth weight, with appropriate management.

Management of Syphilis-exposed Infants/Children

Diagnosing congenital syphilis through laboratory investigations can be difficult and have limited outcomes. It is important to consider the following factors, while evaluating syphilis-exposed infants:

I. Challenge for Interpretation of test results: Maternal nontreponemal and treponemal IgG antibodies can cross the placenta to the foetus, complicating the interpretation of reactive serologic tests in neonates (<30 days old).

- Umbilical cord blood is prone to maternal contamination, leading to false-positive results.
- Wharton's jelly within the umbilical cord can yield false-negative results; therefore, the use of umbilical cord blood is not recommended.
- Treponemal tests on neonatal serum are not recommended due to difficulty in interpretation caused by persistent maternal antibodies (>15 months).

Testing Protocol for Neonates Born to Syphilis Seropositive Mothers:

- Neonates born to sero-reactive mothers should be evaluated with a semi-quantitative RPR or VDRL (non-treponemal test) performed on their serum, at birth.
- The type of nontreponemal test performed on the neonate should match the one done on the mother.
- A four-fold or higher increase in RPR/VDRL titres compared to the mother indicates congenital syphilis in neonates.

Note: Commercially available IgM tests are not recommended under the National Programme.

Management decisions for syphilis exposed infants

The treatment protocols for syphilis-exposed infants are based on the following factors:

- Identification of syphilis in the mother during pregnancy.
- Adequacy of maternal treatment.
- Presence of clinical or laboratory evidence of syphilis in the exposed infant.
- Comparison of maternal (at the time of delivery) and neonatal non-treponemal serologic RPR/VDRL titres by using the same test, preferably conducted by the same laboratory

All syphilis-exposed infants should be managed according to the scenario-based management protocol for syphilis-exposed babies outlined in table 7.4.1.

Table 7.4.1: Scenario-Based Management Protocol for Syphilis-Exposed Babies

Scenario	Is Physical Examination of infant suggestive of Congenital Syphilis? (Yes/No)	Whether Serum quantitative RPR/ VDRL titer of an infant is fourfold (or greater) higher than the mother's titer at delivery? (Yes/No)	Additional Evaluation/ Remarks	Recommended Treatment
Scenario 1	Yes	Yes	Any of the two is present	Curative Treatment
Scenario 2	No	No	Mother was not treated/ inadequately treated/ no documentation of treatment.	Curative Treatment
Scenario 3	No	No	The mother received appropriate treatment. ≥ 4 weeks before delivery AND No evidence of reinfection or relapse	Prophylactic Treatment**

Scenario	Is Physical Examination of infant suggestive of Congenital Syphilis? (Yes/No)	Whether Serum quantitative RPR/ VDRL titer of an infant is fourfold (or greater) higher than the mother's titer at delivery? (Yes/No)	Additional Evaluation/ Remarks	Recommended Treatment
Scenario 4	No	No	Adequate treatment before pregnancy AND Mother's RPR/VDRL titers remained low and stable before and during pregnancy and at delivery	Prophylactic Treatment**

* A serum quantitative non-treponemal (RPR/VDRL) serologic titres that is fourfold (or greater) higher than the mother's titres at delivery (e.g., maternal titres = 1:2, neonatal titer ≥1:8 or maternal titres = 1:8, neonatal titres ≥1:32).

**No treatment can be considered if infant follow-up at the 14th week and 6 months are certain with monitoring of RPR/VDRL titres.

The table 7.4.2 describes the curative and prophylactic treatment regimens for Congenital Syphilis (CS).

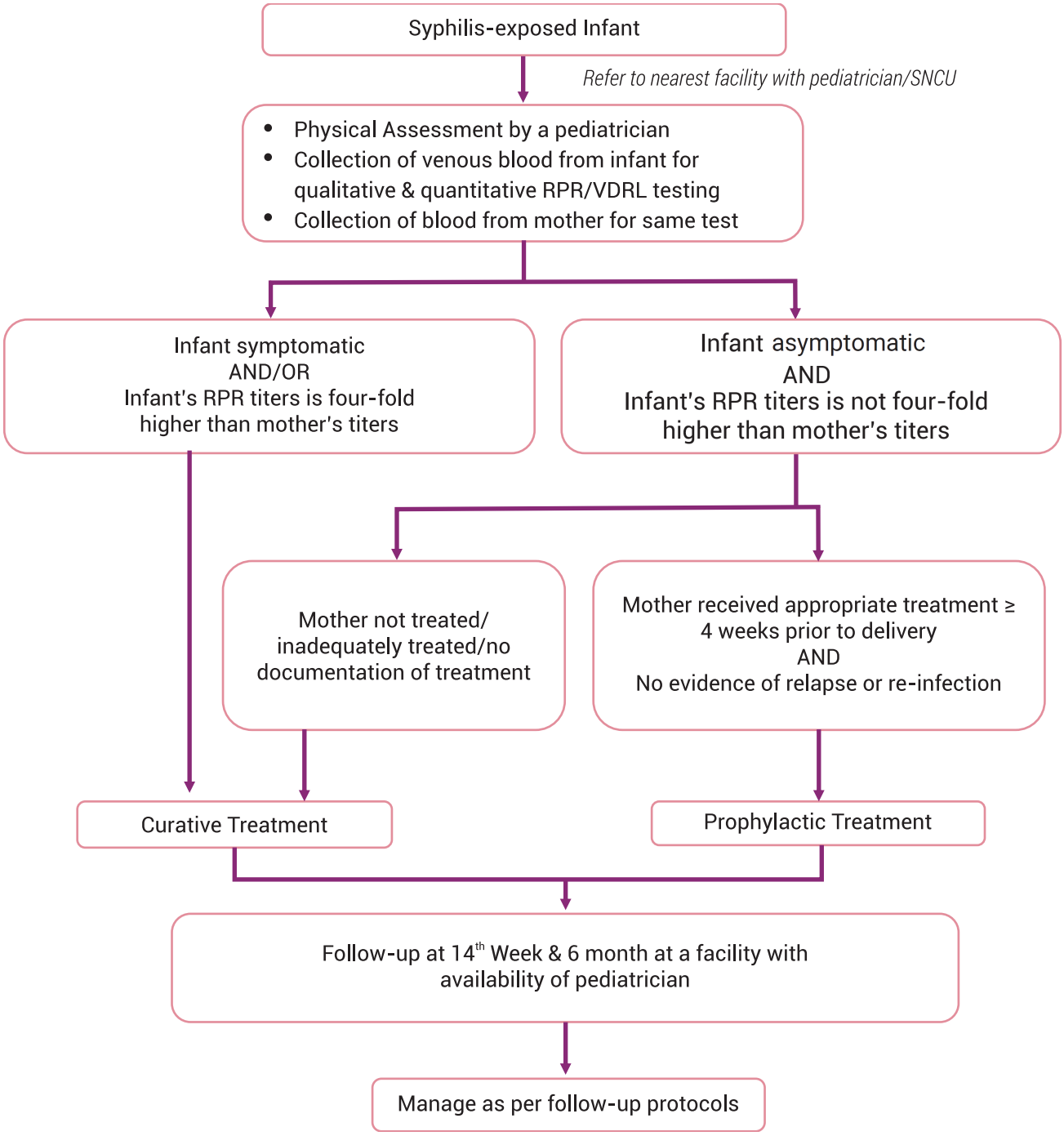
Table 7.4.2: Curative and Prophylactic treatment protocols for Congenital Syphilis

Treatment modality	Medication
Curative Treatment	Aqueous crystalline penicillin G 100,000–150,000 units/kg body weight/day, administered as 50,000 units/kg body weight/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days. Or Procaine penicillin G 50,000 units/kg body weight/dose IM in a single daily dose for 10 days
Prophylactic Treatment	Benzathine penicillin G 50,000 units/kg body weight/dose IM in a single dose

Source: Source: National Strategy and Operational guidelines towards Elimination of Congenital Syphilis, WHO &NACO, 2015; available at following link: http://www.naco.gov.in/sites/default/files/Elimination%20of%20Congenital%20Syphilis%20Book%20%282%29%20%281%29.pdf

The detailed care cascade for the management of syphilis-exposed babies at birth is presented in Figure 7.4.1. The care cascade outlines the various steps that need to be taken to ensure that syphilis-exposed babies receive appropriate care and treatment.

Figure 7.4.1: Care cascade for management of syphilis-exposed babies



Management Considerations for Improving Infant Care: -

- Infants are not allergic to penicillin.
- Hospitalization should be considered in order to provide full course of treatment
- If more than one day of therapy is missed, the entire course should be restarted.
- If intravenous access in the infant is available, aqueous benzyl penicillin may be preferred over intramuscular procaine penicillin.
- Curative treatment with intramuscular procaine penicillin is not preferred for premature or low-birthweight babies with inadequate muscle mass.

- With appropriate treatment of symptomatic syphilis-exposed infants, the clinical features of congenital syphilis (hepatomegaly, jaundice, bone changes, etc.) should subside by 3 months, and RPR/VDRL titres should decline by 3 months.

Follow Up

- Clinical Evaluation

  All infants exposed to syphilis should be evaluated by a paediatrician at the nearest FRU at the 14th week (in alignment with the immunization visit) and at the 6th month. The paediatrician should assess the following:

  - Resolution of clinical signs of congenital syphilis (if present at birth).
  - Comparison of current RPR/VDRL titers with those at birth.
  - Presence of symptoms and signs of congenital syphilis (in incubating cases).
  - Growth and development, which may provide additional evidence of syphilis in exposed infants.

  - The mother/caretaker should receive infant feeding and nutritional counselling.

Immunization and Vitamin A Supplementation for Syphilis-Exposed babies

The routine immunization and Vit A supplementation in Syphilis-exposed babies will be as per the Routine Immunization schedule, as depicted in table 7.4.3

Table 7.4.3: Immunization and Vit A Supplementation for Syphilis-Exposed babies

	Birth	6 Weeks	10 Weeks	14 Weeks	9 months	15 months	18 months
Routine Immunization & Vitamin A Supplements (As per UIP)	BCG OPV-0 Hep B Birth Dose	OPV-1 RVV-1 fIPV-1 Pentavalent-1 PCV-1	OPV-2 RVV-2 Pentavalent-2	OPV-3 RVV-3 fIPV/IPV-2 Pentavalent-3 PCV-2	fIPV-3 MR-1 Vit A JE-1** PCV Booster	MCV -2	 DPT-B1 OPV-B JE-2** Vit A

Note: *5-6 years – DPT-B2, 10 years – Td, 16 years -Td

** Only in JE endemic districts

➢ **Serological Evaluation:**

- All infants with reactive RPR/VDRL tests at birth should be serologically tested every 3 months until the test becomes non-reactive.
- In case scenarios 3 and 4 (refer table 7.4.1), where exposed infants received prophylactic treatment or no treatment, the RPR/VDRL titers should have decreased by the age of 3 months and be non-reactive by the age of 6 months. The following scenarios should be considered in such cases at the age of 6 months:

- If the RPR/VDRL test is non-reactive, no further evaluation or treatment is needed.
- If the RPR/VDRL test is still reactive after 6 months, the infant is likely to be infected and should receive curative treatment.

- Treated infants who exhibit persistent RPR/VDRL titers by age 6-12 months should be referred to experts/paediatric centres of excellence for further evaluation and management.
- The exposed infants should be followed by a paediatrician at the FRU at the 14th week and 6th month for RPR/VDRL screening. The screening test should be the same at every evaluation and preferably should be done by the same laboratory. The follow-ups beyond 6 months can be decided only for monitoring infants receiving re-treatment.

➢ **Radiological Evaluation:**

- Infants receiving re-treatment may undergo radiological evaluation of the long bones to rule out bone changes associated with CS (such as osteochondritis, diaphyseal osteomyelitis, and periostitis). The paediatrician may examine the infant's long bones using X-rays at follow-up visits.

Operational Considerations of Infants Born to Syphilis Sero-reactive Mothers.

Infants born to syphilis sero-reactive mothers should be referred to the nearest SNCU/NICU/other paediatric treatment facility for assessment and further management. The following considerations should be kept in mind for managing these infants:

- Infants falling under case scenarios 1 and 2 (refer table 7.4.1) should be provided with curative treatment and followed up at the 14th week and at the 6th month at the nearest facility with the availability of a paediatrician. The infant should be retreated in case of treatment failure or if there are manifestations of Congenital Syphilis. The infant should be followed up every three months until the titres become non-reactive.
- Infants falling under case scenarios 3 and 4 (refer table 7.4.1) should be provided with appropriate management and followed up at the 14th week and at the 6th month at the nearest facility with paediatrician. The infant should be provided with curative treatment in case of treatment failure or if there are manifestations of Congenital Syphilis. The infant should be followed up every three months until the titres become non-reactive.
- Infants can be anchored for complete follow-ups with DSRC. The counsellor at DSRC is responsible for ensuring appropriate follow-up of the exposed infant with a paediatrician till congenital syphilis is ruled out. This will ensure that the infant receives regular follow-ups and appropriate care.
- The details of management and follow-up of Syphilis-exposed infant will be entered in the EVTHS Syphilis card, on pages number 2, 3 and 4. The responsibility of maintaining the card lies with the DSRC Counsellor/ Paediatrician. Refer to Annexure- 10, for the EVTHS Syphilis Card.
- Suspected new-born/ infants should be given priority for treatment /diagnosis at health facility as per available government schemes.

The table 7.4.4 outlines the roles and responsibilities of healthcare workers (HCWs) in caring for syphilis-exposed babies.

Table 7.4.4: Roles and responsibilities of healthcare workers (HCWs) in caring for syphilis-exposed Babies.

Roles	Primary Provider	Alternative Provider
Management of Syphilis-exposed babies	Pediatrician at SNCU/NICU/ other pediatric treatment facilities	NICU/Pediatric treatment facility
• **Follow-up at 14 weeks, and 6 months** • **Clinical assessment, growth monitoring, developmental assessment** • **Prescriptions for testing and treatment**	FRU- Pediatric treatment facility	-
For follow up of syphilis-exposed babies	Counsellor at DSRC	Counsellor at ICTC

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18. National HIV Counselling and Testing Guidelines, 2024

SECTION III: COMPREHENSIVE AND INTEGRATED EVTHS SERVICE DELIVERY

CHAPTER-8

Hepatitis B infection in pregnant women

Hepatitis B infection in pregnant women

Context

The National Viral Hepatitis Control Program (NVHCP) was launched in 2018. It was proposed to integrate the program with other programs, including Reproductive, Maternal, Newborn, Child and Adolescent Health + Nutrition (RMNCAH+N) in order to leverage on the existing relevant components and move towards the attainment of the Sustainable Development Goal (SDG) 3.3; "it is essential to strengthen health systems, improve access to vaccination and antiviral therapies, enhance public health surveillance, and promote awareness and education regarding hepatitis prevention and treatment."

In India, the seroprevalence of Hepatitis B in pregnant women is 0.85% (95%CI 0.85-O.86) (1)

Need for prevention of mother-to-child transmission (PMTCT) of HBV

A major route of transmission of Hepatitis B Virus (HBV) is from mother to child. The risk of transmission from mother to child ranges from 10% to 90% depending upon the HBV viral load (2). The risk of developing chronic infection is 90% following perinatal infection (up to 6 months of age) and is 20–60% if infected between the ages of 6 months and 5 years (3).

8.1 Screening for Hepatitis B in pregnant women

Universal screening for Hepatitis B among pregnant women

- Screening for HbsAg in all pregnant women is the first step towards prevention of mother to child transmission.
- Screening to be done during first contact of pregnant woman with healthcare system, preferably during the first trimester.
- The screening test should be done at the earliest after informed consent & counselling up to the level of health and wellness centres along with routine blood tests by a trained Laboratory Technician (LT)/Multi-purpose Health Worker (MPHW) maintaining confidentiality.

- Additionally, it is prudent to highlight that as Hepatitis B is a blood borne infection, pregnant women presenting 'directly in labour' without ANC screening for Hepatitis B, should get screened to enable appropriate interventions for prevention of mother to child transmission of hepatitis B.

8.2 Management of Hepatitis B in infected pregnant women

- All HBsAg positive pregnant women must be categorised as 'High-Risk Pregnancy'.
- They must be counselled and referred for institutional delivery at designated Comprehensive Emergency Obstetrics & Newborn Care (CEmONC) centres where Hepatitis B vaccine and Hepatitis B Immunoglobulin (HBIG) is available.
- Hepatitis B in a pregnant woman is not a reason for considering termination of pregnancy. Similarly, the presence of HBV infection is not an indication for caesarean delivery, which should be based on obstetric indications only. Administration of hepatitis B vaccine to pregnant women with HBV provides no benefit either to the mother or the baby.
- Ensure counselling and referral of the mothers to the nearest designated Treatment site under NVHCP for further management.
- All staff engaged in delivery must be vaccinated for Hepatitis B and use personal protective equipment.
- The pregnant women will be counselled to get all her first-degree relatives screened for HBV infection.

The key messages for counselling pregnant women with Hepatitis B infection, are summarized in table 8.2.1.

Table 8.2.1: Key Messages for Counselling for Pregnant women with Hepatitis B infection

Key messages for counselling
• Hepatitis B infection mostly remains without symptoms for years, and if not treated, can lead to chronic conditions like liver cirrhosis and liver cancer. • Hepatitis B most commonly spreads from HBsAg positive mothers to newborn. • Hepatitis B is a vaccine preventable disease • The disease may progress to liver cirrhosis and liver cancer faster, if acquired at an early age. • It should be ensured that newborns of Hepatitis B positive mothers are administration of Hepatitis B Immunoglobulin (HBIG) along with birth dose of Hepatitis B vaccine to the newborn immediately after delivery. • Testing and treatment facilities for management of Hepatitis B are available free of cost in designated government healthcare facilities under NVHCP.

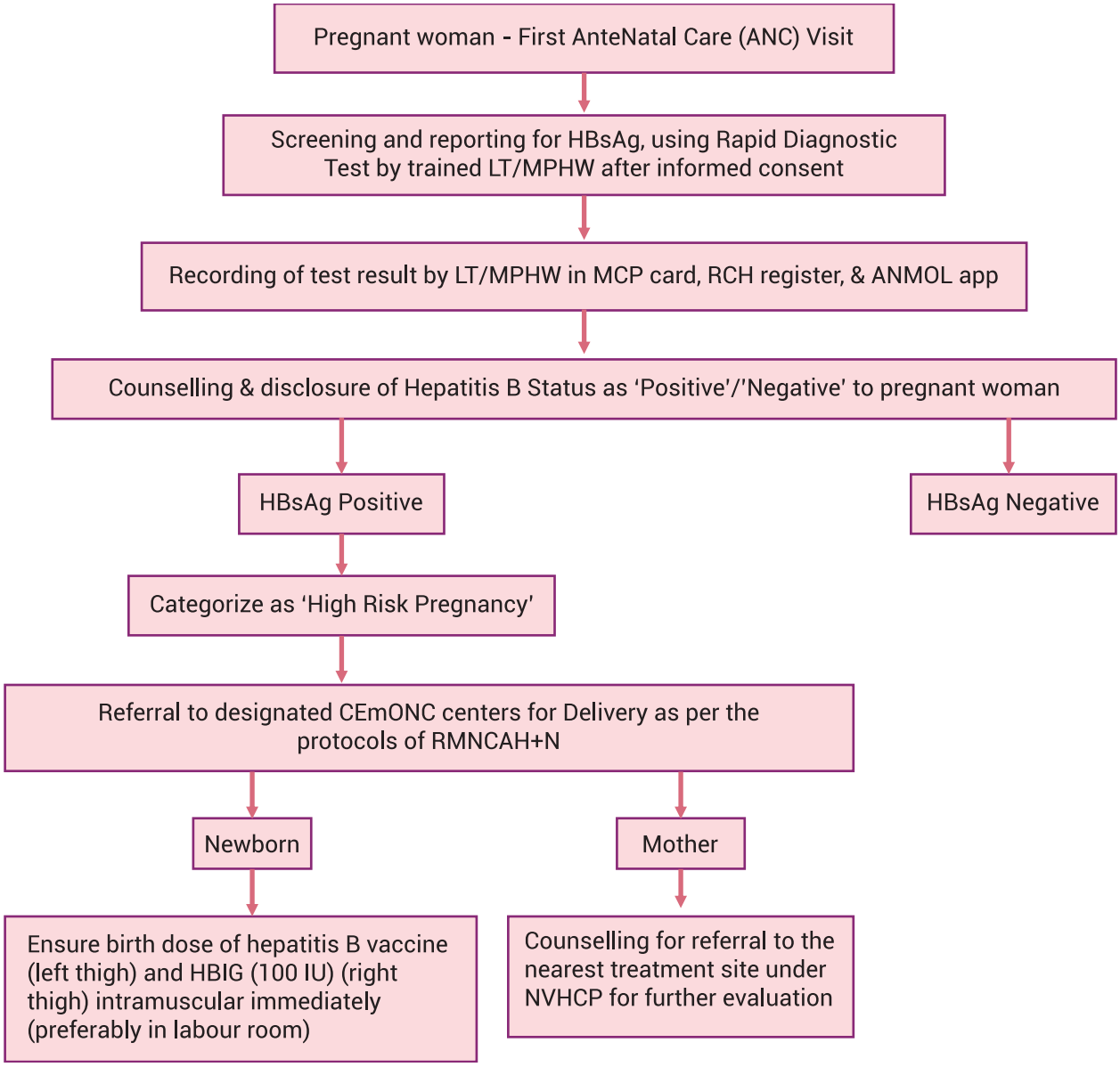
8.3 Management of Hepatitis B in newborn

Irrespective of exposure to HBV, new born should be administered a timely first dose (the 'birth dose') of hepatitis B vaccine immediately after birth, (preferably within 24 hours). Hepatitis B vaccine dose should be administered intramuscularly in the left anterolateral aspect of mid-thigh.

HBIG provides additional protection in situations where there is risk of transmission i.e., babies born to infected HBV mothers.

The newborn of the HBsAg positive woman must be administered HBIG (100 IU) along with birth dose of hepatitis B vaccine, immediately after birth (within 24 hours), in the anterolateral aspect of right and left thigh respectively. The operational flow of services for Prevention of mother to child transmission of Hepatitis B infection is described in figure 8.3.1.

Figure 8.3.1: Operational Flow of Prevention of Mother to Child Transmission of Hepatitis B Infection



8.4 Storage and Transportation of HBsAg Rapid Diagnostic Test & HBIG

- Ensure storage at 2-8°C in domestic refrigerators, ice lined refrigerators or walk-in-coolers, depending upon availability.

- Ensure maintenance of cold chain (2-8 C temperature) using cold boxes/vaccine carriers with ice packs during transport.
- The HBIG will be made available at district level based on assumption of positive deliveries likely, by the district nodal officer through NVHCP.

The activities and persons responsible for care of pregnant women with Hepatitis B, have been summarized in table 8.4.1, as per the level of health facility.

Table 8.4.1: Activities and Person Responsible as per the level of Health Facility

Activity	Person Responsible	Flow of Events
Annual estimation of number of pregnant women	District Reproductive & Child Health (RCH) Officer	In coordination with the health care facilities, the district RCHO will provide the district estimates of number of pregnant women.
Forecasting the quantity of HBsAg kits	District NVHCP Officer	Forecast number of kits required as per available estimates and place an indent for demand for HBsAg kits to the State NVHCP Officer
Procurement of HBsAg kits	State NVHCP Officer	After receiving the forecast from various District NVHCP officers, the State NVHCP Officer will compile the same and procure HBsAg kits as per the technical specifications under NVHCP.
Placement of demand for HBsAg Kits to the State NVHCP Officer as per the forecast	District NVHCP Officer	Place a demand for HBsAg kits to the State NVHCP Officer for quarterly supply.
Receipt of HBsAg kits from State NVHCP officer	District NVHCP Officer	District NVHCP Officer will receive the HBsAg kits from the State NVHCP Officer as per demand and hand over the kits to District RCH Officer
Supply of the HBsAg kits to the health care facilities	District RCH Officer	Ensure supply of the testing kits to all the healthcare facilities as per estimates.

8.5 Data Recording

- The staff performing the HBsAg test for pregnant women must enter the data in Mother-Child Protection (MCP) card, RCH register, and ANMOL app., for better follow up and tracking.
- The staff administering birth dose Hepatitis B vaccination and HBIG to the newborn of HBsAg positive pregnant women should enter the details in the MCP card, RCH portal and RCH Register.
- NVHCP will capture the following indicators of the HBsAg positive pregnant women through the RCH portal and NVHCP- MIS interface.

The reporting format for screening and management of Hepatitis B in pregnant women is summarized in table 8.5.1.

Table 8.5.1: Reporting format for Pregnant Women at the Health Facilities

Monthly reporting Format – Testing of pregnant women for HBsAg	HWC	PWC	CHC	District Hospital
Number of Pregnant women tested for HBsAg	√	√	√	√
Number of pregnant women who are HBsAg positive	√	√	√	√
Number of pregnant women found positive for HBsAg referred to higher centre for institutional delivery	√	√	√	√
Number of pregnant women found positive for HBsAg delivered in institution	√	√	√	√
Number of newborns to pregnant women (found positive for HBsAg) received hepatitis B birth dose	√	√	√	√
Number of newborns to pregnant women (found positive for HBsAg) received HBIG	√	√	√	√

Monitoring & Supervision

- Ensure formation of State Steering Committee under the chairpersonship of Principal Secretary with members as State RCH Officer, State AIDS Control Officer, Representative from the Community, State NVHCP Officer, Assistant Commissioner of Police, State Immunization Officer, etc., for coordination of state level activities under NVHCP.
- Ensure joint State reviews and District level reviews of RCH and NVHCP are conducted under the chairmanship of Mission Director, NHM and District Magistrate/Collector, respectively with focus on physical and financial progress related to testing and intervention for PMTCT of Hepatitis B.

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CHAPTER-9
Coinfections and Comorbidities

Coinfections and Comorbidities

9.1 Tuberculosis in Pregnancy

Introduction

Tuberculosis (TB) remains a major public health challenge worldwide. Tuberculosis is an infectious disease caused by the bacterium Mycobacterium Tuberculosis. It primarily affects the lungs but can also impact other parts of the body.

Women of the reproductive age group (15-49 years) bear a significant burden of TB, both globally and in India. TB among pregnant women can adversely affect the health of the mother, foetus, neonate and child with a wide spectrum of short and long-term implications. TB in pregnancy can have serious and sequential effects, including repeated reproductive failures, foetal ill-health, preterm delivery, and vertical transmission of TB in the newborns and infants, leading to high maternal and perinatal morbidity and mortality.

In the interest of public health, the Government of India, through the TB Gazette Notification, made TB a notifiable disease, making notification of each TB case mandatory.

Prevalence of TB in pregnancy

The prevalence of TB among pregnant women is largely unknown. The incidence of tuberculosis in pregnancy is not readily available in many countries due to a lot of confounding factors. However, it is expected that the incidence of tuberculosis among pregnant women would be as high as in the general population, with possibly higher incidence in the developing countries.

Considering the incidence of tuberculosis among women of reproductive age (around 100 cases per 100,000 populations) and a total of 26 million births annually, Jana et al. estimated that approximately 20,000 to 40,000 pregnant women are likely to suffer from active TB in India annually.

Although congenital TB occurs rarely, there is a significant risk of vertical transmission of TB to infants

in the postpartum period as a result of inhalation of droplets coughed out by the mother.

Impact of Pregnancy on TB

Pregnancy masks the effects and symptoms of tuberculosis, while these effects are exacerbated in the immediate postpartum period. Early postpartum women are twice as likely to develop tuberculosis as non-pregnant women.

Impact of TB on Pregnancy

The presence of tuberculosis disease during pregnancy, delivery and postpartum is known to result in unfavourable outcomes for both pregnant women and their infants, which is compounded by the late presentation, non-specific symptomatology delaying diagnosis and need for prolonged medication. These outcomes include a roughly two-fold increased risk of preterm birth, low birthweight, intrauterine growth restriction and a six-fold increase in perinatal death.

The perinatal outcomes in pregnancies complicated by Pulmonary TB, has been depicted in figure 9.1.1.

Figure 9.1.1: Perinatal Outcomes in Pregnancies complicated by Pulmonary TB

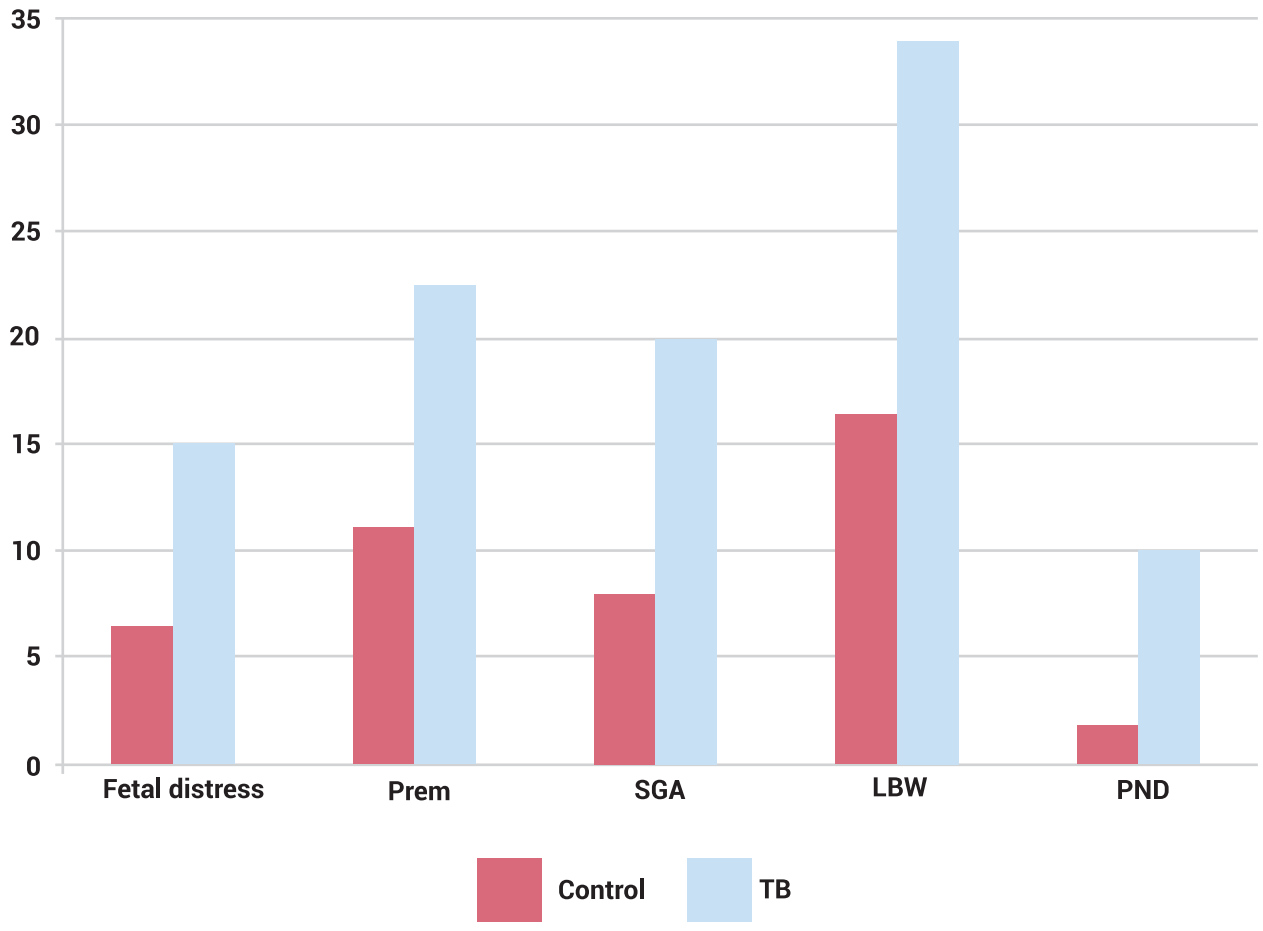

Figure1 : Perinatal outcome in pregnancies complicated by pulmonary tuberculosis (Data from Jana et al. 1994; reference 7 Prem. - prematurity; SGA-Small for gestational age; LBW - Low birthweight; PND - Perinatal death. Data in Y-axis is expressed in percentage)

With the exception of tuberculous lymphadenitis; extrapulmonary tuberculosis – abdominal, vertebral, renal, and meningeal involvement, has adverse outcomes for pregnancy including increased antenatal hospitalization and perinatal complications.

Recent systematic analysis which included studies from India and other countries clearly showed that "active TB in pregnancy is associated with adverse maternal and foetal outcomes." (3). Compared with pregnant women without TB, pregnant women with active TB were associated with significantly increased risks of overall maternal morbidity [odds ratio (OR) 2.8], maternal anaemia (OR 3.9), caesarean section (OR 2.1), preterm birth (OR 1.7), low birth weight neonates (OR 1.7), birth asphyxia (OR 4.6), and perinatal death (OR 4.2). Recent Indian studies also re-affirmed these adverse effects of TB involving pulmonary and extrapulmonary sites on maternal and perinatal morbidity and mortality.

A recent post-mortem analysis of maternal deaths highlights that infection, including TB, is an important contributor to maternal death in India (14). Furthermore, it has been emphasized that TB results in nearly 10 million cumulative orphans because of parental deaths, which include maternal mortality due to TB.

To summarize, active tuberculosis poses grave maternal and perinatal risks, for which early diagnosis, and appropriate and adequate anti-tuberculosis treatment of the mothers are mainstay for successful pregnancy outcomes. Maternal care services could be used as a platform to improve case detection.

For further reading refer to following link: https://tbcindia.gov.in/WriteReadData/l892s/5156619257Print%20ready%20version%20MH-TB%20Framework_Final_Feb%2018.pdf

Screening, Diagnosis and Treatment of Tuberculosis (TB)

All pregnant women should be screened for TB at every ANC visit. Screening is expected to be carried out during every visit to the ANC clinic, throughout the pregnancy and postpartum period. Following questions are to be asked after confirming that the patient is not on active TB treatment.

Four-symptom complex screening for pregnant women includes following symptoms:

- Cough of duration more than 2 weeks
- Fever of duration more than 2 weeks,
- Inadequate weight gain or Weight loss in last 3 months
- Night Sweats
- Extra-pulmonary symptoms - localized swellings/lumps in the body (lymph node)

(Source: "WHO recommendations on antenatal care for a positive pregnancy experience: screening, diagnosis and treatment of tuberculosis disease in pregnant women" - https://iris.who.int/bitstream/handle/10665/365953/9789240057562-eng.pdf)

If any of above symptoms are positive, then arrangements should be made for sputum collection /FNAC in case of localized enlarged lymph node and sample transportation from ANC clinic at all levels, preferably by sending to nearest TB molecular diagnostic centre in coordination with DTO. All TB patients of reproductive age group should also be screened for pregnancy.

Screening for TB will be made an essential component of ANC services wherein service providers will actively screen all pregnant women for TB during each ANC visit. This will be applied to community outreach activities like VHSND and fixed-day ANC service provision platforms like HWCs/PHCs and PMSMA. Both the programmes will also work together in undertaking intensified active case finding activities in this high priority population.

The ANC provider (ANM/Community Health Officer (CHO)/Staff Nurse/MO/OBGY specialist) will do the screening using a four-symptom complex for pulmonary TB and localized enlarged lymph node for extrapulmonary TB. The presumptive TB cases will be referred to the nearest DMC/PHI with a referral slip if found positive on screening for any one or more of the symptoms or for symptoms of extrapulmonary TB. Staff Nurses, CHO/Counsellor and ANMs attending the pregnant women during ANC visits and community outreach activities will enquire about the TB symptom complex and refer the patient. The staff nurse and counselor would be trained by the Medical Officer In-charge to screen the TB symptom complex at PHC.

After screening patients with symptom(s) of TB symptom complex, will be referred to the nearest TB Facility i.e., Direct Microscopy Centre (DMC) or PHI for diagnosis of TB. A referral and feedback mechanism will be developed to enable timely exchange of information. The MO/staff nurse/CHO/ANM will refer the patient with a NTEP Laboratory Request Form to the nearest TB molecular diagnostic centre (sputum samples to be collected and transported preferably) for confirmation of TB disease. The TB clinic staff as guidelines stipulated in NTEP would manage the patients diagnosed with TB appropriately. The DMC will update/return the results of the TB test to the referring facility/service provider through the counterfoil of the Laboratory Request Form with the patient for completing the TB test record in the ANC department and other activities related to TB services will be provided by the NTEP staff.

Pregnant women will be followed for the TB Care cascade from the screening for TB symptoms (Presumptive TB) to testing for TB to being diagnosed with TB and being put on treatment within the routine screening during ANC.

TB Preventive Treatment

Pregnancy should not disqualify women living with or without HIV who are eligible for receiving TPT. TPT can be started during antenatal and postnatal periods taking due care. Pregnant women living with HIV are at higher risk for TB during pregnancy and postpartum period and can have worse prognosis for both mother and child. Isoniazid and Rifampicin are considered safe for use in pregnancy.

There is no evidence to show an association of TPT (6H) with adverse pregnancy outcomes like foetal/neonatal death, prematurity, low birth weight or any congenital anomaly. Statistically, no significant risks for maternal hepatotoxicity, grade 3 or 4 events or deaths were reported. Therefore, routine LFT can be done as per advice of the treating physician. Pyridoxine (Vitamin B6) supplementation should be given routinely to all pregnant and breastfeeding women on TPT.

There is limited data on the efficacy and safety of rifapentine in pregnancy and therefore, 1HP and 3HP should not be used in pregnancy until more safety data is available.

Rifampicin and rifapentine interact with oral and hormonal contraceptive medications with a potential risk of decreased contraceptive efficacy. Women receiving oral contraceptives while on rifampicin or rifapentine should use an alternative (such as depot medroxyprogesterone acetate - DMPA) every eighth week or higher dose of oestrogen (50μ)) in consultation with a clinician; or use another form of contraception, a barrier contraceptive or intrauterine device. In women with hormonal contraceptive implants, the interval for replacing the implants may need to be shortened from 12 weeks to eight weeks. *(Source: Section-7.1, page-33 of National Guidelines for the Programmatic Management of TB Preventive Treatment in India 2021)*

For further reading on this topic refer to page-77 of National Guidelines for the Programmatic Management of TB Preventive Treatment in India 2021; available at: https://tbcindia.mohfw.gov.in/wp-content/uploads/2023/05/Guidelines-for-Programmatic-Management-of-Tuberculosis-Preventive-Treatment-in-India.pdf

Babies born to mothers with TB disease

If the newborn baby born to mother with TB is not well, it is important to refer baby to a specialist/ paediatrician. It is critical that the mother receives effective TB treatment so that she is no longer infectious. Also, ensure that infection control measures are in place in the facility, especially if the baby is in an inpatient facility for care when preterm or small at birth.

If the newborn is well (absence of any signs or symptoms presumptive of TB) TPT must be provided. Experts in India recommend that the Bacille Calmette-Guerin (BCG) vaccination should not be delayed even if TPT is administered. Further, it is advised to administer pyridoxine at 5-10 mg/day.

If the infant is HIV-exposed (mother is a WLHIV and diagnosed with TB) and on nevirapine prophylaxis, then 6H should be started. TPT with 4R and 3HP cannot be given along with nevirapine prophylaxis since rifamycin decreases nevirapine levels and may result in increased risk of vertical transmission of HIV.

If the mother is taking anti-TB drugs, she can safely continue to breastfeed with appropriate practice like using a mask and cough etiquette. Mother and baby should stay together and the baby may be breastfed while on TPT. Infant breastfeeding from a mother on either TB treatment or TPT should receive pyridoxine for the duration of the mother's treatment.

For further reading on TB Preventive Treatment, refer to the National Guidelines for the Programmatic Management of TB Preventive Treatment in India 2021, available at https://tbcindia.gov.in/showfile.php?lid=3625.

Monitoring Indicators for TB Services in Pregnant Women Living with HIV (source: IIMS/ SOCH case-based system)

TB Treatment services

1. Proportion of Pregnant women Living with HIV (PWLHIV) screened for TB
2. Proportion of PWLHIV identified as Presumptive TB case among those screened for TB
3. Proportion of PWLHIV identified as Presumptive TB case, referred for TB testing
4. Proportion of PWLHIV diagnosed as TB among tested for TB
5. Proportion of PWLHIV diagnosed as TB, put on TB treatment

National Framework for Joint TB and Maternal Health Collaborative Activities

The National framework for TB Maternal Health articulates the collaborative activities between the National TB Elimination Programme (NTEP) and Maternal Health (MH) Program to ensure early detection and timely management of TB cases in pregnant women in India.

The goal is to reduce morbidity and mortality due to TB in pregnant women and newborns through prevention, screening for early detection and prompt management of TB in pregnant women and achieve optimum maternal and perinatal outcomes.

The framework is available from - https://tbcindia.gov.in/WriteReadData/l892s/5156619257Print%20ready%20version%20MH-TB%20Framework_Final_Feb%2018.pdf

Early diagnosis, proper management, and adherence to treatment are essential in preventing the transmission of TB from mother to child

9.2 Screening for Non-communicable Diseases in Women Living with HIV

Widespread access to antiretroviral therapy (ART) has transformed HIV disease from a life-threatening condition to a manageable chronic condition by increasing longevity and favourable treatment outcomes in People living with HIV (PLHIV). PLHIV who are on treatment, live near normal life spans and are facing different health challenges due to ageing. They are more likely to develop non-communicable diseases (NCD).

Non-communicable diseases are now becoming one of the leading causes of non-AIDS related morbidity and mortality in HIV infected persons. Screening and early detection of non-communicable diseases especially diabetes, high blood pressure and common cancers is an important component of HIV care.

Common NCD seen in WLHIV are as follows:

- Cardiovascular disease
- Type 2 diabetes
- Cancer
- Mental health issues, including depression

Strategies for prevention and management of NCD in WLHIV include:

1. Health promotion
2. Screening for early detection
3. Referral to diagnosis and management

ART centre shall screen all WLHIV for diabetes, hypertension, cardiovascular diseases and common cancers and identify women who are at a high-risk of developing NCD warranting further investigation/ action. Such screening shall involve simple history (such as family history of diabetes, history of alcohol, tobacco consumption, dietary habits etc.), general physical examination, calculation of BMI, blood pressure monitoring, blood sugar estimation etc.

Routine screening and management of mental health disorders (depression and psychosocial stress) should be provided for women living with HIV in order to optimize health outcomes and improve their adherence to ART. WLHIV screened positive for NCD shall be referred to NCD clinics/higher health facilities for further diagnosis and treatment.

Strategy for screening of PLHIV for hypertension, diabetes, mental illness and cervical cancer is depicted in table 9.2.1.

Table 9.2.1: Strategy for screening of PLHIV for hypertension, diabetes, mental illness and cervical cancer

Screening for	How	For whom	When	Action
Hypertension	Blood pressure measurement	All PLHIV	• At ART initiation • Every six months • At every visit, if hypertension diagnosed	• BP>140/90mmHg+ in PLHIV aged >18 years, or • BP>15/90 mmHg in PLHIV >60 years: - Refer for further work and management - Counselling for lifestyle modification (avoid alcohol/ tobacco use and high salt, increase in fruits and vegetables intake, physical activity and stress management)
Diabetes	Random blood glucose	All PLHIV	• At ART initiation • Every six months • At every visit, if diabetes diagnosed	If Sugar Random >120mg/dl): - Refer for further workup and management - Counselling for lifestyle modification (avoid alcohol / tobacco use and high sugar intake, increase physical activity and stress management)
Screening for cervical cancer	Visual inspection with Acetic Acid (VIA)/ cervical PAP smear (at the concerned department)	All women and girls who have initiated sexual activity	• At ART initiation • Every 3 years • Women who have been treated should receive follow-up screening at 1 year	- If screened positive, refer to gynaecologist/ lady medical officer wherever available, or NCD clinic at CHC/DH, for confirmation

Screening for	How	For whom	When	Action
Screening for and management of mental health issues	PLHIV has at least one of the core symptoms of mental health illness (depression) for at least 2 weeks: 1. Persistent depressed mood or sadness 2. Markedly reduced interest or pleasure doing things	All PLHIV**	• At ART initation • At each visit	PLHIV who have either of the core symptoms, should be referred to undergo thorough screening for depression

Source: Chapter- 9.3: Non-Communicable Diseases and Mental Health among PLHIV, in the National Operational Guidelines for ART services 2021.

Early detection of cancers in WLHIV

- Create awareness about the early warning signs of cancer like the following:
  - Change in bowel or bladder habits
  - Wound that does not heal
  - Unusual bleeding or discharge
  - Thickening or lump in the breast or elsewhere
  - Indigestion or difficulty swallowing
  - Obvious change in a wart or mole
  - Nagging cough or hoarseness of voice
- Educate patients on self-examination and reporting for unusual signs/symptoms.
- Examine patients for warning signs and routine examination of oral cavity, breasts and cervix. Prompt referral of WLHIV with a suspicious lesion for accurate diagnosis and appropriate treatment, is of utmost importance.

Screening for Cervical Cancer in WLHIV

Women living with HIV are at 4–5 times greater risk of developing cervical cancer, have more rapid progression to pre-cancer and cancer than women not infected with HIV. Hence, regular screening for Cervical cancer in WLHIV becomes essential. Modalities of Cervical cancer Screening in WLHIV is depicted in the table 9.2.2.

Table 9.2.2: Modalities of Cervical cancer Screening in WLHIV

PLHIV Group	All women and girls living with HIV who have initiated sexual activity
Screening frequency	• At ART initiation • Repeat screening within 3 years if the initial test is negative. • Women who have been treated should receive follow-up screening at 1 year. • Any other time if related signs/symptoms are reported
Method of screening	Visual inspection with Acetic Acid (VIA): 3%-5% acetic acid is generously applied to the mouth of the cervix (ectocervix) area and presence of any aceto- white lesion is noted.
Observations	• Normal squamous epithelium (of vagina) appears pink. • Columnar epithelium of uterus appears red. • In conditions like inflammation, benign and malignant growth, the epithelium contains a lot of cellular proteins because of increased nuclear activity, thereby giving a dramatic dense white patch (VIA positive).
Referrals	If screened positive, refer to a gynaecologist/lady medical officer wherever available or NCD Clinic at CHC/DH for confirmation and further management.

Source: Chapter-5.1: Non-Communicable Diseases and Mental Health, Prevention, Screening and Management among PLHIV, in the National Guidelines on HIV Care and Treatment, 2021

For further details on Screening and management of NCDs in WLHIV, refer to following guidelines:

- Chapter-9.3: Non-Communicable Diseases and Mental Health among PLHIV, in the National Operational Guidelines for ART services 2021.
- Chapter-5.1:Non-Communicable Diseases and Mental Health, Prevention, Screening and Management among PLHIV, in the National Guidelines on HIV Care and Treatment, 2021; available at https://www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment%202021.pdf

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CHAPTER-10

Optimizing delivery of EVTHS services

Optimizing delivery of EVTHS services

10.1 Referrals and Linkages

The referral and linkages of pregnant women/ lactating mother, exposed babies, and WLHIV in reproductive age-group to appropriate facilities is essential to ensure delivery of adequate and effective services to achieve EVTHS.

According to WHO, 'Referral' can be defined as "a dynamic process in which a health professional at one level of the health system –having insufficient resources (equipment, skills, knowledge, drugs) or power to decide to manage a clinical condition – seeks the help of another facility (often better or differently resourced) at the same or higher level to assist in the care of a given patient".

The cross-cutting nature of EVTHS services across health systems mandates the strengthening of referral and linkages of pregnant women/lactating mother, their babies, and women in reproductive age-group. The following services (not an exhaustive list) could be requiring cross-cutting referral and linkages in context of EVTHS in India:

1. Screening and diagnostic services for HIV and STIs (including syphilis) to pregnant women/ Direct in labour cases
2. Routine antenatal/intrapartum and postpartum care to pregnant women/ mothers infected with HIV and/or Syphilis
3. Routine child health services to exposed babies
4. Care, support, and treatment services to infected women
5. Screening, diagnostic and treatment services for HIV/ Syphilis-exposed babies
6. Healthy Timing and Spacing of Pregnancy (HTSP) Services
7. Prevention services for high-risk/ at-risk women

The responsibility to provide services under the umbrella of EVTHS lies jointly with NHM and NACP

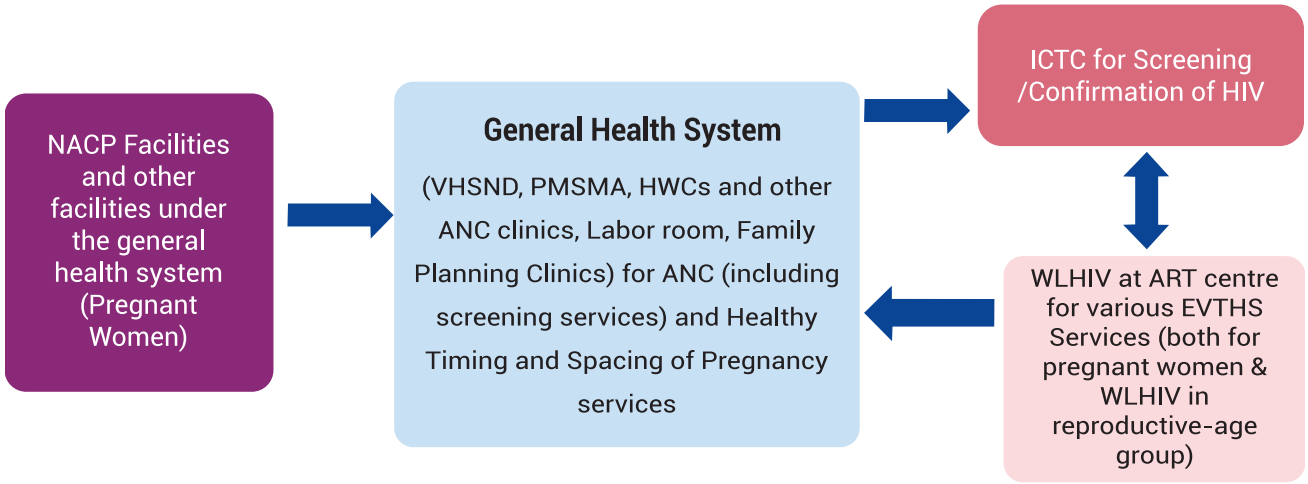
facilities in close co-ordination with all relevant stakeholders.

Referral and Linkages in context of HIV

- The screening services for pregnant women/ DIL cases for HIV is provisioned at VHSND/ PMSMA/HWCs, other ANC sites, Labour Room and ICTC. The screened reactive cases should be linked to ICTC for confirmation and further follow-up.
- All the HIV confirmed pregnant women/ DIL cases should be linked to ART centres for care, support, and treatment services.
- WLHIV in reproductive-age group should be referred and linked to Family Planning services under the health systems for Healthy Timing and Spacing of Pregnancy (HTSP), to prevent unintended pregnancies and ensure healthy pregnancy planning.
- All the WLHIV (including newly diagnosed) should receive routine ante-natal/intrapartum and post-partum services in the general health system.
- The high-risk/at-risk pregnant women under NACP should receive all routine RMNCAH+N services under general health system.
- HIV-exposed babies should be linked to NACP facilities (ART centre and ICTC as mother-baby pair) for various HIV follow-up and EID services.
- These babies will be under regular follow-up as high-risk babies. These visits should coincide with the routine visits to health system for immunization/ health issues/growth monitoring, etc. These visits require close coordination between NACP team, immunization and MO/ Paediatrician of the health facility.
- All the sick babies should be linked with pediatric facilities for specialized care and follow-up services.
- The referral from private sector to NHM/NHM systems can happen at any level for range of services under EVTHS.

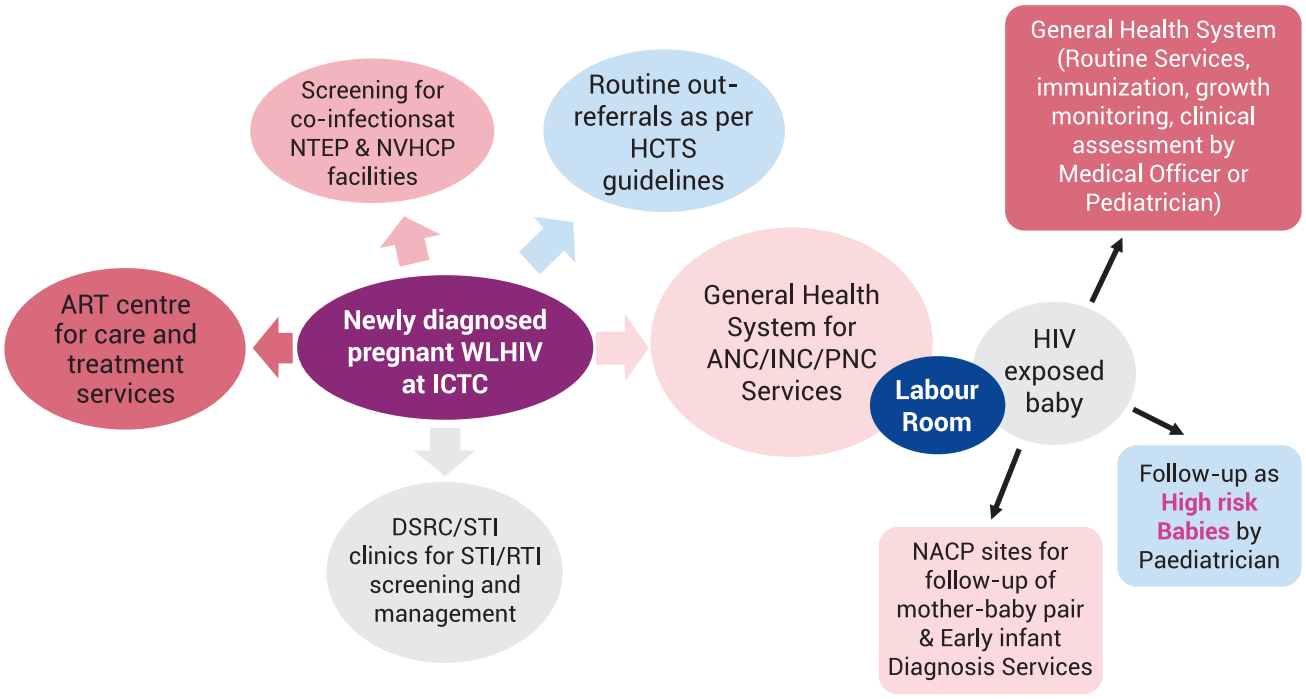
The referral and linkages in context of HIV under EVTHS, are depicted in figure 10.1.1 and 10.1.2.

Figure 10.1.1: Referral and Linkages in context of HIV under EVTHS



Note : The referral from private sector to NHM/NHM systems can happen at any level for range of service under EVTHS

Figure 10.1.2: Out-referrals from ICTC under EVTHS



Note: The referral from private sector can happen to NACP/NHM systems for range of services for HIV-exposed babies under EVTHS

Referral and Linkages in context of Syphilis

- The screening services for pregnant women/ DIL cases for Syphilis is provisioned at VHSND/ PMSMA/HWCs, other ANC sites, Labour Room and ICTC/DSRC. The screened reactive cases should be linked to DSRC for assessment, management, and further follow-up.
- All pregnant WLHIV should be linked from ARTC to ICTC/DSRC for syphilis/STI/RTI screening and management.
- All the pregnant women infected with syphilis should receive routine ante-natal/intrapartum and post-partum services in the general health system.
- The Syphilis-exposed baby should be linked to nearest SNCU/NICU/pediatric treatment facility for assessment, appropriate management, and routine follow-ups. These babies should be linked with DSRC for ensuring adequate follow-up.
- The Syphilis-exposed baby should receive all routine healthcare services (including immunization) in the general health system.
- The referral from private sector to NHM/NHM systems can happen at any level for range of services under EVTHS.

The in and out-referrals from DSRCs under EVTHS, are depicted in figure 10.1.3 and figure 10.1.4, respectively.

Figure 10.1.3: In-referrals to DSRCs under EVTHS

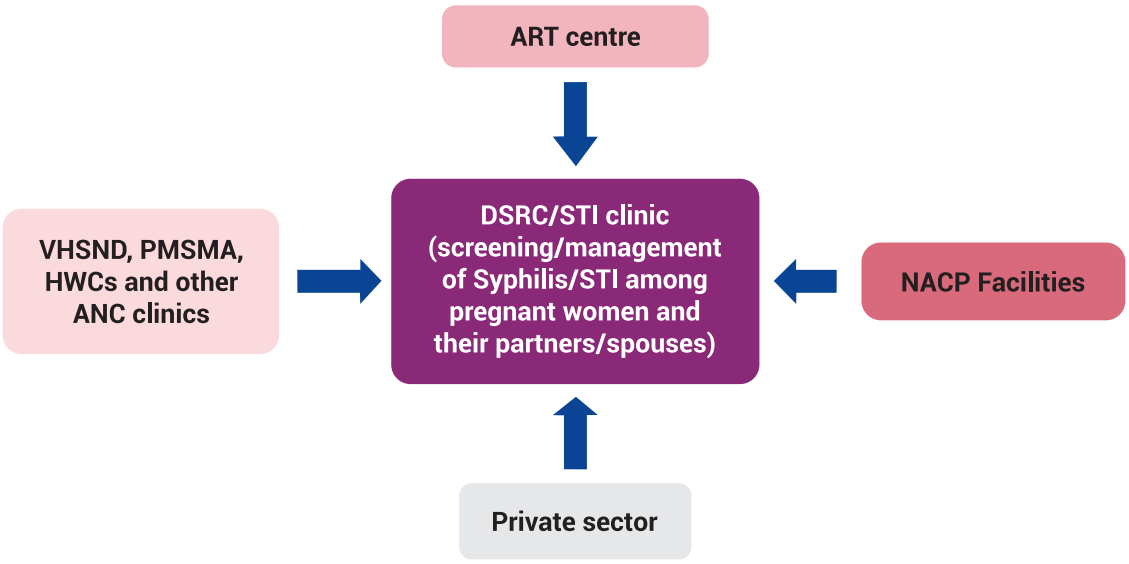
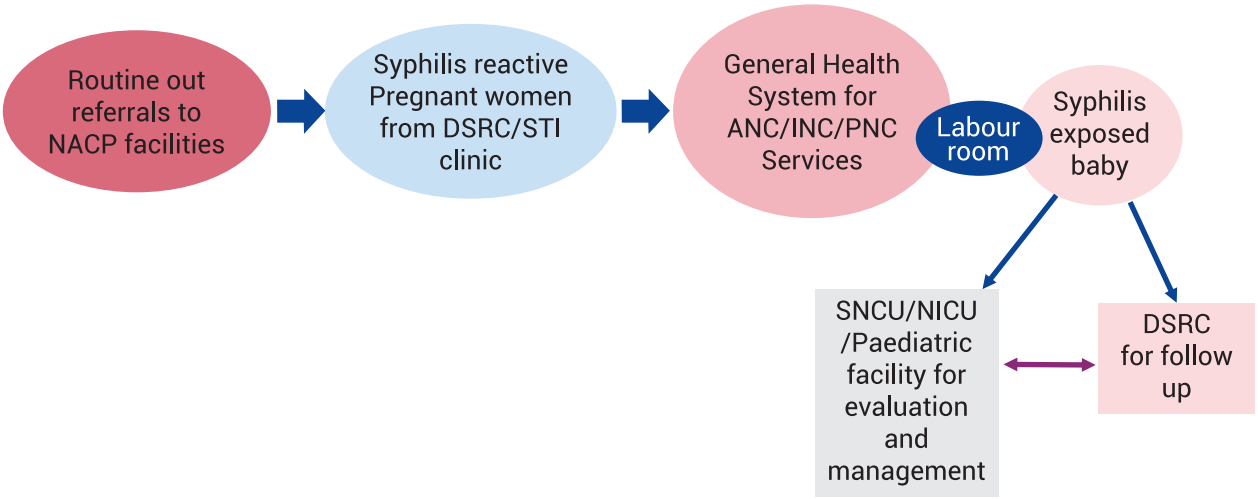


Figure 10.1.4: Out-referrals from DSRCs under EVTHS



Note : The referral from private sector can happen to NACP/NHM systems for range of services for Syphilis - exposed babies under EVTHS

Effective Referral management:

1. **Mapping of facilities**: The relevant service providers within the geographic area should be identified so that referral can be made as per the convenience of the pregnant women. The counsellor/health care worker should provide details such as address, contact details, focal person, timings, etc, of referred service to the pregnant woman.
2. **Assess and prioritizing need**: Identifying the need is the first step and should start immediately during the first contact with the pregnant woman. One of the important referrals is for childbirth. The counsellor/health care worker with support from medical officer should prepare a birth plan in discussion with the pregnant women and her family.
3. **Facilitate**: Counsellor should identify the barrier to linkage and explore the solutions on a case-to-case basis. To ensure pediatric follow up services, counsellor should provide the referral slip (Annexure-13) which can be used by the mother of exposed baby. Wherever possible,

accompanied referral may be offered with help of peers, outreach workers, counsellors, or any other health care providers.

4. **Follow Up**: Medical officer at the ART centre and DSRC should ensure that maternal and child health services are availed. The medical officer should ensure and monitor minimum visit prescribed under ANC and pediatric care.

10.2 Roles and Responsibilities of Personnel involved in EVTHS service delivery

The smooth functioning of EVTHS services depends on the active participation and coordination of different stakeholders at multiple levels. This section outlines the roles and responsibilities of these stakeholders, noting that their responsibilities are not limited to these descriptions. Their roles will adapt to meet the changing needs of the EVTHS services.

The responsibility for implementing these prevention measures lies with various functionaries at different levels:

At National Level: National Working Group on Elimination of Vertical Transmission of HIV and Syphilis

The National Working Group - EVTHS, chaired by the Chairperson TWG-EVTHS and co-chaired by Deputy Commissioner, RCH (MOHFW), will drive the national EVTHS agenda and provide stewardship to achieve Goal-3 of NACP-V.

Representation From:

- NHM
- NACP
- RMNCAH+N
- NTEP
- NVHCP
- Other Line Ministries (including Division of Pharmaceuticals)
- Developmental Organizations: WHO, UNICEF, UNAIDS, UNFPA, CDC, USAID, Global Fund Partners and other Development Partners.
- Professional Organizations: FOGSI, IMA, NNF, IAP
- Private health care providers
- Civil society organizations and community-based organizations
- Community Representatives

The NWG will work under joint chairpersonship of NHM and NACP. The National Working Group on EVTHS will convene at least bi-annual meetings to review progress, discuss challenges and plan future actions for successful implementation of EVTHS services.

The National Working Group have the following responsibilities:

- Provide guidance for overall policy planning, implementation, strengthening, scale-up, institutionalization, and sustainability of EVTHS interventions across the country

- Ensuring integration of EVTHS services in cross-cutting programs under the health system.
- Provide technical support for development/revision of technical and operational guidelines, IEC, SOPs, training modules, recording and reporting mechanism, etc.
- Periodic review, monitoring, and evaluation of the program.
- Act as the National Validation Committee (NVC) for elimination of vertical transmission of HIV and Syphilis.
- Provide technical assistance and guidance on strategic roadmap, validation process, and action framework for elimination of vertical transmission of HIV and Syphilis.
- Any other responsibility as per the need of the program.

At State Level: State Steering Committee on Elimination of Vertical Transmission of HIV and Syphilis

The State Steering Committee for EVTHS Elimination, co-chaired by the Mission Director (NHM) and Project Director (SACS) will provide oversight across the state. The State Steering Committee will convene for quarterly meetings to review progress, discuss challenges and plan future actions for successful implementation of EVTHS services.

State Representation From

- NHM
- State AIDS Control Society (SACS)
- RMNCAH+N
- NTEP and NVHCP
- Other relevant line ministries
- Developmental Organizations
- Professional Organizations: FOGSI, IMA, NNF, IAP
- Private health care provider
- Civil society organizations and community-based organizations
- Community representatives

The State Steering Committee has the following responsibility:

- Ensure coordination and oversee the implementation of EVTHS program at the state level.
- Provide technical guidance and support to districts for effective EVTHS service delivery.
- Ensure availability of adequate resources for implementation of activities as per the approved strategic plan.
- Facilitate capacity building and training programs for healthcare professionals involved in EVTHS services.
- Ensure regular joint visits by NHM-SACS officials, to monitor field level implementation.
- Collaborate with national stakeholders for sharing best practices and lessons learnt.
- Need based customization of the operational guidelines, training materials, and standard operating procedures.

- Implement state-specific strategies to address challenges in the EVTHS service delivery.
- Conduct regular review, monitoring and evaluation, to assess the state's progress towards achieving EVTHS of HIV and Syphilis.
- Any other responsibility as per the need of the program.

At District Level: District Task Force for Elimination of Vertical Transmission of HIV and Syphilis

The District Task Force for EVTHS services, will be chaired by the District Magistrate/Collector and convened by the Chief Medical Officer. The District Task Force should convene monthly meetings to review progress, discuss challenges and plan future actions for successful implementation of EVTHS services.

Representation at District level:

- District Collector/District Magistrate
- Chief Medical Officer (CMO)
- District Health Officer
- DISHA officer
- RMNCAH+N, NVHCP, NTEP etc.
- Representatives from private healthcare facilities, and PMAs
- CSOs, CBOs and community representatives

District Task Force for EVTHS have the following responsibilities:

- Ensure coordination and oversee the implementation of EVTHS program at the district level.
- Ensure availability of adequate resources for implementation of activities as per the strategic plan.
- Provide technical guidance and support to healthcare facilities and personnel involved in EVTHS services.
- Conduct integrated trainings and capacity building programs for healthcare providers.
- Facilitate community outreach and awareness activities for EVTHS.
- Liaise with state-level authorities for necessary support and resources.
- Ensure regular joint visits by NHM-DISHA officials, to monitor field level implementation.
- Ensure timely reporting and documentation of EVTHS activities and outcomes.
- Conduct regular review, monitoring and evaluation, to assess the district's progress towards achieving EVTHS of HIV and Syphilis.
- Any other responsibility as per the need of the program.

Responsibilities of Health facilities for EVTHS service delivery

The roles and responsibilities of facilities in context with EVTHS service delivery has been compiled in the table 10.2.1.

Table 10.2.1: Role & Responsibilities of facilities for EVTHS service delivery

Care Component	Services to be provided	Facilities delivering the EVTHS services	Focal persons
Primary Prevention	• Awareness Generation, • IPC/Counseling • Prevention and risk reduction • HIV/STI screening, • Referral services for at-risk women to ensure that they stay negative and healthy	Stakeholders: NACP and NHM SACS at state level, DISHA and district RCH at district level Facilities • Family Planning service delivery points • AFHC • School Health and Wellness Program • NACP facilities: ARTC, SSK, DSRC, ICTC, TI Private Clinic/ facilities	NHM- • Counsellors/ other service providers, at Family Planning service delivery points • Counsellor/ANM at Adolescent Health Friendly Clinics • Health and Wellness Ambassadors of the School Health and Wellness Program NACP- • NACP Counsellors/ Staff Nurse/MO Private clinics- Treating Clinician/ Staff Nurse

Care Component	Services to be provided	Facilities delivering the EVTHS services	Focal persons
Healthy Timing and Spacing of Pregnancy Services for PLHIV	• ART initiation in all WLHIV after adequate preparedness counselling • Counseling for family planning for WLHIV and Spouse • Condom provisioning at ART Centres • Linkage and accompanied referral to Family Planning service delivery points • Access to stigma-free family planning services to prevent unintended pregnancies among WLHIV • Inclusion of WLHIV for post-partum/post abortion services of family planning • Adherence Counselling of WLHIV to achieve viral suppression • Nutritional Counselling for optimal health of the couple. • Screening and management of STI/ RTI for the couple • Linkage to OBG clinics for specialist care	NACP and NHM at state and district level • ART Centre • Family Planning service delivery points • OBG clinics/ OPDs Private Clinic/ facilities	NHM- Counsellors/MO/ Nurse/ other service providers, at Family Planning service delivery points NACP- NACP Counsellors/ Staff Nurse/MO Private clinics- Treating Clinician/ Staff Nurse
HIV and Syphilis Screening During Pregnancy	• Screen for HIV & Syphilis in the first trimester preferably at the ANC registration • Provide pre-test and post-test counselling for HIV testing as per guideline • At-risk pregnant women, should be screened again in the third trimester and at-labour • Linkage of HIV reactive cases to ICTC for HIV confirmation and referral for treatment • Linkage of Syphilis reactive cases to treatment sites after providing first dose of Injection Benzathine Penicillin	NHM and NACP • ANC clinics • OPDs including VHSND/HWC • labour room • ICTC Private Hospitals and maternity facilities	NHM- • Gynecologist/ MO/Staff Nurse/ other service providers • Labour Room Nurse/MO NACP- • NACP Counsellors/ LT/ Staff Nurse/MO Private hospitals/ maternity facilities • Treating Clinician/ Staff Nurse/LT

Care Component	Services to be provided	Facilities delivering the EVTHS services	Focal persons
Index Testing HIV and Partner testing for Syphilis	• Counsel the pregnant women to disclose her status to her sexual partners • Encourage index testing (spouse/ partner and biological children) of pregnant WLHIV • Encourage partner testing for Syphilis	NACP • ICTC • ART centre • DSRC Private Hospitals and maternity facilities	NACP Counsellors/ LT/Staff Nurse/MO
Care of Pregnant and Breastfeeding WLHIV	• Routine ANC services and high-risk pregnancy care • Rapid ART initiation, Adherence counselling to achieve viral suppression for EVTHS • Counselling for safer sex practices, infant feeding options, adequate nutrition, care of nipple and breast and institutional delivery • Viral load testing at 32-36 weeks of pregnancy, to assess the HIV transmission risk for the baby • Birth planning and pre-sensitization of delivery sites for care during labour • Encourage access for existing services for high-risk pregnancies like referral transportation for institutional delivery and Stigma free delivery services	NACP and NHM • ANC Clinics/ OPDs • ART centre • Labour room Private Hospitals and maternity facilities	NHM- • Gynecologist/ MO/Staff Nurse/ other service providers • Labour Room Nurse/MO NACP- • NACP Counsellors/ LT/ Staff Nurse/MO Private hospitals/ maternity facilities • Treating Clinician/ Staff Nurse/LT

Care Component	Services to be provided	Facilities delivering the EVTHS services	Focal persons
Care of Syphilis Infected Pregnant Women	• Routine ANC services and high-risk pregnancy care • One dose of injection benzathine penicillin should be given all the pregnant women as soon as she screens reactive for Syphilis at the nearest treatment facility • Ensure complete treatment for all syphilis infected pregnant women (Three doses of inj. BPG) • Treatment monitoring at DSRC • Repeat serological titers preferably at least after 12 weeks of treatment/ 32nd week of pregnancy/ at the time of labour • Birth planning and pre-sensitization of delivery sites for care during labour and referral to SNCU/NICU/ other pediatric treatment facilities • Encourage access for existing services for high-risk pregnancies like referral transportation for institutional delivery and Stigma free delivery services	NACP and NHM • ANC Clinics/ OPDs • HWC/PHC/ CHC/SDH • Labour room • DSRC • ICTC Private Hospitals and maternity facilities	NHM- • Gynecologist/ MO/ANM/ other service providers • Skin and VD OPD • Labour Room Nurse/MO NACP- • NACP Counsellors/ LT/ Staff Nurse/MO Private hospitals/ maternity facilities • Treating Clinician/ Staff Nurse/LT
Care of HIV-exposed babies	• Provide immediate care at birth • Provide ARV prophylaxis immediately after birth, preferably within one hour • Follow-up as high-risk babies by Pediatrician • Routine health services, including immunization, growth monitoring, clinical assessment by Medical Officer or Pediatrician • Follow-up Protocol including Early Infant Diagnosis for HIV, for HIV-exposed infants up to 18 months or three months after complete cessation of breastfeeding	NACP and NHM • ART Centre • ICTC • Labour Room • Pediatric OPD/ treatment facilities Private Hospitals and maternity facilities	NHM- • Pediatrician/ MO/ Staff Nurse • Labour Room Nurse/MO NACP- • NACP Counsellors/ LT/ Staff Nurse/MO Private hospitals/ maternity facilities- • Pediatrician/ Staff Nurse/LT

Care Component	Services to be provided	Facilities delivering the EVTHS services	Focal persons
Care of Syphilis-exposed babies	• Provide immediate care at birth • Evaluation by pediatrician at birth and management of the Syphilis-exposed infants at Pediatric Facilities as high-risk babies • Follow up at 14 weeks and 6 months by pediatrician	NACP and NHM • ART Centre • DSRC • Labour Room • SNCU/NICU/ Paediatric facilities Private Hospitals and maternity facilities	NHM • Pediatrician/ LT/ Staff Nurse/MO • Labour Room Nurse/MO • Skin OPD NACP- • NACP Counsellors/ LT/ Staff Nurse/MO Private hospitals/ maternity facilities Treating Clinician/ Staff Nurse/LT

10.3 Community Engagement for EVTHS implementation

Community engagement is an essential element of the Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) Services. The goal is to prevent the transmission of HIV and Syphilis from a pregnant woman to her child during pregnancy, childbirth and breastfeeding. Community engagement is necessary to achieve the programme's objectives as communities will create a supportive environment for pregnant women to access the necessary services and care.

Community engagement involves a range of activities aimed at educating and raising awareness among the public, including pregnant women, their partners and their families. It helps to ensure that individuals have access to the appropriate information to make informed decisions about their health and well-being. Effective community engagement can also increase demand for services and help to overcome the social and cultural barriers that prevent women from accessing care.

One key aspect of community engagement for the EVTHS is the involvement of community-based organizations (CBOs) and civil society organizations (CSOs). These organizations play a crucial role in raising awareness and promoting the programme's objectives within the community. They work with local leaders, community groups, and other stakeholders to create a supportive environment for pregnant women to access the necessary services. CBOs and CSOs can also provide vital support to pregnant women, such as transportation and childcare, to facilitate their access to care.

Another essential component of community engagement is involving pregnant women in the planning and implementation of the programme. This ensures that the programme meets the needs of the community and takes into account the social and cultural factors that may influence women's access to health care. Pregnant women can provide valuable insights into the challenges they face in accessing care and can help to identify solutions that are relevant to their needs.

Community engagement for the EVTHS services should also involve the active participation of health care providers, including doctors, nurses, midwives and community health workers. These individuals play a crucial role in implementing the programme and can provide valuable insights into the challenges and opportunities associated with delivering care to pregnant women. Involving health care providers in the planning and implementation of the programme can help to ensure that the services provided are of high quality and meet the needs of the community.

Community engagement for the EVTHS services should involve the use of a range of communication strategies to reach different segments of the community. These may include mass media campaigns, such as radio and television advertisements, as well as targeted messages aimed at specific populations. For example, messages aimed at men may focus on the importance of supporting their partners during pregnancy and accessing care for themselves to prevent transmission of HIV and Syphilis.

Engagement of Community Champions

The Community Championship Initiative aims to enhance community participation in the National AIDS and STD Control Programme (NACP) by engaging Community Champions from key populations, People Living with HIV (PLHIV), and vulnerable groups. These Champions actively support their communities by increasing awareness about the NACP, providing valuable inputs, and encouraging their peers to participate. Champions undergo capacity building and receive necessary resources. The initiative anticipates Community Champions becoming local resources and plans to evolve based on feedback and learning from ongoing implementations. This user-friendly approach empowers communities and strengthens their role in the NACP.

The Community Champions are expected to fulfil, the following roles in the context of eliminating vertical transmission of HIV and Syphilis:

- Enhance their understanding of the various components of the program aimed at eliminating vertical transmission and disseminate this knowledge within their peer networks. These Community Champions may also actively participate in EVTHS activities, contributing to the program's success.
- Contribute their valuable insights to the program, utilizing available methods, and inspire their peers to actively participate in the initiative. They may play an active role in EVTHS activities, encouraging community engagement and attendance.

10.4 Private sector engagement/ participation

According to data from the most recent NFHS round, around 38% of institutional deliveries (48% in urban regions and 35% in rural areas) took place in a private setting[1].The achievement of EVTHS goals is dependent on the engagement of the private sector as the private sector contributes to EVTHS by providing HIV and Syphilis screening during pregnancy and linkage to the treatment to public or private facilities. Some of the private hospitals/medical colleges also have ART centres. Collaborations with private health care professionals and organizations can enhance access to prevention and treatment services, making a significant impact on maternal and child health.

Efforts should be taken at all levels to ensure dissemination of national guideline with private sector providers and health professionals so that care is provided to pregnant and exposed babies as per the national guidelines. Antenatal registration, HIV and Syphilis screening and pregnancy management

should be reported on the HMIS and RCH 2.0 portal.

The mechanism of service provision and reporting by private sector is as described below:

1. **ANC registration, HIV and Syphilis screening during pregnancy and reactive cases:** The state NHM should ensure all private maternity facilities are reporting in HMIS/RCH portal. The facilities reporting HIV and Syphilis reactive cases in the HMIS/RCH portal should be followed up by DISHA to ensure that the EVTHS care cascade is provided to the identified cases, through private sector or public sector as per client's preference.
2. **Training and Sensitization:** The SACS and DISHA should ensure need-based sensitization and training of the HCW from private facilities.
3. **Regulatory Compliance:** Private health care facilities must comply with regulatory requirements for testing and reporting as described in the HIV/AIDS (Prevention and Control) Act 2017. They must obtain informed consent before conducting HIV testing or providing treatment.

   Private health care providers are required to maintain the confidentiality of an individual's HIV status and related information and ensure stigma free services. The Act emphasizes the right to access treatment for all individuals living with HIV/AIDS, including those seeking services from private health care providers.
4. **Quality Compliance:** The private facilities providing HIV and Syphilis screening should ensure compliance with the quality standards provided under the National HIV Counselling and Testing Guidelines.

Engagement of Professional Medical Association (PMA): PMA play a pivotal role in dissemination of updated national guidelines. The representation of PMA such as FOGSI, IAP, NNF, IMA should be ensured in all national, state, district and sub-district level EVTHS coordination meetings. Also, PMA should be encouraged to take ownership and discuss the updates in their existing programmes such as CMEs, conferences and through their newsletters.

The existing training mechanism of PMAs should be leveraged by sharing the training modules prepared at national, state and district level for further dissemination of guidelines and programme updates.

10.5. Focused Strategies for high burden districts

Despite global progress in combating HIV and AIDS, specific regions and districts bear a disproportionate burden. These high-burden districts face challenges like:

- High HIV prevalence: Many residents are already living with HIV, increasing transmission risk.
- Limited access to services: Testing, treatment and prevention resources are scarce or hard to reach.
- Structural barriers: Poverty, stigma and social inequality hinder effective interventions.

One-size-fits-all approaches fall short, wherein these districts require focused strategies tailored to their unique needs, which are mentioned below:

A. Strengthening Review Mechanisms:

- Integrate data from multiple sources (e.g., HIV surveillance, electronic medical records) for a more comprehensive view.
- Utilize spatial analysis to identify clusters and hotspots of new infections and EVTHS.

- Implement regular programme reviews involving stakeholders at all levels for timely course correction.

B. Customized Strategies for Diverse Scenarios:

i) High Coverage, but Low Identification:

- Conduct targeted testing campaigns for high-risk groups and other key population.
- Implement partner notification strategies to reach hidden cases.

ii) Emerging New Infection Districts:

- Implement immediate outbreak response measures based on local transmission dynamics.
- Strengthen interventions like condom distribution and other need-based prevention interventions under the program.
- Conduct contact tracing and offer post-exposure prophylaxis (PEP) to exposed individuals.

iii) High Prevalence Districts:

- Scale up access to testing strategies along with affordable and effective antiretroviral therapy (ART).
- Implement test-and-treat strategies to rapidly suppress viral load and prevent onward transmission.
- Address social determinants of HIV infection like gender inequality and poverty.

C. Optimizing ART Coverage:

i) Suboptimal ART Coverage but achieved Testing and identification targets:

- Address the challenges for implementing same-day ART initiation, such as the logistics and infrastructure challenges.
- Expand community-based ART delivery models, considering feasibility and cost-effectiveness.
- Prioritize decentralization to primary health care facilities for easier access.
- Integrate HIV care into other healthcare services like maternal and child health programs.
- Analyze reasons for suboptimal coverage, considering factors like treatment fatigue, stigma, and adherence challenges.
- Implement client-centered interventions promoting adherence and retention in care.
- Enhance provider training and address any gaps in clinical knowledge or management skills.

D. Refining HIV Testing Strategies:

i) Suboptimal Testing with good Linkage:

- Prioritize targeted testing in high-risk groups and low-testing settings.
- Combine facility-based testing with community outreach activities for high-risk populations.

- Consider new testing technologies like point-of-care viral load assays.
- Implement strategies like index testing and partner notification to reach undiagnosed individuals.
- Enhance community awareness and reduce stigma associated with HIV testing.
- Utilize mobile testing vans and innovative approaches to reach geographically isolated populations.

10.6 Training and Capacity Building

Training and capacity building are essential components of the comprehensive approach to eliminating vertical transmission of HIV and Syphilis. Health care professionals at all levels play a crucial role in this endeavour, requiring adequate knowledge, skill and resources to effectively implement EVTHS guidelines. This section outlines the comprehensive plans for training and capacity-building towards ensuring health care professionals are equipped to prevent vertical transmission of HIV and Syphilis.

A. Training Needs Assessment:

- Conduct a thorough assessment of training needs among healthcare professionals at various levels, including doctors, nurses, midwives, laboratory technicians and counsellors.
- Identify gaps in knowledge, skills and resources related to EVTHS guidelines and vertical transmission prevention strategies.

B. Curriculum Development:

- Develop a standardized curriculum based on EVTHS guidelines, covering key topics such as antenatal screening, HIV and Syphilis testing algorithms, ART initiation, syphilis treatment, counselling and follow-up care.
- Ensure the curriculum is evidence-based, culturally sensitive, and tailored to the needs of different healthcare professionals.

C. Training Delivery Methods:

- Utilize a variety of training delivery methods, including in-person workshops, online webinars, and on-the-job training.
- Incorporate interactive learning activities, case studies, role-plays and simulations to enhance engagement and retention of knowledge.
- Provide opportunities for hands-on practice and clinical skill-building in real-world settings.

D. Targeted Training Programs:

- Implement targeted training programs for specific cadres of healthcare professionals, such as obstetricians, pediatricians, midwives and laboratory technicians.
- Customize training content and delivery methods to address the unique roles and responsibilities of each cadre in preventing vertical transmission.

E. Training of Trainers:

- Train a cadre of master trainers who can cascade training to healthcare professionals at the facility level.

- Provide comprehensive training-of-trainers programmes to ensure trainers possess the expertise and skills to deliver high-quality training sessions.

F. Continuous Professional Development:

- Establish mechanisms for ongoing professional development and continuous learning among healthcare professionals.
- Offer refresher courses, updates on new guidelines and technologies, and opportunities for peer learning and knowledge exchange.
- The training schedule in Annexure-14 can be taken as a reference.

G. Infrastructure and Resource Provision:

- Ensure access to necessary infrastructure and resources for training, including training facilities, audiovisual equipment, training materials and job aids.
- Provide access to relevant guidelines, protocols and reference materials to support health care professionals in their daily practice.

H. Monitoring and Evaluation:

- Implement a robust monitoring and evaluation system to assess the effectiveness of training programs and identify areas for improvement.
- Regularly evaluate the knowledge, skills, and performance of healthcare professionals post-training to measure the impact on vertical transmission prevention outcomes.

The training modules on EVTHS will serve as the core material for the training sessions. Two sample agendas outlining the topics to be covered during the training are provided in Annexure-14.

Supportive Supervision of EVTHS Services

Supportive supervision is a crucial component of the Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) interventions, aimed at ensuring continuous improvement and effective delivery of services. This section outlines the essential aspects for conducting supportive supervision within the EVTHS framework.

A. Methodologies:

- Mentoring and Coaching: Providing ongoing mentorship and coaching to NACP staff to support their professional growth and development.
- On-site Visits: Conducting regular on-site visits to NACP facilities to observe service delivery, provide feedback and address any issues in real-time.
- Capacity Building Workshops: Organizing workshops and training sessions to build the capacity of EVTHS personnel on relevant topics, including EVTHS guidelines, counselling techniques and data management.

B. Roles of Supervisors:

- Nodal Officers: Responsible for supervising Confirmatory Facilities, LACs, ARTCs, and DSRC staff at the district level, ensuring adherence to EVTHS guidelines and protocols.
- External Experts: Engaged by the EVTHS Coordination Committee or external agencies to provide specialized support and guidance to NACP staff.

- EVTHS Consultants/Experts: Managing and overseeing the EVTHS interventions at the national and state levels, providing technical expertise and leadership.

C. Frequency of Supervision Visits:

- Quarterly Visits: Conducting regular quarterly visits to NACP facilities at the district and state levels to monitor service delivery, provide feedback and identify areas for improvement.
- As Needed: Additionally, supervisors should be available for ad hoc visits in response to specific challenges or issues that arise between scheduled visits.

D. Tools and Resources:

- EVTHS Guidelines and Protocols: Providing supervisors with comprehensive guidelines and protocols for EVTHS service delivery to ensure consistency and quality.
- Supervision Checklist: Standardized checklist to guide supervisors during on-site visits, covering key areas such as counselling practices, testing protocols, and data management.
- Training Modules: Utilizing training modules specifically designed for EVTHS personnel to reinforce key concepts and skills related to service delivery and patient care.
- Data Management Systems: Implementing robust data management systems to track and monitor EVTHS activities, including client records, testing outcomes and follow-up appointments.

SECTION IV: CROSS CUTTING THEMES

CHAPTER-11

Supply Chain Management of commodities under NACP

Supply Chain Management of commodities under NACP

11.1 Commodities under EVTHS

The successful implementation of the EVTHS Services relies heavily on a well-managed supply chain that ensures timely delivery of medical interventions and care to HIV positive mothers and their children. To achieve this goal, the following essential commodities must be available and managed effectively:

- Antiretroviral Medications: These drugs play a critical role in treating HIV and preventing mother-to-child transmission of the virus. They include antiretroviral therapy (ART) for the mother and prophylactic treatment for the infant.
- HIV and Syphilis Rapid Diagnostic Testing (Dual RDT) Kits: These diagnostic tests quickly and accurately diagnose HIV and Syphilis infections in pregnant women. Early diagnosis allows for timely initiation of treatment and care.
- Laboratory Supplies: HIV positive mothers and their children require various laboratory supplies for testing and monitoring. These supplies include viral load testing, CD4 cell counts, and other necessary laboratory tests.
- Personal Protective Equipment (PPE): Health workers providing care to HIV positive mothers and their children must have appropriate PPE to protect themselves from virus transmission.

By effectively managing these critical commodities, the EVTHS services can ensure that HIV positive mothers and their children receive the necessary medical interventions and care, leading to better health outcomes.

The procurement and distribution of commodities for the Elimination of Vertical Transmission of HIV (EVTHS) services involves various components at different levels of the health care system:

➢ **At NACO level:**

- Central procurement of HIV test kits, RPR kits and injection BPG.

➢ **At SACS level:**

- Procurement of ARV prophylaxis drugs (Syp. Nevirapine and Syp. Zidovudine), pediatric formulation of penicillin for management of congenital syphilis and DBS commodities based on estimated requirements.
- Making appropriate budgetary provisions in the Annual Action Plan (AAP) based on the estimated forecasts.
- Coordinating with State NHM for inclusion of budget in State NHM PIP for procurement of dual testing kits by NHM.

➢ **At Regional Warehouse level:**

- Storage and distribution of commodities to facilities based on their requirements.

➢ **At Facility level:**

- Ensuring the availability of necessary commodities for the screening and treatment of HIV-positive mothers and their children, including antiretroviral medications, rapid HIV test kits, laboratory supplies, and personal protective equipment (PPE).
- Monitoring and reporting of commodity usage to higher levels of the healthcare system.

The availability of HIV and Syphilis diagnostic test kits and ARV drugs is crucial to the success of the Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) programme. The effective procurement and distribution of these commodities are necessary to reduce and ultimately eliminate mother-to-child transmission of HIV.

Respective State AIDS Control Societies (SACS) will procure ARV prophylaxis drugs (Syp. Nevirapine and Syp.Zidovudine) and DBS commodities based on estimated requirements. SACS will make appropriate budgetary provisions in the Annual Action Plan (AAP) based on the estimated forecasts, as per guidelines provided by Supply Chain Management (SCM) of the National AIDS Control Organization (NACO). In cases where Zidovudine syrup is not available, syrup Lopinavir/ritonavir should be used after 14 days of birth. Procurement of Syp. Lopinavir/ritonavir should be done locally, as per need.

The distribution of ARV prophylaxis drugs and DBS commodities will be state-specific. Based on the specific requirements of the state, SACS may choose to keep the supplies DISHA or at the facility-level. If the commodities are placed at DISHA, decisions about further distribution to the facilities shall be taken based on the facility-level requirement. SACS shall coordinate with State NHM for procurement of dual testing kits for screening of pregnant women.

It is important to note that the timely availability of necessary commodities, including antiretroviral medications, rapid HIV test kits, laboratory supplies and personal protective equipment (PPE) is critical at the facility level. Facilities must ensure that these commodities are available for the screening and treatment of HIV positive mothers and their children. Moreover, they must monitor and report their commodity usage to higher levels of the healthcare system to enable effective planning and distribution of resources.

11.2 Managing the EVTHS Commodities

Commodity Stocking and Logistics for the EVTHS Services: The successful implementation of the Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) programme relies heavily on the availability and effective distribution of essential commodities. These commodities include antiretroviral medications, diagnostic test kits, laboratory supplies, and personal protective equipment (PPE). In

this regard, the procurement and distribution of these commodities play a critical role in reducing and ultimately eliminating vertical transmission of HIV and Syphilis. The table 11.2.1 will discuss the commodity stocking and logistics for the EVTHS services, highlighting the procurement, storage, and distribution of essential commodities at different levels of the health care system.

Table 11.2.1: Commodity Procurement and Logistics for EVTHS Services

S. No.	Item	Storage	Procurement and Supply Chain management
1	HIV test kits include, the three principal test kits and WBFP test kits	Cold chain	• Procured by NACO and SACS (emergency basis) for the testing of priority population including pregnant women, visiting confirmatory site. • The WBFP test kits are to be used only for Presumptive TB and Notified TB cases.
2.	RPR/VDRL	Cold chain	• Procured by NACO and SACS (emergency basis) and supplied to confirmatory facilities.
3.	HIV and Syphilis dual RDT	Cold chain	• Procured by NACO for testing of at-risk clients at TI, SSK, DSRC, P&OCS, Outreach camps and LWS. • Procured by NHM for screening of pregnant women at sites other than confirmatory facilities.
4.	Adult ART Regimens	Cool dry place	• Procured by NACO and SACS (emergency basis) • Supplied by SACS to ART centre to LAC
5.	Nevirapine Syrup, Zidovudine Syrup, LPV/r Syrup	Cool dry place	• Procured by SACS
6.	Injection Benzathine Penicillin	Cool dry place/ Room temperature	• Procured by NACO and SACS (emergency basis) • Supplied by SACS to DISHA to Treatment facilities
7.	Paediatric Formulation of Penicillin (crystalline penicillin/ procaine penicillin)	Refrigerate between 2 to 8 degrees Celsius, do not freeze	• Procured by SACS
8.	DBS collection test kits and DBS commodities	Cool dry place	• Procured by SACS
9.	EID test kits	Cold chain	• Procured by NACO

CHAPTER-12

Legal and Ethical implications for EVTHS Services

Legal and Ethical implications for EVTHS Services

12.1 Background

The HIV and AIDS (Prevention & Control) Act, 2017 is landmark legislation which came into effect from September 10, 2018 with the objective to prevent and control the spread of HIV and AIDS and for reinforcing the legal and human rights of persons infected with and affected by HIV and AIDS. It also aims to protect the rights of the health care providers in relation to HIV and AIDS.

The HIV and AIDS (Prevention and Control) Act, 2017 strives to provide a conducive and enabling environment for people infected with and affected by HIV and AIDS.

The provisions of the HIV and AIDS (Prevention and Control) Act, 2017 addresses stigma and discrimination and strives to create an enabling environment for enhancing access to services. It provides for diagnostic facilities related to ART and opportunistic infection management to people living with HIV and AIDS and promotes safe workplace in healthcare setting to prevent occupational exposure. The Act also provides for a robust grievance redressal mechanism in the form of Ombudsman at the State level and Complaints Officer at the establishment level aiming to provide speedy redressal of discriminatory.

12.2 Important definitions under section 2 of the HIV and AIDS (Prevention & Control) Act, 2017

There are 25 terms which have been defined under section 2 of the Act. Below, we have provided the definitions that are crucial from a healthcare setting perspective.

Section 2 (a):

"AIDS" means Acquired Immune Deficiency Syndrome, a condition characterized by a combination of signs and symptoms, caused by Human Immunodeficiency Virus, which attacks and weakens the body's immune system making the HIV-positive person susceptible to life threatening conditions or

other conditions, as may be specified from time to time;

Section 2 (b):

"Capacity to consent" means ability of an individual, determined on an objective basis, to understand and appreciate the nature and consequences of a proposed action and to make an informed decision concerning such action;

Section 2 (d):

"Discrimination" means any act or omission which directly or indirectly, expressly or by effect, immediately or over a period of time,— (i) imposes any burden, obligation, liability, disability or disadvantage on any person or category of persons, based on one or more HIV-related grounds; or (ii) denies or withholds any benefit, opportunity or advantage from any person or category of persons, based on one or more HIV-related grounds, and the expression "discriminate" to be construed accordingly.

Explanation 1. for the purposes of this clause, HIV-related grounds include—

(i) being an HIV-positive person;

(ii) ordinarily living, residing or cohabiting with a person who is HIV-positive person;

(iii) ordinarily lived, resided or cohabited with a person who was HIV-positive.

Explanation 2. for the removal of doubts, it is hereby clarified that adoption of medically advised safeguards and precautions to minimise the risk of infection shall not amount to discrimination;

Section 2 (h):

"Healthcare Provider" means any individual whose vocation or profession is directly or indirectly related to the maintenance of the health of another individual and includes any physician, nurse, paramedic, psychologist, counsellor or other individual providing medical, nursing, psychological or other healthcare services including HIV prevention and treatment services;

Section 2 (i):

"HIV" means Human Immunodeficiency Virus;

Section (j):

"HIV-affected person" means an individual who is HIV-positive or whose partner (with whom such individual normally resides) is HIV-positive or has lost a partner (with whom such individual resided) due to AIDS;

Section 2 (k):

"HIV-positive person" means a person whose HIV test has been confirmed positive;

Section 2 (l):

"HIV-related information" means any information relating to the HIV status of a person and includes—

(i) information relating to the undertaking performing the HIV test or result of an HIV test;

(ii) information relating to the care, support or treatment of that person;

(iii) information which may identify that person; and

(iv) any other information concerning that person, which is collected, received, accessed or recorded in connection with an HIV test, HIV treatment or HIV-related research or the HIV status of that person;

Section 2 (m):

"HIV test" means a test to determine the presence of an antibody or antigen of HIV;

Section 2 (n):

"Informed consent" means consent given by any individual or his representative specific to a proposed intervention without any coercion, undue influence, fraud, mistake or misrepresentation and such consent obtained after informing such individual or his representative, as the case may be, such information, as specified in the guidelines, relating to risks and benefits of, and alternatives to, the proposed intervention in such language and in such manner as understood by that individual or his representative, as the case may be;

Section 2 (v):

"Significant-risk" means—

(a) the presence of significant-risk body substances;

(b) a circumstance which constitutes significant-risk for transmitting or contracting HIV infection; or

(c) the presence of an infectious source and an uninfected person.

Explanation for the purpose of this clause are as follows:

(i) "significant-risk body substances" are blood, blood products, semen, vaginal secretions, breast milk, tissue and the body fluids, namely, cerebrospinal, amniotic, peritoneal, synovial, pericardial and pleural;

(ii) "circumstances which constitute significant-risk for transmitting or contracting HIV infection" are as follows

(A) sexual intercourse including vaginal, anal or oral sexual intercourse which exposes an uninfected person to blood, blood products, semen or vaginal secretions of an HIV-positive person;

(B) sharing of needles and other paraphernalia used for preparing and injecting drugs between HIV-positive persons and uninfected persons;

(C) the gestation, giving birth or breast feeding of an infant when the mother is an HIV-positive person;

(D) transfusion of blood, blood products, and transplantation of organs or other tissues from an HIV-positive person to an uninfected person, provided such blood, blood products, organs or other tissues have not been tested conclusively for the antibody or antigen of HIV and have not been rendered non-infective by heat or chemical treatment; and

(E) other circumstances during which a significant-risk body substance, other than breast milk, of an HIV-positive person contacts or may contact mucous membranes including eyes, nose or mouth, non-intact skin including open wounds, skin with a dermatitis condition or abraded areas or the vascular system of an uninfected person, and including such circumstances not limited to needle-stick or puncture wound injuries and direct saturation or permeation of these body surfaces by the significant-risk body substances:

Provided that "significant-risk" shall not include any of the following:

(i) exposure to urine, faeces, sputum, nasal secretions, saliva, sweat, tears or vomit that does not contain blood that is visible to the naked eye;

(ii) human bites where there is no direct blood to blood, or no blood to mucous membrane contact;

(iii) exposure of intact skin to blood or any other blood substance; and

(iv) occupational centres where individuals use scientifically accepted Universal

Precautions, prohibitive techniques and preventive practices in circumstances which would otherwise pose a significant-risk and such techniques are not breached and remain intact

Section 2 (y):

"Universal Precautions" means control measures that prevent exposure to or reduce, the risk of transmission of pathogenic agents (including HIV) and includes education, training, personal protective equipment such as gloves, gowns and masks, hand washing, and employing safe work practices.

12.3 Key Provisions in Sections 3, 4, 5, 6, 7, 8, 9, 11, 16, 18, 19, 20, 21, 23, 24, 32

Section-3 Prohibition of discrimination

This provision of the Act prohibits discrimination against protected individuals on various grounds, including employment, healthcare, education, public services, accommodation, movement, property rights, public office access, and more. It specifically outlines conditions for terminating employment, requiring a written assessment by a qualified healthcare provider in cases involving significant risk of HIV transmission or if they are unfit to perform their duties of the job. Additionally, it prohibits the requirement of HIV testing as a prerequisite for obtaining employment, accessing healthcare, or pursuing education.

Section 4 Prohibition of certain acts

This provision states that it is prohibited to use spoken or written words, signs, visible representations, or any means to promote hatred against protected individuals or groups. It further restricts the dissemination of information, advertisements, or notices that may incite hatred, discrimination, or physical violence against these protected persons, whether in a general or specific context.

Section 5: Informed Consent for undertaking HIV test or treatment

This provision specifies that no HIV testing or medical treatment, interventions, or research can be conducted on any individual or protected person without obtaining their informed consent or the consent of their representative. The consent process must follow guidelines and include pre-test and post-test counselling for the person being tested or their representative. The Guidelines on Informed Consent in context of the HIV and AIDS (Prevention and Control) ACT 2017, was notified by the Government of India on 4th July 2022.

Section 6: Exceptions to Informed Consent

This section outlines certain cases where informed consent for HIV testing is not required. These situations include:

a) where a court determines, by an order that the carrying out of the HIV test of any person either as part of a medical examination or otherwise, is necessary for the determination of issues in the matter before it;

b) for procuring, processing, distribution or use of a human body or any part thereof including tissues, blood, semen or other body fluids for use in medical research or therapy:

- Provided that where the test results are requested by a donor prior to donation, the donor shall be referred to counselling and testing centre and such donor shall not be entitled to the results of the test unless he has received post-test counselling from such centre;

c) for epidemiological or surveillance purposes where the HIV test is anonymous and is not for the purpose of determining the HIV status of a person: Provided that persons who are subjects of such epidemiological or surveillance studies shall be informed of the purposes of such studies; and

d) for screening purposes in any licensed blood bank.

Section 7: Guidelines for Testing or Diagnostic Centre or Pathology Laboratory or Blood Bank for HIV Test

This clause specifies that no HIV test can be carried out by any testing centre, diagnostic laboratory, or blood bank unless they adhere to the established guidelines for conducting such tests. These guidelines are mandatory for all facilities performing HIV tests, and they must uphold the "5 Cs" principles, which include obtaining consent, maintaining confidentiality, providing counselling, ensuring accurate results, and establishing a connection with the individuals undergoing testing.

Section 8: Disclosure of HIV status

This section outlines rules regarding the disclosure of HIV-related information. It states that individuals cannot be forced to reveal their HIV status unless by an order of the court that the disclosure of such information is necessary in the interest of justice for the determination of issues in the matter before it.

Moreover, it prohibits the disclosure of another person's private information shared in confidence or a fiduciary relationship, except with the informed consent of that person or their representative, recorded in writing.

However, informed consent is not required when disclosure is made by healthcare providers for the patient's care, ordered by a court, in legal proceedings, as required by specific provisions, when the information is statistical and not personally identifying, or for government monitoring, evaluation, or supervision purposes.

Section 9: Disclosure of HIV-positive status to partner of HIV-positive person

This clause specifies rules for the disclosure of an individual's HIV-positive status to their partner by healthcare providers. It states that healthcare providers, except physicians or counsellors, cannot disclose this information.

Physicians or counsellors may disclose the HIV positive status of a person under his direct care to his/her partner, if such health care provider-

a. reasonably believes that the partner is at the significant risk of transmission of HIV from such person; and

b. such HIV positive person has been counselled to inform such partner; and

c. is satisfied that the HIV positive person will not inform such partner; and

d. has informed the HIV positive person of the intention to disclose the HIV positive status to such partner

Disclosure must be done in person after counselling, and the provider is not obligated to identify or locate the partner.

The section also provides an exception in case of an HIV positive woman. The health care provider should refrain from disclosing to a woman's partner if there is a reasonable apprehension that such information may result in violence, abandonment or actions.

Additionally, health care providers under this section are protected from criminal or civil liability for disclosure or non-disclosure.

Section 11: Guidelines on Confidentiality of Data for Protected Persons

This provision mandates that every establishment maintaining records of HIV-related information for protected individuals must implement data protection measures as per the provided guidelines. These measures encompass procedures to safeguard information from disclosure, control access to the data, establish security systems for data in all formats, and institute mechanisms for accountability and liability of individuals within the establishment.

Section 16: Protection of property of children affected by HIV or AIDS

This provision stipulates that the Central Government or State Government, as applicable, is obligated to undertake appropriate measures for the preservation of property belonging to children affected by HIV or AIDS. The purpose of these measures is to ensure the protection of the property rights of such children. This section authorizes parents, guardians, or representatives acting in the best interest of children affected by HIV and AIDS, as well as the affected children themselves, to approach the Child Welfare Committee. This approach may be made for the purpose of securing the safekeeping and deposit of documents pertaining to the property rights of the child. Additionally, it permits the filing of complaints in instances where a child is subject to dispossession, actual dispossession, or trespass into their dwelling. The provision is designed to establish a legal framework for the safeguarding of the property interests of children affected by HIV or AIDS.

Section-18: states that no HIV positive woman, who is pregnant, shall be subjected to sterilization or abortion without obtaining her informed consent.

Section 19: Obligation of establishments to provide safe working environment

Every establishment, engaged in the healthcare services and every such other establishment where there is a significant risk of occupational exposure to HIV, shall, for the purpose of ensuring safe working environment, —

(i) provide, in accordance with the guidelines, —

(a) Universal Precautions to all persons working in such establishment who may be occupationally exposed to HIV; and

(b) training for the use of such Universal Precautions;

(c) Post Exposure Prophylaxis to all persons working in such establishment who may be occupationally exposed to HIV or AIDS; and

(ii) inform and educate all persons working in the establishment of the availability of Universal Precautions and Post Exposure Prophylaxis.

Sections 20 & 21: Designation of Complaints Officer at workplace settings

Every establishment consisting of 100 or more persons, whether as an employee or officer or member or director or trustee or manager and in the case of a healthcare establishment, consisting of 20 or more persons shall designate such person, as it deems fit, as the Complaints Officer who shall dispose of complaints of violations of the provisions of this Act in the establishment.

The Complaints Officer shall decide a complaint promptly and in any case within seven working days:

Provided that in case of emergency or in the case of health care establishment where the complaint relates to discrimination in the provision of, or access to health care services or provision of universal precautions, the Complaints Officer shall decide the complaint on the same day on which he receives the complaint.

Sections 23 & 24: Appointment of Ombudsman

Each State Government is required to appoint one or more Ombudsman who shall inquire into the violations of the provisions of this Act, particularly those related to acts of discrimination as outlined in section 3, and the provision of healthcare services by individuals, as determined by the State Government's prescribed methods.

The Ombudsman must issue an order within thirty days of receiving a complaint. In cases of medical emergencies involving HIV positive individuals, the Ombudsman should aim to issue an order as quickly as possible, ideally within twenty-four hours of receiving the complaint.

Section 32: Recognition of guardianship of older sibling

This provision grants authority to individuals aged between twelve and eighteen years, possessing sufficient maturity of understanding, and managing the affairs of their family affected by HIV/AIDS, to act as guardians for their younger siblings under eighteen years old. This provision allows them to undertake various responsibilities on behalf of their siblings, including admission to educational institutions, care and protection, medical treatment, managing bank accounts, handling property matters, and fulfilling other duties as a guardian. The section further clarifies that a family affected by HIV/AIDS encompasses situations where both parents and the legal guardian are incapacitated due to HIV-related illnesses or AIDS, or where the legal guardian and parents are unable to fulfil their obligations towards the children.

For further reading please refer to the:

1. National HIV Counselling and Testing Guidelines, 2024
2. HIV and AIDS (Prevention and Control) ACT 2017
3. HIV and AIDS Policy for Establishments, 2022; available at: https://naco.gov.in/sites/default/files/HIV_and_AIDS_Policy_for_Establishments_2022_0.pdf

SECTION V: MONITORING AND EVALUATION OF EVTHS SERVICES

Chapter 13 Monitoring and Evaluation Framework of EVTHS services

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Chapter 14 EVTHS Validation Framework

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- Prepare the roadmap
- Undertake periodic review of progress on roadmap
- Initiate validation process
- Coordinate with RSV and support them to undertake validation assessment

CHAPTER-13

Monitoring and Evaluation Framework of EVTHS services

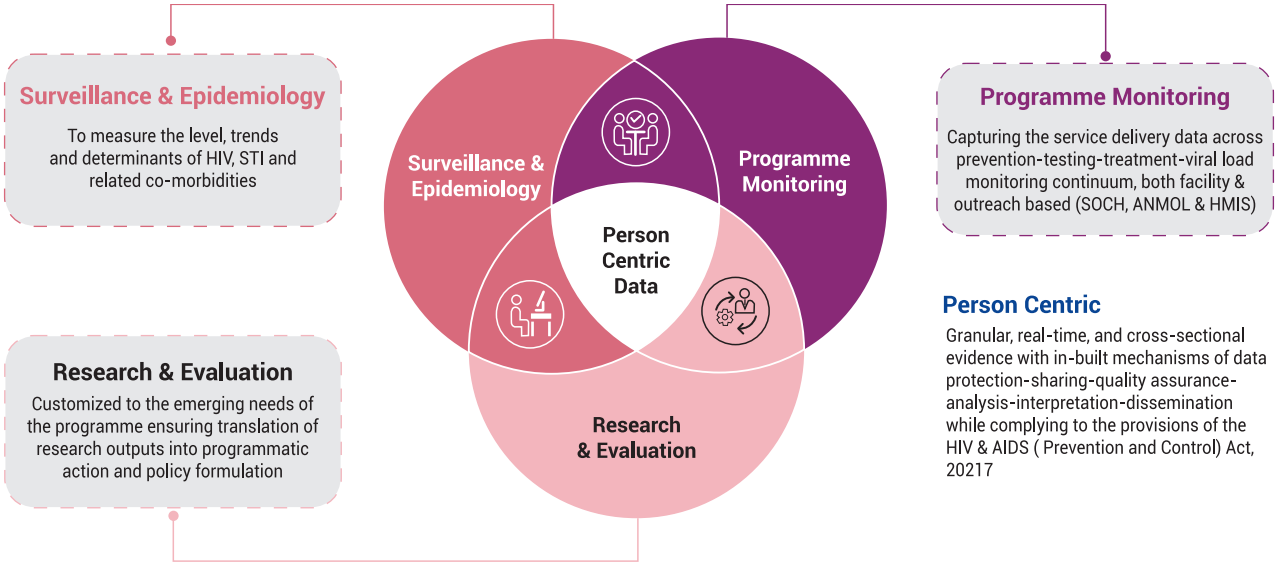
Monitoring and Evaluation Framework of EVTHS services

13.1 Background

NACP's response to vertical transmission of HIV and Syphilis has evolved significantly since its launch in 2001. In line with the evolution of the national programme's outlook on vertical transmission from prevention to elimination, a robust strategic information system on related key services like pre-conception care, screening, confirmation, care, support, and treatment, including follow-up services is critical to not only plan and track the delivery of required services but also to measure the progress and provides evidence for mid-course corrections. EVTHS related strategic information will come through various mechanisms under NACP. These include routine programmatic data from service delivery facilities, cross-sectional and longitudinal surveillance and epidemiological activities, and research (including of operational research). This chapter details the strategic information framework for EVTHS under NACP.

IT enabled SOCH (Strengthening Overall Care for HIV beneficiaries) portal is the backbone of the information management system under NACP. SOCH as a person-centric monitoring, evaluation, and surveillance system will continue to be fundamental to the generation of EVTHS-related person-centric service delivery data across the prevention-detection-treatment-viral load monitoring continuum. Activities under the integrated and enhanced surveillance & and epidemiology (IESE) framework and research & and evaluation framework of NACP also have EVTHS-related data generation activities. The complementary action-oriented SI systems of programme monitoring-surveillance, epidemiology-research and evaluation, with in-built mechanisms of data protection-sharing-quality assurance-analysis-interpretation-dissemination while complying with the provisions of the HIV & AIDS (Prevention and Control) Act, 2017 will be fundamental to EVTHSunder NACP (Figure 13.1.1).

Figure 13.1.1: Data generation activities under strategic information systems of NACP phase V



13.2. Overview of SI framework for EVTHS

Progress toward the attainment of elimination of the vertical transmission of HIV and Syphilis is measured through standard criteria and processes for validation prescribed by WHO in its global guidance. While impact and process indicators as noted under WHO validation guidelines would be central, the complementary SI systems under NACP will have additional indicators generating actionable evidence under the EVTHS framework.

The table 13.2.1 enumerates the WHO Impact and process indicators and targets for validation of elimination of vertical transmission of HIV and Syphilis

Table 13.2.1: Impact and Process indicators and Targets for validation of EVTHS

Infection	Indicator Type	Indicator	Target
HIV	Impact	HIV mother-to-child transmission (MTCT) rate, and	<5% (breastfeeding populations) OR <2% (non-breastfeeding populations)
		Case rate of new paediatric HIV infections due to MTCT	<50 per 100,000 live births
	Process	ANC-1 coverage (at least one visit)	≥95%
		Coverage of HIV testing among pregnant women	≥95%
		ART coverage of pregnant women living with HIV	≥95%
Syphillis	Impact	Case rate of Congenital Syphilis (CS)	≤50 per 100,000 live births
	Process	ANC-1 coverage (at least one visit)	≥95%
		Coverage of syphilis testing among pregnant women	≥95%
		Adequate treatment coverage of Syphilis reactive PW	≥95%

Programme Monitoring

Programme monitoring under NACP refers to the routine collection, recording, reporting, analysis, and use of all service delivery data, including both aggregate and individual level, encompassing persons-outputs-outcomes, in alignment with the national plan, target and goals. For EVTHS, the programme monitoring systems will refer to the systems of Health Management Information System (HMIS) and Reproductive and Child Health (RCH)/ANM Online (ANMOL) portal of the National Health Mission (NHM) as well as the SOCH portal of the NACP (Figure 13.2.1). Each of the systems has been briefly summarized below.

A. HMIS

The Ministry of Health & Family Welfare, Government of India uses a web-based HMIS portal to monitor all of its health programs. The portal captures the aspects of service delivery, human resources and infrastructures from the facility level to the sub-district, district, state and national levels. Monthly aggregated reports on a range of service delivery statistics, including HIV and Syphilis screening, testing and referrals, are monitored through the portal. Approximately 2.5 lakh health care establishments (across all States/UTs) are currently providing monthly facility-specific service delivery data uploads. Data reported through HMIS forms the primary basis for the programme review at the block, district and State levels.

B. RCH portal/ANMOL App

The RCH portal, based on the integrated register, is an individual-based system capturing information for early identification and tracking of the individual beneficiary throughout the reproductive lifecycle for all RCH-related services for eligible couples, pregnant women, and children. The portal facilitates the timely delivery of full components of antenatal, postnatal and delivery services and the tracking of children for complete immunization services. As individual eligible couples are registered in the RCH portal through the integrated register, RCH portals aim to avoid the re-entry of data for already registered pregnant women and children.

ANMOL is the extension of the RCH portal on the Android ecosystem to facilitate the capturing of real-time information about services provided to the beneficiary and its reporting by ANMs. ANMOL allows ANMs to enter and update data for their beneficiaries. ANMOL also acts as a job aid to the ANMs which provides them with readily available information such as due list, dashboard etc. based on data entered. ANMOL is currently operational in most of the States except a few. For further details refer to https://rch.nhm.gov.in/rch/Anmol_Status.aspx

C. SOCH

SOCH is the person-centric web and mobile-based information management system under NACP to track and record services and related inventory transactions improving the service delivery and health outcome. The system captures inventory and service delivery information about individual beneficiaries throughout the HIV continuum. The system will integrate into the overall IT landscape of MOH, FW, having API-based linkages with other MOH, FW MIS systems that intersect with the HIV continuum.

SOCH, based on individual IDs (both system-generated and facility-created), digitize service delivery data across all key service delivery facilities under NACP including the prevention-testing-treatment-viral load monitoring continuum with an embedded supply chain system. SOCH is designed for patient portability with a seamless flow of beneficiaries across the facilities avoiding duplication in capturing

information which has been already captured at previous facilities. In terms of EVTHS, SOCH is operational at the confirmatory HIV counselling and testing centres, designated STI/RTI clinics, anti-retroviral therapy (ART) centres, early infant diagnosis (EID) laboratories and viral load (VL) laboratories.

Figure 13.2.1: EVTHS-related programme monitoring systems

RCH Portal/ANMOL APP
Persons-based MIS for eligible couples, pregnant women, and children across antenatal, postnatal & delivery services as well as immunization services. Operational in almost all States.

SOCH
IT-enabled, case based MIS under NACP, which includes the provision of tracking of pregnant women and exposed babies across ICTC, DSRC, ART, EID labs and VL labs.

HMIS
Aggregated web-based monthly reporting system for all health programs under MoHFW from approximately 2.5 lakhs health care establishment including Pvt across all states/UTs.

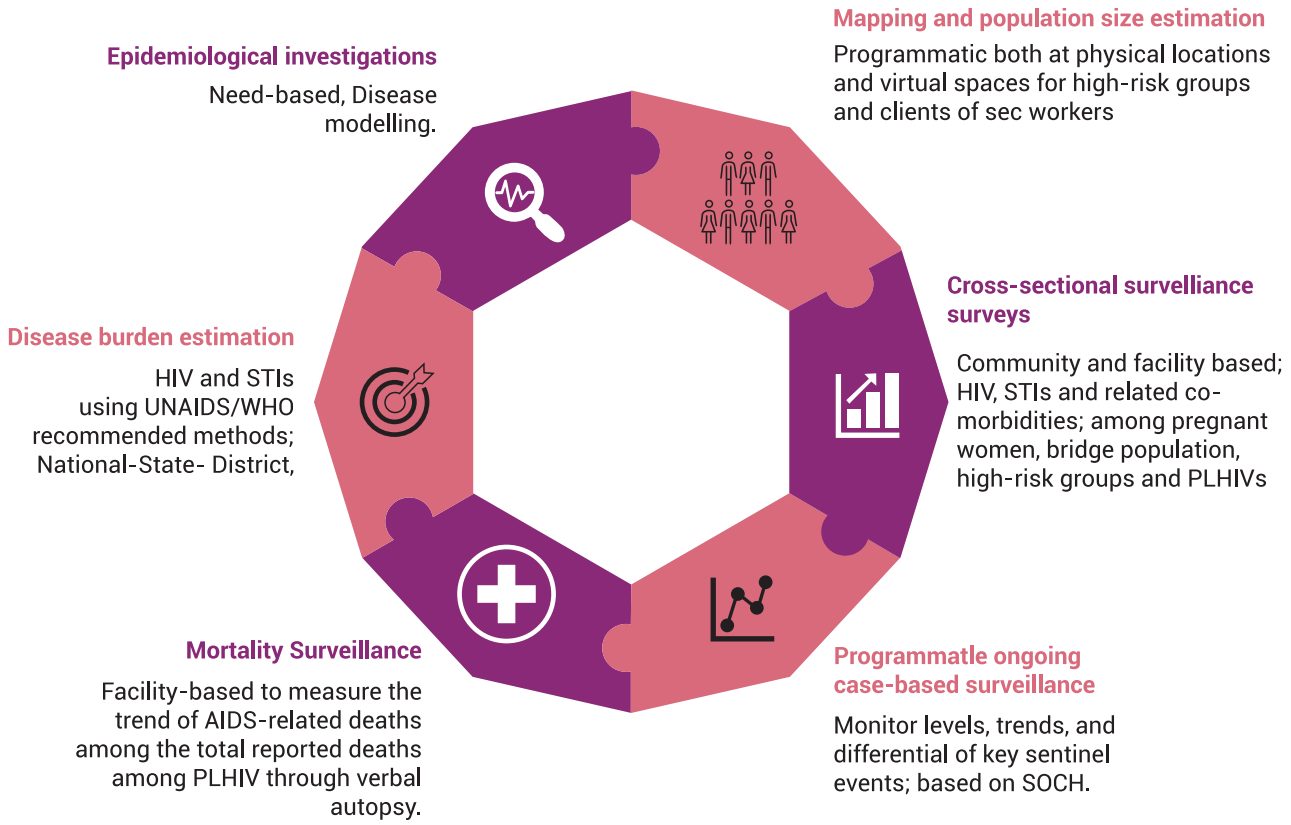
Integrated and Enhanced Surveillance & Epidemiology Framework

Reductions of new infections and AIDS-related mortalities, along with the elimination of vertical transmission of HIV and Syphilis, are three of the high-level goals under NACP phase V. Given the ambitious agenda of focusing on the incidence, AIDS-related mortality and EVTHS, strategic framework for integrated and enhanced surveillance and epidemiology (IESE) of HIV, STI and related co-morbidities has been firmed up under NACP[1]. The IESE framework aims to measure the level, trends, and determinants of HIV, STI and related co-morbidities using systems of the highest possible scientific rigour. (Figure 13.2.2)

For EVTHS, cross-sectional surveillance surveys among pregnant women and PLHIV and disease burden are of specific interest. While cross-sectional surveys among pregnant women would be key to quantifying the level and monitoring the trends of HIV and Syphilis among pregnant women, the surveillance surveys among women living with HIV will inform the contraceptive use, fertility patterns and breast-feeding practices among women living with HIV. Estimates based on the mathematical models inform the progress on the impact indicators targets for EVTHS.

[1] https://naco.gov.in/sites/default/files/Stretegic_Framework_On_IESE_of_HIV_STD_and_Related_Co_Morbidities.pdf

Figure 13.2.2: IESE framework under NACP.

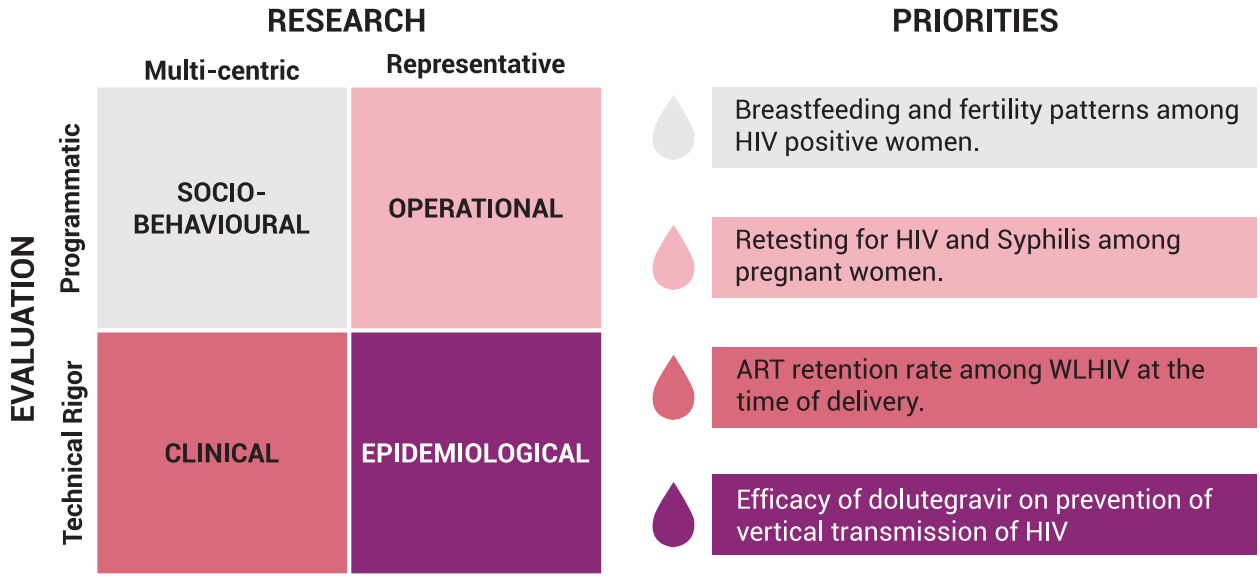


Research and evaluation

Research and evaluation (R&E) is one of the key components of the strategic information under NACP. It is done through systematic identification of key evidence gaps and research needs of the programme and then systematically addressing them through scientific research. The focus is on ensuring the translation of research outputs into programmatic action and policy formulation. NACP phase V envisaged that research priorities will be customized to the goals and emerging needs of the programme. Undertaken through robust review and monitoring mechanisms under the stewardship of NACO's Technical Resource Group-R&E (TRG-R&E), the research activities are coordinated centrally as well as through State AIDS Control Societies. Capacity Building/ Scientific writing/ Publications are integral to the R&E framework (Figure 13.2.3).

Strengthening the strategic information in the context of EVTHS is one of the key strategies under goal 3 of NACP phase V. Recognizing the evidence gap on EVTHS through various technical groups, select areas have been already identified as priority areas for evidence generation through research. These topics include, but are not limited to, areas of repeat testing, breastfeeding practices, retention rate and fertility rates.

Figure 13.2.3: R&E framework under NACP with EVTHS-related select priorities areas.



13.3. EVTHS related progress monitoring indicator framework

Under the current section, the minimum set of indicators for measuring progress on EVTHS is presented. The indicators cover the service delivery areas of family planning, screening and diagnosis, treatment services for pregnant and breastfeeding women infected with HIV and/or Syphilis, and services for exposed infants. Indicators, under the broad aspects of impact and process, will provide information to assess performance towards EVTHS through established systems. Additional indicators may be worked-out by State Managers to meet the local programmatic needs.

Overall, there are 29 indicators under the progress monitoring framework of EVTHS. These include 3 impact indicators framework (2 for HIV and 1 for Syphilis) measured at the population level. While the population level impact indicators will be measured using modelling tools as recommended by UNAIDS and WHO, insights into the same will be also provided by collecting the data at the facility level as applicable. The impact indicators are the same as those prescribed in WHO guidelines for the validation of the vertical transmission and are described in table 13.3.1.

Table 13.3.1: Impact indicator in context of syphilis

Impact indicator in context of syphilis
In context of the monitoring of vertical transmission of Syphilis, either congenital syphilis estimation tool or the surveillance case definition for congenital syphilis will be used for calculation of Impact Indicator (IS3) on Syphilis rather than a clinical case definition In line with WHO global guidance on criteria and processes for validation on triple elimination. A surveillance case definition is a presumptive definition and provides a uniform set of criteria to define a condition for public health surveillance purposes. The following may be used as the surveillance case definition of CS: 'A live birth or foetal death at >20 weeks of gestation or >500 g (including stillbirth) born to a woman with positive syphilis serology and without adequate syphilis treatment'.

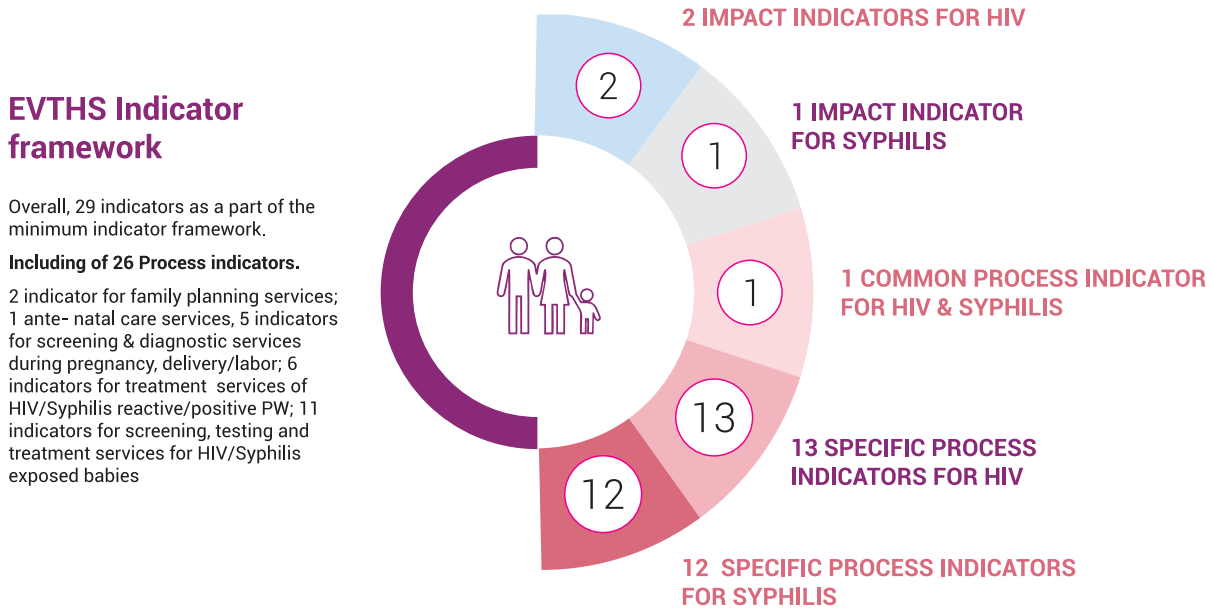
There are 26 process indicators as a part of the EVTHS validation framework. The process indicators in the EVTHS monitoring framework include 5 process indicators as in the validation guidelines. These

include indicators for ANC visits (common for both HIV & Syphilis), HIV screening/testing and treatment (for HIV) and Syphilis screening/testing and treatment.

For monitoring the elimination of vertical transmission of HIV, there are 11 additional process indicators. These are in the areas of family planning (2), treatment retention, viral load suppression, and breastfeeding practices (3), and services for exposed babies in terms of prophylaxis/treatment and early infant diagnosis (6) in alignment with programmatic domains.

There are 10 additional process indicators for measuring the progress on the elimination of vertical transmission of Syphilis. These include 3 indicators on screening and diagnostic services for PW and her spouse, 1 indicator on treatment completion coverage for PW, one indicator on pregnancy outcome and 5 indicators on the services for exposed infants. Similar to the early infant diagnosis component for HIV related interventions, the indicator framework tracks syphilis testing and treatment among exposed/confirmed babies. These will also form the basis for the case-based congenital syphilis surveillance. The summary of the key indicator framework for EVTHS is depicted in figure 13.3.1.

Figure 13.3.1: Summary of key indicator framework for EVTHS



The table 13.3.2 below details the key indicator framework in five sub-sections, namely, impact indicators (HIV), impact indicators (Syphilis), process indicators (common), process indicators (HIV) and process indicators (Syphilis). These indicators would anchor the progress on EVTHS at the national and State level. The process indicators of this framework would be also used for the monitoring at the district level, albeit with facility-level denominators. More indicators may be used for monitoring the progress by State and district depending upon the context and availability of data elements in the MIS.

Each indicator is presented in terms of indicator name, definition, programme areas, data items (largely referring to numerators and denominators) and data source. The programme areas refer to pre-conception care, screening and diagnosis, treatment services for pregnant and breastfeeding women infected with HIV and/or Syphilis and services for exposed infants.

Table 13.3.2: Key indicator framework for EVTHS

S No	Indicator	Definition	Programme areas	Data items	Source
Impact Indicators (HIV)					
IH1	Case rate	Case rate HIV infections due to vertical transmission per 100,000 live births (Population-level)	Cross-cutting	Estimated annual new vertical HIV infections. Estimated annual live births	Spectrum
IH2	Vertical transmission rate	Estimated percentage of children newly infected with HIV from vertical transmission among women living with HIV delivering in the past 12 months (Population-level)	Cross-cutting	Estimated annual new vertical HIV infections. Estimated annual births to women living with HIV	Spectrum
Impact Indicators (Syphilis)					
IS3	Case rate	Case rate of congenital syphilis per 100,000 live births (Population-level)	Cross-cutting	Number of congenital syphilis cases (live births and stillbirths) in the past 12 months. Estimated annual live births.	SOCH, Congenital Syphilis Estimation Tool SOCH; HMIS; Spectrum
Process Indicators (Common)					
PHS1	ANC services coverage rate	The proportion of pregnant women (PW) women who attended at least one antenatal care visit (Population-level)	Antenatal care services	Annual number of women aged 15–49 receiving at least one visit for ANC care. Estimated number of Pregnant women	NFHS, HMIS/RCH Portal

S No	Indicator	Definition	Programme areas	Data items	Source
Process Indicators (HIV)					
PH2	HIV testing coverage	The proportion of pregnant women tested for HIV (Population-level)	Screening and diagnosis services	Number of pregnant women who had an HIV test during pregnancy or delivery. Estimated number of Pregnant women	HMIS/RCH Portal HMIS
PH3	ART coverage in pregnant WLHIV	Proportion of HIV-positive pregnant women who received ART during pregnancy and/ or at labour and delivery (population based)	Treatment services	Number of pregnant WLHIV who received ART during pregnancy and/or at labour and delivery. Estimated annual births to women living with HIV.	SOCH Spectrum
PH4	ART Retention in pregnant WLHIV	Proportion of known HIV positive pregnant women retained on treatment at time of delivery.	Treatment services	Number of known HIV positive pregnant women who were retained on-ART at the time Number of known WLHIV who became pregnant when already on ART and delivered during the reporting period.	SOCH
PH5	Viral suppression at 32-36 weeks of gestation	Proportion of pregnant WLHIV who are virally suppressed at 32-36 weeks of gestation.	Viral load suppression	Number of pregnant on-ART WLHIV who were virally suppressed (VL <1000 copies/ml) at 32-36 weeks of gestation. Number of pregnant on-ART WLHIV who had a VL test during 32-36 weeks of gestation.	SOCH
PH6	ART retention among WLHIV with babies upto age of 2 years	Proportion of surviving HIV-exposed babies whose mothers are receiving ART at 12 (and 24 months) postpartum	Treatment services	Number of surviving HIV-exposed babies whose mothers are receiving ART at 12 (and 24 months) postpartum. Number of surviving HIV-exposed babies attending the age of 12-month (and 24-month).	SOCH

S No	Indicator	Definition	Programme areas	Data items	Source
PH7	Unmet need for family planning	Proportion of WLHIV who are fecund and sexually active but are not using any method of contraception, and report not wanting any more children or wanting to delay the next child.	Family planning services	WLHIV (1) are not pregnant and not postpartum amenorrhoeic, are considered fecund, and want to postpone their next birth for 2 or more years or stop childbearing altogether, but are not using a contraceptive method, or (2) have a mis-timed or unwanted current pregnancy, or (3) are postpartum amenorrhoeic and their last birth in the last two years was mis-timed or unwanted. All currently married WLHIV, and sexually active unmarried WLHIV age 15-49.	PLHIV Surveillance
PH8	Modern Contraceptive Prevalence in WLHIV (15-49 yrs)	Proportion of WLHIV (15-49yrs) who are fecund, sexually active and currently using any modern method of contraception (spacing or limiting)	Family planning services	Number of WLHIV (15-49 yrs) who are fecund, sexually active and currently using any modern method of contraception (spacing or limiting). Total Number of WLHIV (15-49 yrs) who are fecund and sexually active.	SOCH
PH9	Infant ARV prophylaxis coverage	Proportion of HIV-exposed newborns who were initiated ARV prophylaxis within 72 hours of birth	Services for exposed babies	Number of HIV-exposed babies who were started on ARV prophylaxis within 72 hours of births. Number of live births among HIV-positive women within the past 12 months.	SOCH
PH10	Early infant diagnosis (EID) coverage	Proportion of HIV-exposed babies who receive a virological test for HIV within two months of birth (population level coverage)	Services for exposed infants	Number of babies who received an HIV test within two months of birth during the reporting period. Estimated number of HIV-positive women who had a birth during the reporting period.	SOCH Spectrum

S No	Indicator	Definition	Programme areas	Data items	Source
PH11		Proportion of HIV-exposed babies who receive a virological test for HIV in <6 months of birth	Services for exposed infants	Number of babies who received an HIV test in <6 months of birth during the reporting period. Number of surviving HIV-exposed babies who attended age of one year in the reporting period.	SOCH
PH12		Proportion of HIV-exposed babies who receive a test for HIV in >6 months of birth	Services for exposed infants	Number of babies who received an HIV test in >6 months of birth during the reporting period. Number of surviving HIV-exposed babies who attended age of one year in the reporting period.	SOCH
PH13	Final outcome of PMTCT	Proportion of HIV-exposed infants whose final HIV outcome status is known	Services for exposed infants	HIV-exposed infants born attending age of 18-24 months who have known final HIV outcome status. Number of surviving HIV-exposed babies who attended age of 18-24 months in the reporting period.	SOCH
PH14	Feeding Practices by age	Percent distribution of children under 3 years, borne to WLHIV, by feeding practices by age	Services for exposed infants	Number of children (in age groups), borne to WLHIV, who are not breastfeeding/exclusively breastfeeding/ breastfeeding with complementary foods. Number of children by age groups.	SOCH PLHIV Surveillance
Process Indicators (Syphilis)					
PS2	Syphilis testing coverage	Proportion of pregnant women with at least one test for Syphilis (Population-level).	Screening and diagnosis services for PW/Spouse	Number of PW attending antenatal care services who were screened /tested at least once for syphilis. Estimated number of Pregnant women	HMIS/RCH Portal HMIS
PS3	Syphilis positivity among Pregnant Women	Proportion of PW tested positive for syphilis.	Screening and diagnosis services for PW/Spouse	Number of PW who tested positive/reactive for syphilis. Number of ANC attendees who were screened/ tested for syphilis	HMIS/RCH Portal

S No	Indicator	Definition	Programme areas	Data items	Source
PS4	Adequate syphilis treatment coverage	Proportion of syphilis sero-positive PW who received adequate treatment.	Treatment services for PW/Spouse	Number of PW attending ANC services with a positive/ reactive syphilis test who received at least one dose of benzathine penicillin 2.4 mU intramuscularly. Number of PW attending ANC services who were reactive/positive for syphilis.	SOCH
PS5	Complete syphilis treatment coverage	Proportion of syphilis sero-positive PW who received complete treatment.	Treatment Services for PW/Spouse	Number of PW attending ANC services with a positive/ reactive syphilis test who received three doses of benzathine penicillin 2.4 mU intramuscularly. Number of PW attending ANC services who were reactive/positive for syphilis.	SOCH
PS6	Partner testing coverage	Proportion of syphilis reactive PW with at least one partner screened for syphilis.	Screening and diagnosis services for PW/Spouse	Number of syphilis-reactive PW with at least one partner screened for Syphilis. Number of PW attending ANC services who were reactive/positive for syphilis.	SOCH
PS7	Pregnancy Outcome (Syphilis-exposed Infants)	Proportion of live births among syphilis positive PW who completed 20 weeks of gestation	Pregnancy outcome	Number of live births reported among syphilis positive/reactive PW. Number of syphilis positive/reactive PW who completed 20 weeks gestation.	SOCH
PS8	Non-treponemal test coverage among PW at delivery	Percentage of syphilis reactive/positive PW who were tested with non-treponemal test (RPR/VDRL) at delivery	Screening and diagnosis services for PW/Spouse	Number of PW attending ANC services with a positive syphilis test during ANC care and retested for syphilis using non-treponemal test at delivery. Number of PW attending ANC services with a positive/reactive syphilis test during ANC.	SOCH

S No	Indicator	Definition	Programme areas	Data items	Source
PS9	Non-treponemal test coverage among Syphilis-exposed infants	Percentage of Syphilis-exposed newborns who were tested for congenital syphilis using non-treponemal test at-birth	Services for exposed infants	Number of newborns who received a non-treponemal syphilis test at birth. Number of live births among Syphilis reactive/ positive PW.	SOCH
PS10		Percentage of Syphilis-exposed infants who were tested for congenital syphilis using non-treponemal test at 14 weeks	Services for exposed infants	Number of syphilis-exposed infants who received a non-treponemal syphilis test at age of 14 week. Number of surviving Syphilis-exposed infants attending the age of 14 weeks.	SOCH
PS11		Percentage of Syphilis-exposed infants who were tested for congenital syphilis using non-treponemal test at 6 months	Services for exposed infants	Number of syphilis exposed infants who received a non-treponemal syphilis test at age of 6 months. Number of surviving Syphilis-exposed infants attending the age of 6 months.	SOCH
PS12	Diagnosis of Congenital Syphilis	Percentage of infants diagnosed with congenital syphilis	Services for exposed infants	Number of babies diagnosed with congenital syphilis. Number of surviving syphilis-exposed infants tested for congenital syphilis.	SOCH
PS13	Complete treatment coverage of congenital syphilis	Percentage of infants diagnosed with congenital syphilis received complete treatment	Services for infants diagnosed with CS	Number of infants diagnosed with congenital syphilis received complete treatment for 10 days (curative treatment) Number of infants diagnosed with congenital syphilis	SOCH

13.4. MIS systems for EVTHS indicator framework

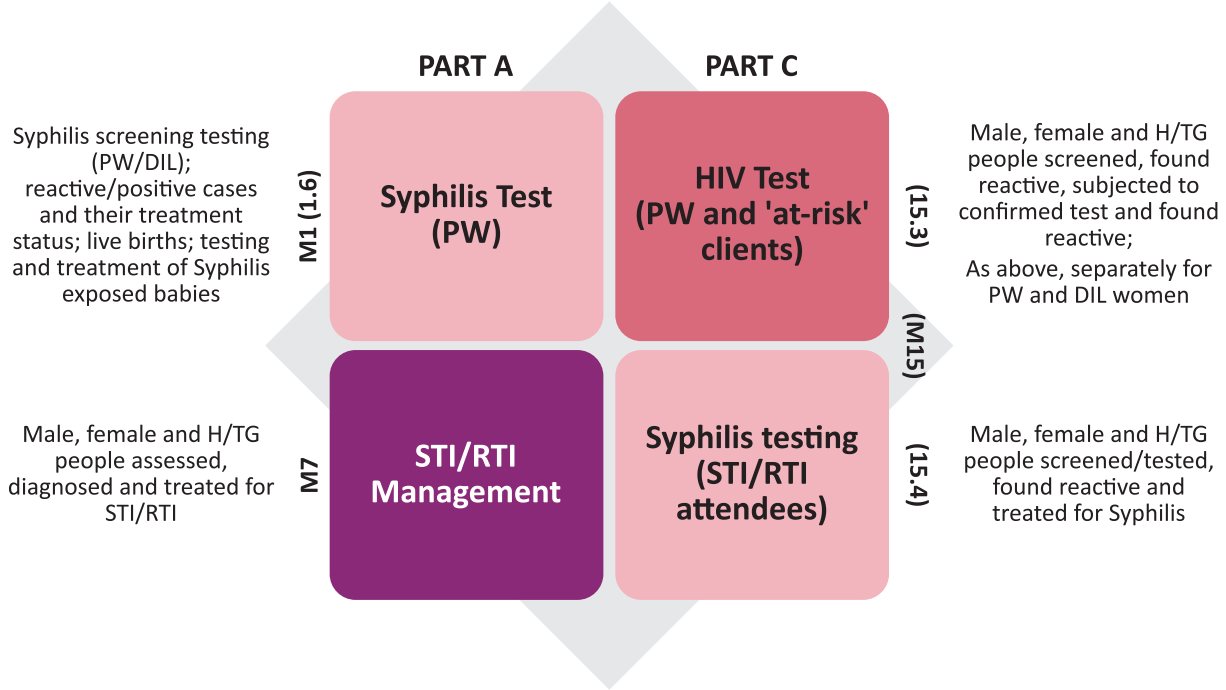
HMIS

The aggregated monthly reporting format of HMIS, capturing data from all the health facilities, will be the basis for measuring the progress on various indicators. The format reports on various aspects of national health programmes in six parts. These parts, denoted as part A, part B, part C, part D, part E and part F cover the areas of reproductive and child health, national programmes, health facility services, mortality details, quality control and inventories respectively. Data items for EVTHS-related indicators in HMIS are reported in parts A and part C.

Specifically, the current format of HMIS has EVTHS related indicators in domains of pregnant women with syphilis (section M1 in part A) and HIV testing (section M15 in part C). The format also has reporting indicators in the domain of management of STI/RTI management and HIV and Syphilis screening/ testing of at-risk persons. Overall, there are 45 indicators related to NACP in the current format of HMIS (Figure 7.6). The indicators under the HMIS would further evolve based on insights from implementation experiences and programmatic needs. Guidance notes on the updates in indicators under HMIS would be released as and when required.

HMIS is the report of the establishment (SC, PHC, CHC, DH, MC etc.) for the defined indicators across national health programmes. Every facility providing services in the context of assessment, screening/ testing and management for HIV, Syphilis and STI/RTI shall include their progress on NACP related indicators in the monthly HMIS report of the establishment concerned based on the applicability (Figure-13.4.1). This shall include service delivery points in NACP like confirmatory HIV counselling and testing centres, Designated STI/RTI Clinics (DSRC) and Sampoorna Suraksha Kendras. It would be the responsibility of one of the NACP supported counsellors/laboratory technicians to get the number for NACP related indicators to be included in establishment HMIS report after collating from all concerned. Further details may please be seen at https://hmis.mohfw.gov.in/#!/

Figure 13.4.1: NACP-related indicators in HMIS



HMIS will be the primary data source for measuring the progress on indicators of ANC visits (PHS1), HIV testing (PH2) and Syphilis testing (PS2) being the reporting system with the highest reach. HMIS will be also the key data source for providing information on the estimated number of pregnant women. The HMIS informed progress on ANC visits (PHS1) would also be triangulated by corresponding rounds of the National Family Health Survey as and when available.

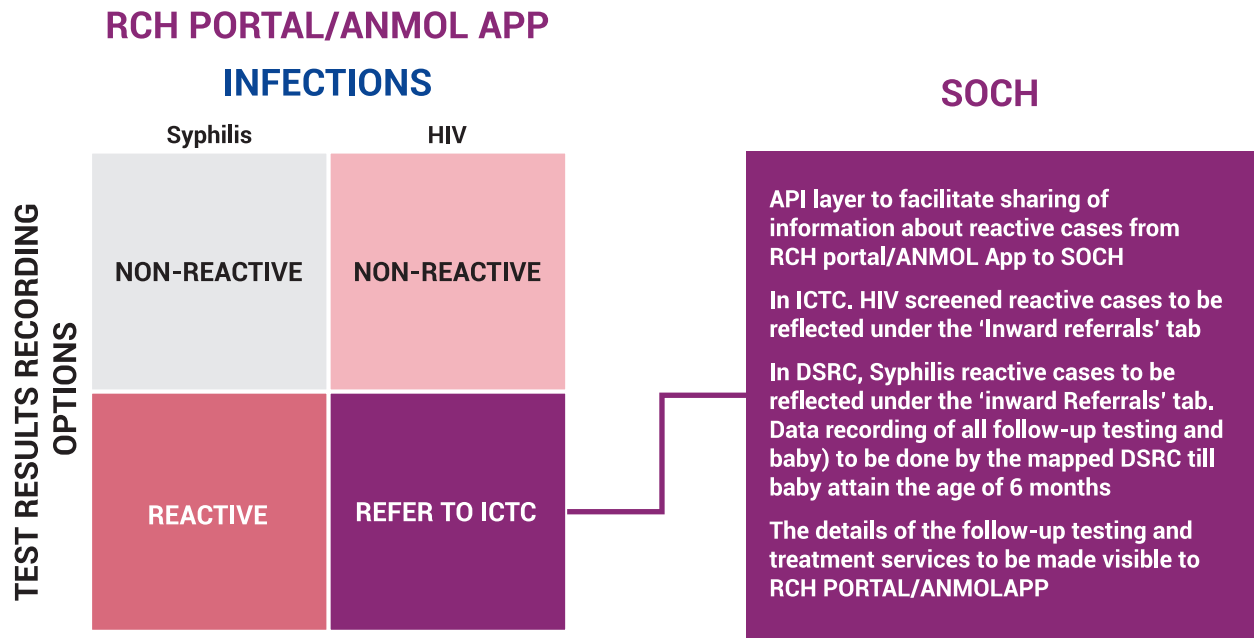
NACP officials at District, State and National levels will access the data reported in HMIS through dedicated login credentials for the HMIS portal. NACP will also make all the efforts to develop an application programming interface (API) for automating the flow of information from HMIS into the SOCH. This will help the officials in accessing all the required data to monitor the progress of EVTHS related indicators in the unified SOCH portal of NACP.

RCH portal/ANMOL App

While aggregated data reported through HMIS will be the primary data source for measuring the progress on indicators of ANC visits and HIV and Syphilis screening/testing, the EVTHS indicator framework strongly encourages engagement with the persons-based digital health information system of the RCH portal/ANMOL App augmenting the quality of data with better handling of issues like double counting.

Integrated RCH register (Version 2.0) forms the basis for data entry in the RCH portal/ANMOL App capturing the service delivery details for eligible couples, pregnant women, and children at the village/ field level. The register has a summary sheet capturing the profile of coverage areas followed by five sections. section A is for eligible couple/pregnant women registration and subsequent tracking of services, section B is for child registration and subsequent tracking of services, section C is about ASHA incentive, section D is for record of logistics & supply and section E is related to annexures like national immunization schedule, job aid for calculation of LMP and EDD and Aadhaar consent form. Further details may please be seen at https://rch.nhm.gov.in/RCH/

Figure 13.4.2: Interoperability between ANM portal/ ANMOL App with SOCH



Under the section A of the integrated RCH register, details for HIV and Syphilis screening/testing are captured under the ANC services. For Syphilis, the details captured includes the date of test and result

type (reactive and non-reactive). For HIV also (HIV screening test), the details include date of test and result type. The result type is captured in the form of "non-reactive" and "refer to ICTC".

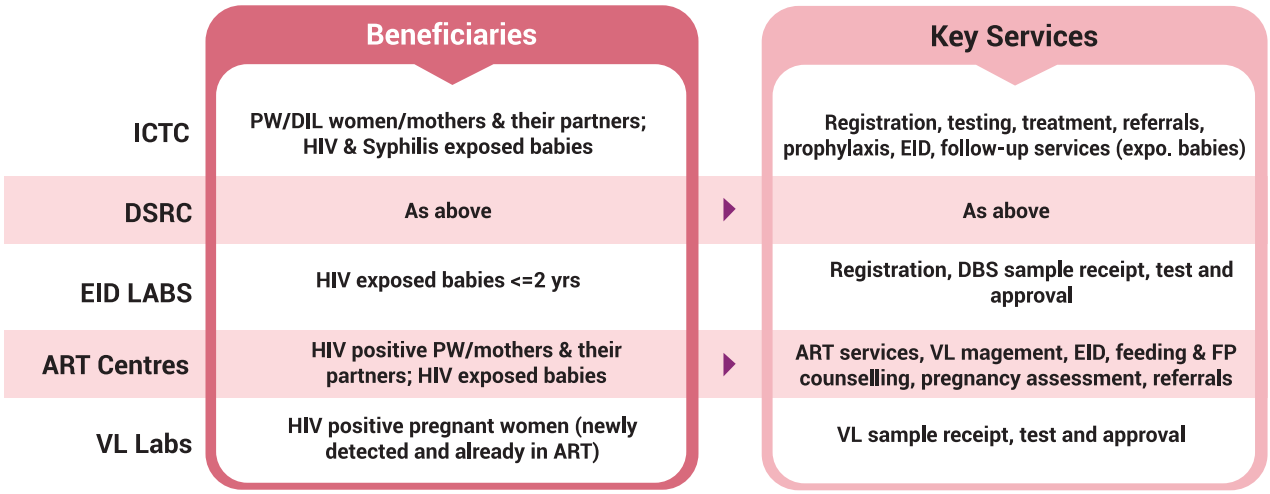
EVTHS M&E framework aims to capitalize the provisions available in RCH portal. Given that uptake of RCH portal/ANMOL is increasing, the use of this system for informing indicators of registrations and HIV and Syphilis screening/testing shall be done in phased manner by State. However, information about the cases with screened reactive results would be also transitioned to ICTC and DSRC module of SOCH through API using push or pull mechanism (Figure 13.4.2). This will be critical to anchoring and ensuring of follow-up testing and treatment services to the reactive pregnant women.

The current format of integrated RCH register doesn't have information on the treatment update for Syphilis reactive/positive cases. Similarly, provisions for capturing syphilis testing status of pregnant women/newborn at the time of delivery is lacking. NACP will work with NHM to work-out the incorporation of minimum data items required for augmented reporting of HIV and Syphilis reactive cases in the RCH portal/ANMOL App.

SOCH

SOCH, the IT-enabled MIS for recording and reporting the transaction of services under NACP by beneficiaries, has five main modules corresponding to the related service delivery points in the context of the EVTHS-related functions. These include that of ICTCs, DSRCs, EID labs, ART, and viral load laboratories. The data recorded under each of these modules is by person covering all the transactions as mandated for the service delivery point (Figure 13.4.3). Data reporting in SOCH would be also supported through registers and formats like counselling registers, White Card, Green Book, Dispensation Book etc. to facilitate quality data management.

Figure 13.4.3: EVTHS-related modules, target groups and key services in SOCH



ICTC

Currently, there are around 4,450 confirmatory HIV counselling and testing registered in the SOCH portal. Key services that can be recorded in the ICTC module of SOCH are of registration (direct and in-wards referral), sample collection, testing, out-referrals and spouse registration/testing.

From the EVTHS perspective, the key beneficiaries in the ICTC module of EVTHS include pregnant/ direct-in-labour women/mothers with babies aged <=2 years and their sexual partners and exposed babies <=2 years. SOCH can register the EVTHS related beneficiaries directly or through inward

referrals from other facilities. Once registered, the adult clients' test results will be recorded followed by the recording of various other details in the post-test counselling page. The recording of details on the post-test counselling page includes a recording of details about the Syphilis testing, results, and adequate treatment status (Table-13.4.1).

For HIV positive pregnant/DIL/ mothers with babies aged <=2 years, SOCH will create a list to record the details of the pregnancy outcomes. The outcome of live births would be automatically pushed for beneficiary registration with a pre-populated mother's ID and treatment details. The registration details will also include prophylaxis administration and feeding practices details. These registered cases of exposed babies would be available for recording the data for EID testing protocol in line with the programme guidelines. At each of the EID sample collection dates, the details of the feeding practices would be also captured. The results would be recorded under the EID DBS and EID anti-body test results tab. For EID cases noted as HIV positive as per the programme guidelines, the cases would be transferred to ART centres for treatment services from the EID test results tab (DBS and antibody).

The ICTC module in SOCH will also have the provisions to track and record the details of services provided to Syphilis reactive mothers and their babies. The post-test counselling page in ICTC will record the Syphilis testing and referral and linkages to DSRC/treatment facility for all pregnant women and mothers. All the cases which are recorded as reactive/positive for Syphilis would be reflected in the follow-up due list for elimination of congenital syphilis. While updating the due list for Syphilis would be primarily the responsibility of the DSRC counsellor, the provision would be also available with the ICTC counsellor to update the list in case the need arises.

The due list will also include the cases referred through the RCH portal/ANMOL App as well as those whose syphilis status is unknown. The due list would enable recording the details of follow-up services by a counsellor, including that for follow-up confirmatory RPR/VDRL testing services, RPR/VDRL testing services of PW and the live births at the time of delivery and follow-up RPR/VDRL testing and treatment services at age of 14 weeks and 6 months.

Figure 13.4.4: depicts the Core EVTHS-related data recoding domains in the ICTC and DSRCs module of SOCH.

Figure 13.4.4: Core EVTHS-related data recoding domains in ICTC and DSRCs module of SOCH

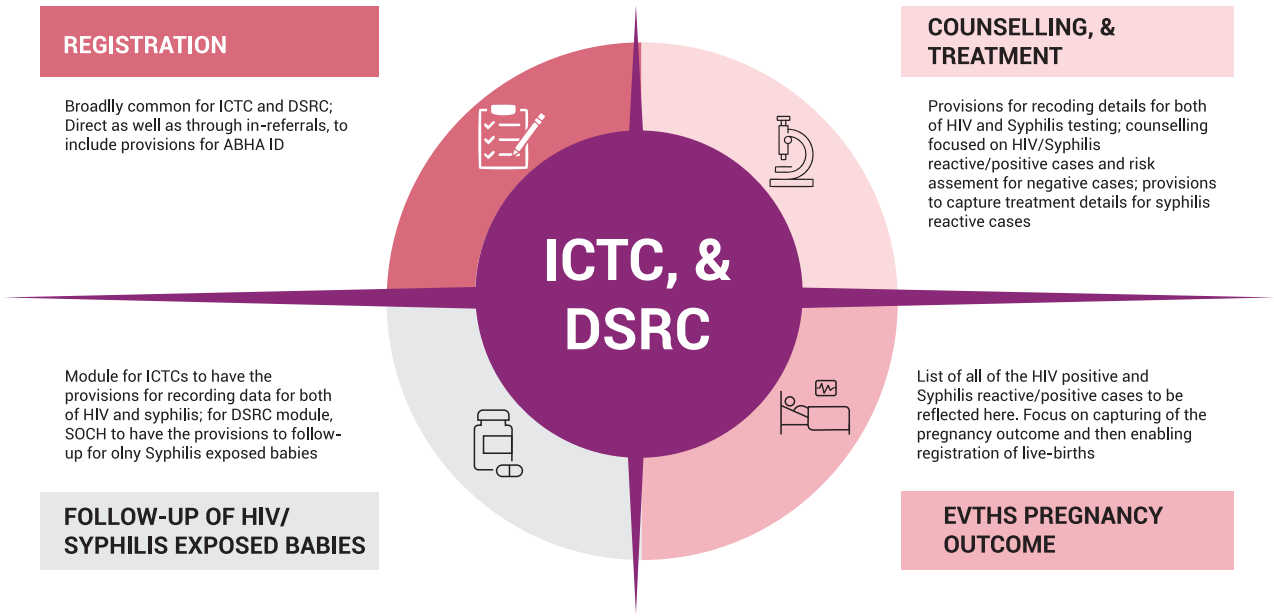


Table 13.4.1: Minimum data elements for EVTHS in the ICTC module and DSRC module

Registration, counselling, and testing (Adult)						HIV and/or Syphilis-exposed babies		
Registration	**Testing**		**Counselling**		**EVTH pregnancy outcome follow-up list**	**Registration (in DSRC, registrations only for Syphilis babies)**	**Testing (HIV) (Only in the ICTC module)**	**Testing (Syphilis) (Both in ICTC and DSRC module)**
	HIV	**Syphilis**	**Positive/Reactive**	**Negative/ non-reactive/ indeterminate**				
Visit date	Date (Tested and result posted)		Result received date	Risk profile	Identifiers (pre-populated)	Visit date	EID <6 months (sample collection, type, dispatch, result-view for DBS); referral to ART for confirmed DBS	RPR/VDRL at-birth (test date and results); Assessment and treatment details
Type of clients (PW/DILW/ Mother/HIV-exposed/ Others)	Test type (Rapid/Dual/ WB)	Test type (RPR/ VDRL/ Dual/PoC)	LMP and EDD	Out-referral	HIV status (pre-populated)	Type of baby (HIV-exposed baby/ Syphilis-exposed baby/both)	EID >6 months but less than 18 months (sample collection, type, dispatch, result-view for DBS & entry for antibody), referral to ART for confirmed DBS	RPR/VDRL at 14 weeks (test date and results); assessment and treatment details

Registration, counselling, and testing (Adult)						HIV and/or Syphilis-exposed babies		
Registration	**Testing**		**Counselling**		**EVTH pregnancy outcome follow-up list**	**Registration (in DSRC, registrations only for Syphilis babies)**	**Testing (HIV) (Only in the ICTC module)**	**Testing (Syphilis) (Both in ICTC and DSRC module)**
	HIV	**Syphilis**	**Positive/Reactive**	**Negative/ non-reactive/ indeterminate**				
Source of referral	Result (Positive/ reactive, negative/ non-reactive, indeterminate)	Result (Reactive/ Non-Reactive) with titres, treatment monitoring after 3 months	RoT (HIV-positive cases)		Syphilis status (pre-populated)	Source of referral	EID> 18 months (sample collection, testing and entry with dates), referral to ART for treatment for confirmed positive; Referral to ART for viral load for indeterminate results, five test sample collection steps for Discordant results	RPR/VDRL at 6 months (test date and results); assessment and treatment details
Beneficiary identifiers (name, address, Aadhar, mobile)	HIV type (HIV I, HIV, HIV I & II)	Titre (RPR/ VDRL)	Treatment details (Syphilis)		LMP (pre-populated)	Identifiers		
ABHA ID			Partner status (HIV and Syphilis)		EDD (pre-populated)	ABHA ID		
Age			Out-referral		Pregnancy outcome and date	Prophylaxis Status (HIV)		

Registration, counselling, and testing (Adult)						HIV and/or Syphilis-exposed babies		
Registration	**Testing**		**Counselling**		**EVTH pregnancy outcome follow-up list**	**Registration (in DSRC, registrations only for Syphilis babies)**	**Testing (HIV) (Only in the ICTC module)**	**Testing (Syphilis) (Both in ICTC and DSRC module)**
	HIV	**Syphilis**	**Positive/Reactive**	**Negative/ non-reactive/ indeterminate**				
Education						Feeding type		
Marital Status						Mothers' details (ART/ Syphilis)		
Occupation (Self/partner)						Consent Status		
Consent Status						PID number		
PID number								

DSRC

Like ICTCs, the SOCH module for DSRC would also have provisions for recording the services provided in terms of registration, Syphilis testing, its results and treatment status (for Syphilis reactive cases). The provisions for recording of the Syphilis related data will be primarily the responsibility of DSRC. SOCH MIS will also evolve to allow the recording of services like HIV screening using dual test kits and subsequent follow-up services for reactive cases. Syphilis-exposed infants will be captured at DSRC as a follow-up. (Figure 13.4.5 and Figure 13.4.6). However, the DSRC module will not have any provisions for registering HIV-exposed babies or offering any EID and related services.

Figure 13.4.5: EVTHS related key services and data items at DSRC SOCH Module when inward referral from ICTC

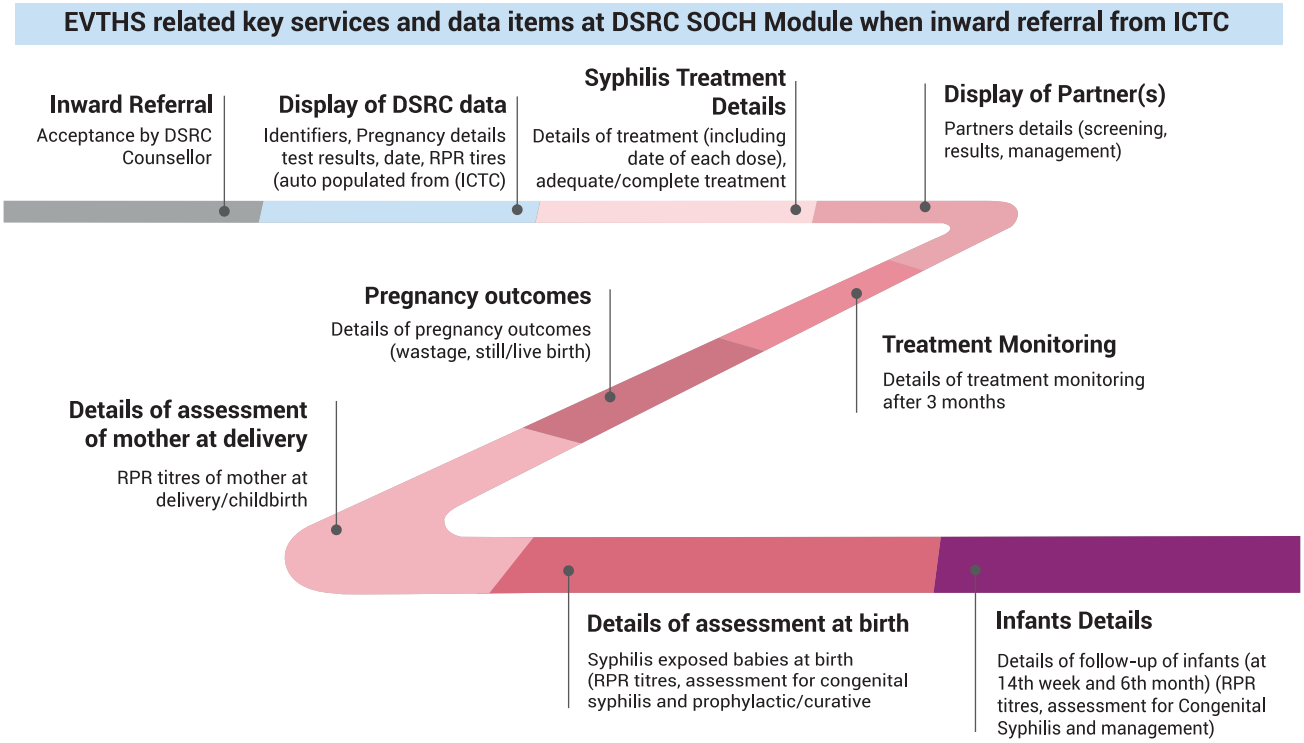
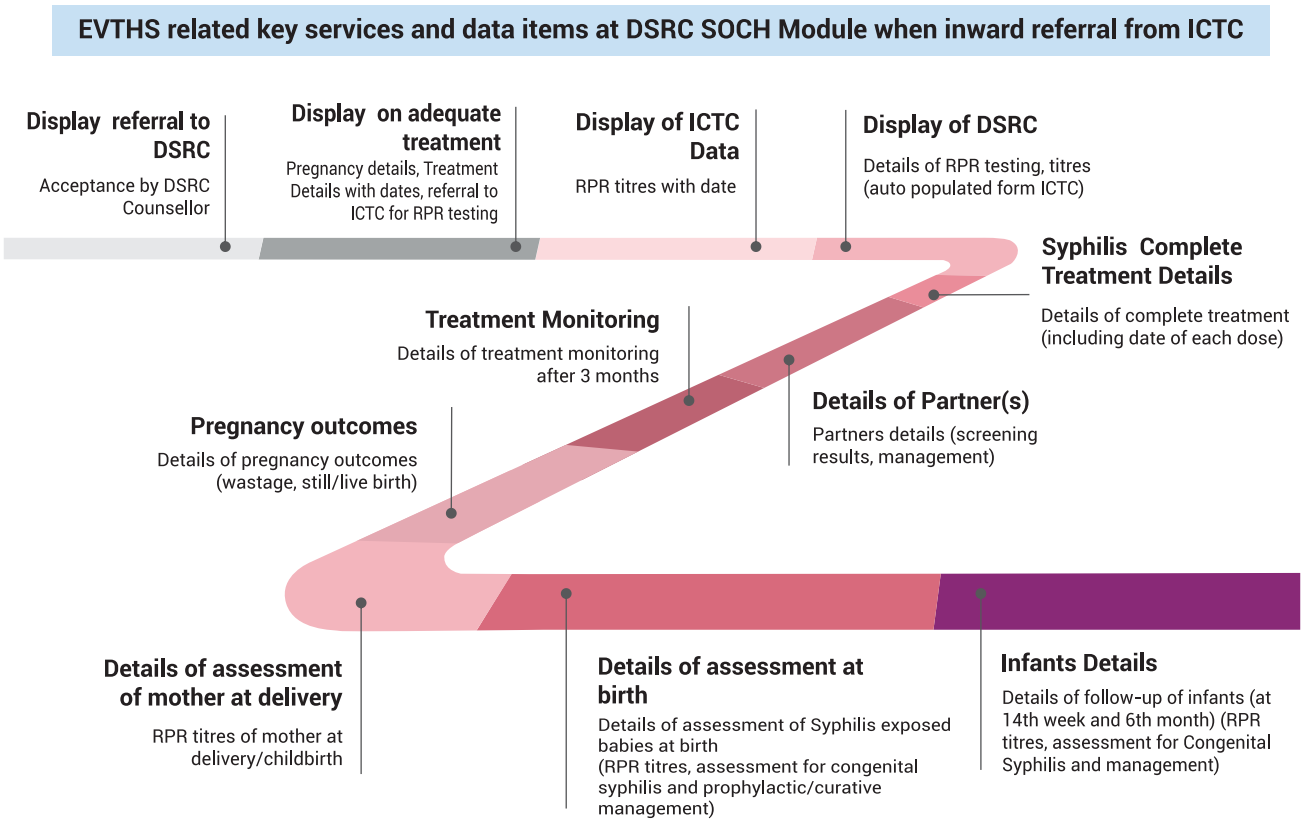


Figure 13.4.6: EVTHS related key services and data items at DSRC SOCH Module when referral from screening sites



The table 13.4.2 describes the EVTHS related flow and key data items in the DSRC module of SOCH for pregnant women infected with syphilis reflected as direct referral from a screening site (PMSMA, VHSND, CHC, PHC etc.).

Table 13.4.2: EVTHS-related flow and key data items in DSRC module of SOCH for pregnant women referred from screening sites

Data Elements	Roles
Patient ID	DSRC Counsellor
Gravida, Para	
LMP, EDD	
Date of syphilis screening and type of test for screening	
Details on RPR/VDRL titres (baseline) (auto populated from ICTC)	
Details on treatment of PW – on-spot dose, 2nd and 3rd dose (date, details on adequate and complete treatment)	
Details on partner notification, screening and management	
Details on treatment monitoring of PW after 3 months (including RPR/VDRL titres)	

Data Elements	Roles
Details on pregnancy outcome and related complications in syphilis-exposed infants (Abortion/Still Birth/Live Birth – LBW, Prematurity etc.)	DSRC Counsellor
Details on delivery	
Details of RPR/VDRL monitoring at birth (both mother and infant)	
Details on assessment of SEI at birth, 14th week and 6 months (including details on RPR titres and assessment by a pediatrician)	
Details on diagnosis of congenital syphilis and adequate treatment of infants	

The table 13.4.3 describes the EVTHS-related flow and key data items in the DSRC module of SOCH for pregnant women infected with syphilis reflected as inward referral from ICTC

Table 13.4.3: EVTHS-related flow and key data items in DSRC module of SOCH for pregnant women referred from screening sites

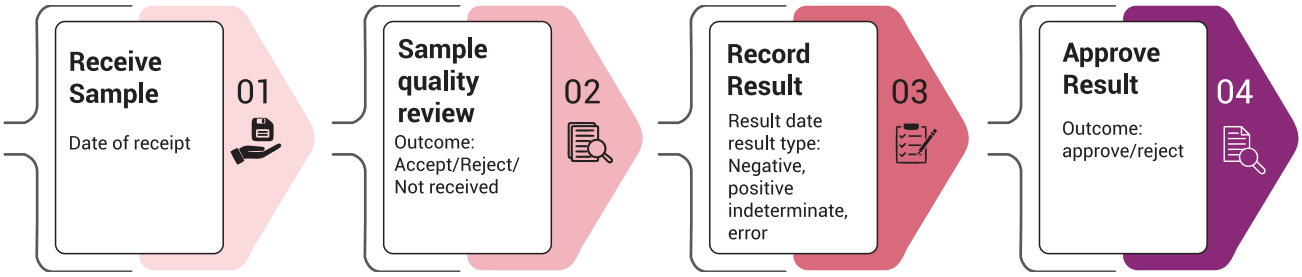
Data Elements	Roles
Patient ID (auto populated from ICTC)	DSRC Counsellor
Gravida, Para (auto populated from ICTC)	
LMP, EDD (auto populated from ICTC)	
Date of syphilis screening and type of test for screening (auto populated from ICTC)	
Details on RPR/VDRL titres (baseline) (auto populated from ICTC)	
Details on treatment of PW – on-spot dose, 2nd and 3rd dose (date, details on adequate and complete treatment)	
Details on partner notification, screening and management	
Details on treatment monitoring of PW after 3 months (including RPR/VDRL titres)	
Details on pregnancy outcome and related complications in syphilis-exposed infants (Abortion/Still Birth/Live Birth – LBW, Prematurity etc)	DSRC Counsellor
Details on delivery	
Details of RPR/VDRL monitoring at birth (both mother and infant)	
Details on assessment of SEI at birth, 14th week and 6 months (including details on RPR titres and assessment by a pediatrician)	
Details on diagnosis of congenital syphilis and adequate treatment of infants	

EID

Currently, there are 6 EID laboratories registered in the SOCH portal. The key EVTHS related functions in the EID module are recording the data for receipt of EID DBS samples (received both from ICTC and ART), quality assurance, results posting and results approval. SOCH in it's current version also allows for registering infants for EID in a scenario where samples are received by an EID lab from an ICTC but data for the same has not been recorded in the SOCH portal. The data items to record the beneficiary details about registration, EID sample collection and dispatch remain the same as those in the ICTC module.

Figure 13.4.7 depicts the EVTHS-related flow and key data items in the EID module of SOCH.

Figure 13.4.7: EVTHS-related flow and key data items in the EID module of SOCH



ART

ART module in SOCH will record the key services crucial for eliminating the HIV transmission risk from mothers to babies during pregnancy/delivery/breastfeeding including that of EID services for the exposed babies. Besides, SOCH will also record the details of the family planning services being offered at ARTC to avoid unwanted pregnancies among WLHIV.

SOCH will tag all sexually active WLHIV in the reproductive age (i.e. 15 -49 yr. of age) and not using the permanent contraceptive method as women in need of EVTHS related services. This will include the WLHIV who are currently pregnant and WLHIV who currently have a baby of <=2 years of age as a specific sub-population cohort.

For WLHIV who were already registered in the ARTC and became pregnant later, the data of such cases would be also mapped to an ICTC for related services like screening of Syphilis, EID testing of exposed babies etc.

In each of the scenarios, the outcome of family planning services like counselling and referral/linkages to the eligible WLHIV as well as use of modern contraceptive methods will be also recorded in SOCH. If a WLHIV in the EVTHS list start using the permanent contraceptive method or passes the reproductive age, she will be automatically shifted to the pool of the rest of the PLHIV.

SOCH will also tag all HIV-exposed children in the age group of <=2 yrs as children in need of EID services and facilitate recording of the EID related data for such children. SOCH will also have the provisions to enable the recording of the EID details in the ART module. The minimum data elements for recording EID details in the ART module will remain the same as those of the ICTC module.

As soon as a child is declared positive through EID, the case will be automatically shifted to the pool of children living with HIV (CLHIV). However, alerts for such CLHIV would be generated for antibody tests as he/she attains the age of 18 months.

The figures 13.4.8, 13.4.9 and 13.4.10 and Tables 13.4.4, 13.4.5 and 13.4.6 below present the key EVTHS-related services and data items in the ART module of SOCH.

The figure-13.4.8 details these aspects for pregnant WLHIV reflected as an in-ward referral from ICTC, Figure 13.4.9 details the same for WLHIV mothers reflected as an in-ward referral from ICTC while Figure 13.4.10 does so for WLHIV in ARTC (aged 15-49 yrs) who are not using a permanent method of contraceptives.

For newly detected pregnant WLHIV whose data have been reflected in the inward referral section in

the ART module, the acceptance as a beneficiary of ARTC will be recorded by the care coordinator (CC)/ counsellor/data manager (DM) roles of the facility by providing a pre-ART number to pregnant WLHIV.

Once the pregnant WLHIV is registered in ARTC, her HIV test details along with the obstetric and Syphilis details will be pulled from the ICTC module and reflected in the login of the Counsellor (and data manager) for review and update, if any. After reviewing the data points, the counsellor will push the records to the lab technician for baseline tests after counselling the WLHIV.

The LT will record the results of baseline investigations and push the data to MO for review and ART initiation. MO would initiate the WLHIV on ART by prescribing a regimen. The ART number and regimen would be entered by DM in SOCH and the data would be referred to the pharmacist who would be doing the dispensation as per the prescription.

The WLHIV would be visiting ARTC every month (or as per the prescription of MO) to collect the ARVs. In each visit, the counsellor would interact with the WLHIV and update the details of the pregnancy outcome in due course. He/she will also refer the data to LT for viral load sample collection as per the guidelines. Based on the outcome of the VL testing, which will be also visible to the linked ICTC for the case, the prophylaxis for the baby will be planned. The data for the outcome of the delivery and prophylaxis administration for live births will be entered by the ICTC counsellor which will also be visible to the ARTC team. Provisions would be available in the ART module of SOCH to enable data entry on the pregnancy outcome and prophylaxis administration for live births. In each of the subsequent visits post-live births, the ARTC counsellor would record the data for the infant feeding and family planning practices.

For WLHIV mothers detected HIV positive after delivery of the baby (aged 2 years or younger), the focus will be on recording the EID and Syphilis details for the baby which would be prioritized in collaboration with the ICTC concerned. The rest of the data items recorded in such cases remain the same as that of a newly detected PW coming to ARTC.

For WLHIV in ARTC (aged 15-49 yrs) and not using a permanent method of contraceptives, the counsellor would record the data for current family planning status and also for the current pregnancy status if no contraceptive method is being used by WLHIV. This will be done by the counsellor in each of the visits of the WLHIV concerned. The pharmacist would also assess the pregnancy status of WLHIV, as in the case of the proxy dispensation. Once the pregnancy of WLHIV is confirmed, the data would be also linked with the ICTC to facilitate the entry of data for EVTHS-related services like that of Syphilis testing and treatment. Subsequent data entry items would broadly remain the same as in the first scenario.

Figure 13.4.8: EVTHS-related key services and data items in ART module of SOCH for pregnant WLHIV reflected as in-ward referral from ICTC

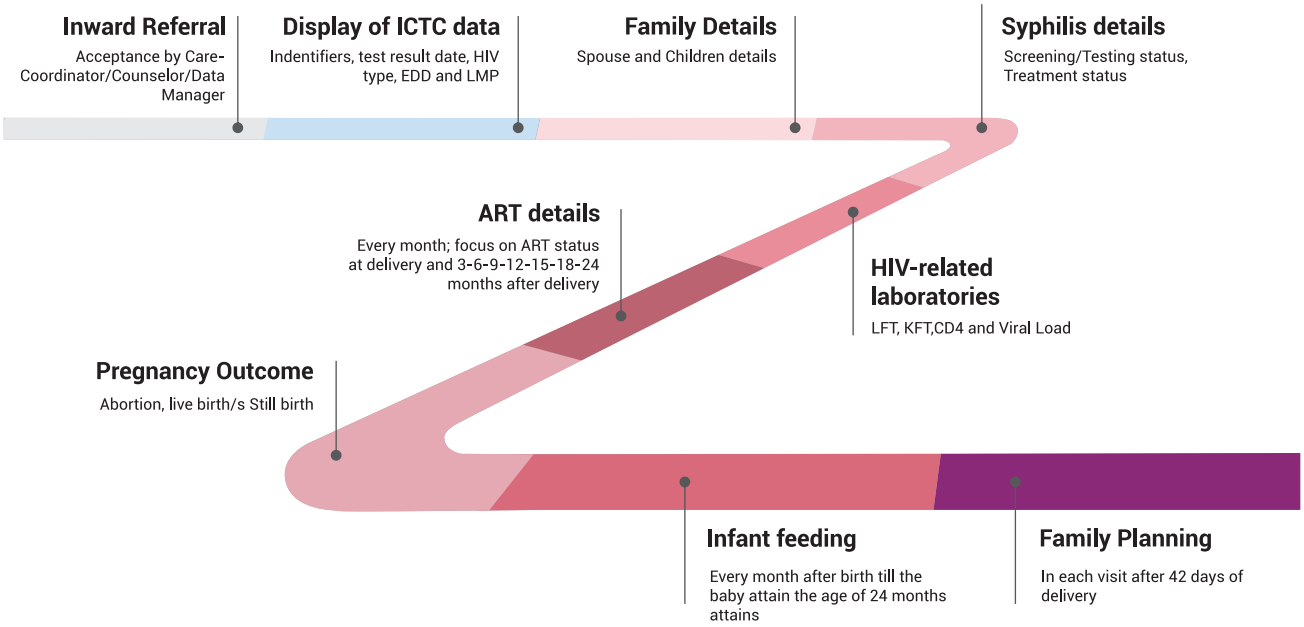


Figure 13.4.9: EVTHS-related key services and data items in the ART module of SOCH for WLHIV mothers reflected as in-ward referral from ICTC

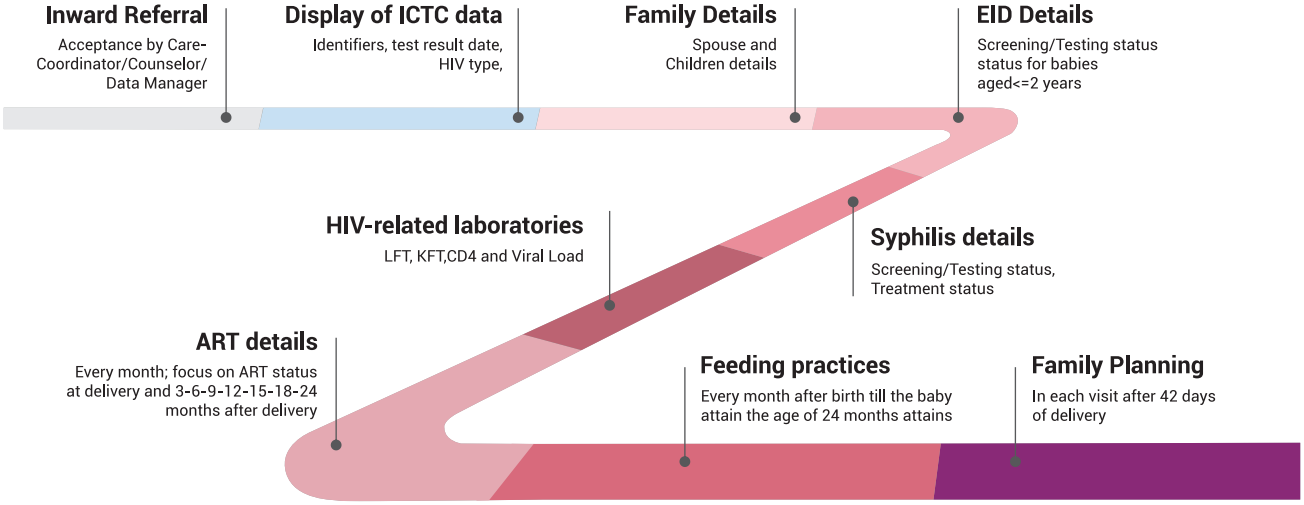


Figure 13.4.10: EVTHS-related key services and data items in the ART module of SOCH for WLHIV in ARTC (aged 15-49 yrs and not using a permanent method of contraceptives)

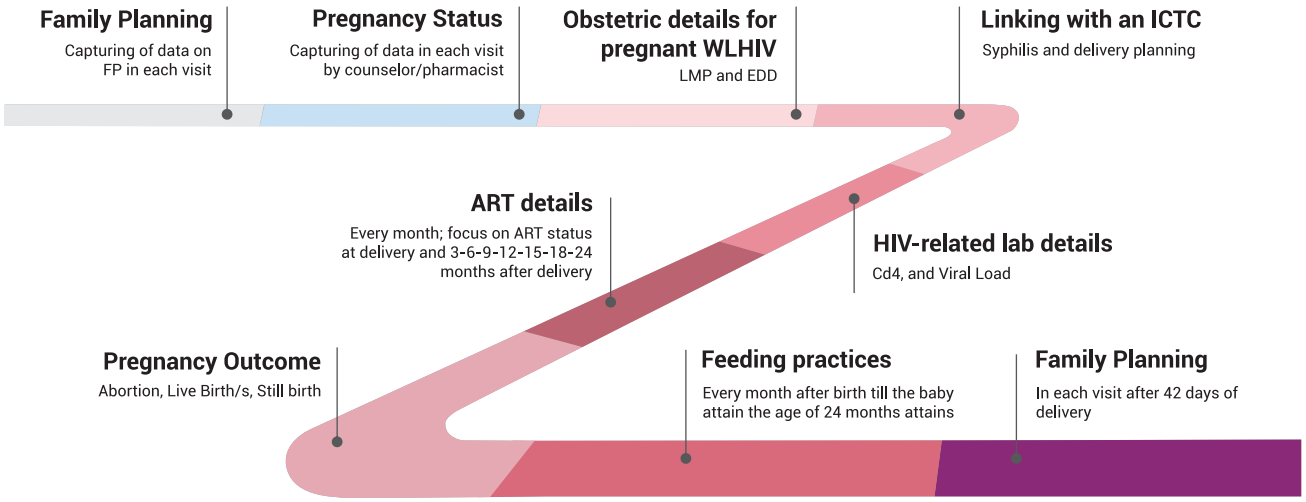


Table 13.4.4: EVTHS-related flow and key data items in the ART module of SOCH for pregnant WLHIV reflected as inward referral from ICTC

Data elements	Related role in ART
Pre-ART number	Care Coordinator (CC)/Counsellor/ Data Manager at the time of doing pre-ART registration of WLHIV
Identifiers (pre-populated to be pulled from the ICTC module)	
Date of confirmed HIV result (pre-populated)	
Gestation months at the time of being detected positive (pre-populated)	
HIV type (pre-populated)	
LMP & EDD (pre-populated)	
Syphilis status (Positive/Negative/Unknown)	
Syphilis Treatment Status (Adequately Treated/Unknown)	
CD4 test details (date of sample collection, date of result, test result)	LT/DM
Viral load test details (date of sample collection, date of result, test result)	LT/DM
Current ART Status	Counsellor/DM
Date of Initiation of ART	Counsellor/DM
ARV regimen	MO/DM
Gestation months at the time of being initiated on-ART	Auto populated
Subsequent ART dispensation (date and dose)	Pharmacist
Pregnancy Outcome (Date and outcome)	Counsellor/DM
ART status at the time of pregnancy outcome	Auto populated
VL Status 0-4 weeks before delivery (suppressed/unsuppressed/unknown)	
VL Status 4-8 weeks before delivery (suppressed/unsuppressed/unknown)	
VL Status 8-12 weeks before delivery (suppressed/unsuppressed/unknown)	
ARV prophylaxis to infant (date and prophylaxis dispensed)	Counsellor (ICTC/ARTC)/DM
Details of CPT initiation and stopping	Counsellor (ARTC)/DM

Data elements	Related role in ART
EID <6 months (sample collection, type, dispatch, result-view for DBS); referral to ART for confirmed DBS and initiated on ART	Primarily responsibility of ICTC. However, provisions available for entry by LT (ART) as and when need arises
EID >6 months but less than 18 months (sample collection, type, dispatch, result-view for DBS & entry for antibody), referral to ART for confirmed DBS and initiated on ART	
EID> 18 months (sample collection, testing and entry with dates), referral to ART for treatment for confirmed positive and initiated on ART; Referral to ART for viral load for indeterminate results, Five test sample collection steps for Discordant results and baby's ART was continued or interrupted	
Infant feeding practices (In each visit till the child attains 24 months of age)	Counsellor/DM
Family planning practices (immediately after delivery and follow every month / visit till the next pregnancy or use of a permanent method of FP)	Counsellor/DM
Reason in case not using any FP method	Counsellor/DM

Table 13.4.5: EVTHS-related flow and key data items in the ART module of SOCH for mothers with children <= 2 years of age reflected as inward referral from ICTC

Data elements	Related role in ART
Pre-ART number	Care Coordinator (CC)/Counsellor/ Data Manager at the time of doing pre-ART registration of WLHIV
Identifiers (pre-populated to be pulled from the ICTC module)	
Date of confirmed HIV result (pre-populated)	
HIV type (pre-populated)	
Date of delivery (pre-populated)	
ARV prophylaxis to infant (date and prophylaxis dispensed))	
Syphilis status (Positive/Negative/Unknown)	
Syphilis Treatment Status (Adequately Treated/Unknown)	
CD4 test details (date of sample collection, date of result, test result)	LT/DM
Viral load test details (date of sample collection, date of result, test result)	LT/DM
Current ART Status	Counsellor/DM
Date of Initiation of ART	Counsellor/DM
ARV regimen at initiation	MO/DM
Subsequent ART dispensation (date and dose)	Pharmacist
EID <6 months (sample collection, type, dispatch, result-view for DBS); referral to ART for confirmed DBS	**Primarily responsibility of ICTC. However, provisions available for entry by LT (ART) as and when need arises**
EID >6 months but less than 18 months (sample collection, type, dispatch, result-view for DBS & entry for antibody), referral to ART for confirmed DBS	
EID> 18 months (sample collection, testing and entry with dates), referral to ART for treatment for confirmed positive; Referral to ART for viral load for indeterminate results, Five test sample collection steps for Discordant results	
Infant feeding practices (In each visit till the child attains 24 months of age)	Counsellor/DM

Data elements	Related role in ART
Family planning practices (immediately after delivery and follow every month / visit till the next pregnancy or use of a permanent method of FP)	Counsellor/DM
Reason in case not using any FP method	Counsellor/DM

Table 13.4.6: EVTHS-related flow and key data items in the ART module of SOCH for WLHIV in ARTC (aged 15-49 yrs and not using a permanent method of contraceptives)

Data elements	Related role in ART
Current use of Family Planning Methods	Counsellor
Current Pregnant (Yes/No)	Counsellor/ pharmacist
Obstetric details if pregnant (LMP, EDD etc.)	Counsellor
Gestation months at the time of being detected positive (pre-populated)	Counsellor
Linkage with an ICTC	Counsellor
Syphilis status (Positive/Negative/Unknown)	To be displayed in counsellor login based on the data entry in ICTC/DSRC
Syphilis Treatment Status (Adequately Treated/Unknown)	
HIV type (pre-populated)	LT
CD4 test details (date of sample collection, date of result, test result)	
Viral load test details (date of sample collection, date of result, test result)	
Current ART regimen	Pharmacist
Subsequent ART dispensation (date and dose)	
Pregnancy Outcome (Date and outcome)	Counsellor
ART status at the time of pregnancy outcome	Auto-calculated
VL Status 0-4 weeks before delivery (suppressed/unsuppressed/unknown)	
VL Status 4-8 weeks before delivery(suppressed/unsuppressed/unknown)	
VL Status 8-12 weeks before delivery(suppressed/unsuppressed/unknown)	
ARV prophylaxis to infant (date and prophylaxis dispensed)	Primarily responsibility of ART LT. However, provisions available for entry by ICTC as and when the need arises.
EID <6 months (sample collection, type, dispatch, result-view for DBS); referral to ART for confirmed DBS	
EID >6 months but less than 18 months (sample collection, type, dispatch, result-view for DBS & entry for antibody), referral to ART for confirmed DBS	
EID> 18 months (sample collection, testing and entry with dates), referral to ART for treatment for confirmed positive; Referral to ART for viral load for indeterminate results, Five test sample collection steps for Discordant results	
Infant feeding practices (In each visit till the child attains 24 months of age)	ART counsellor
Family planning practices (immediately after delivery and follow every month / visit till the next pregnancy or use of a permanent method of FP)	ART counsellor
Reason in case not using any FP method	ART counsellor

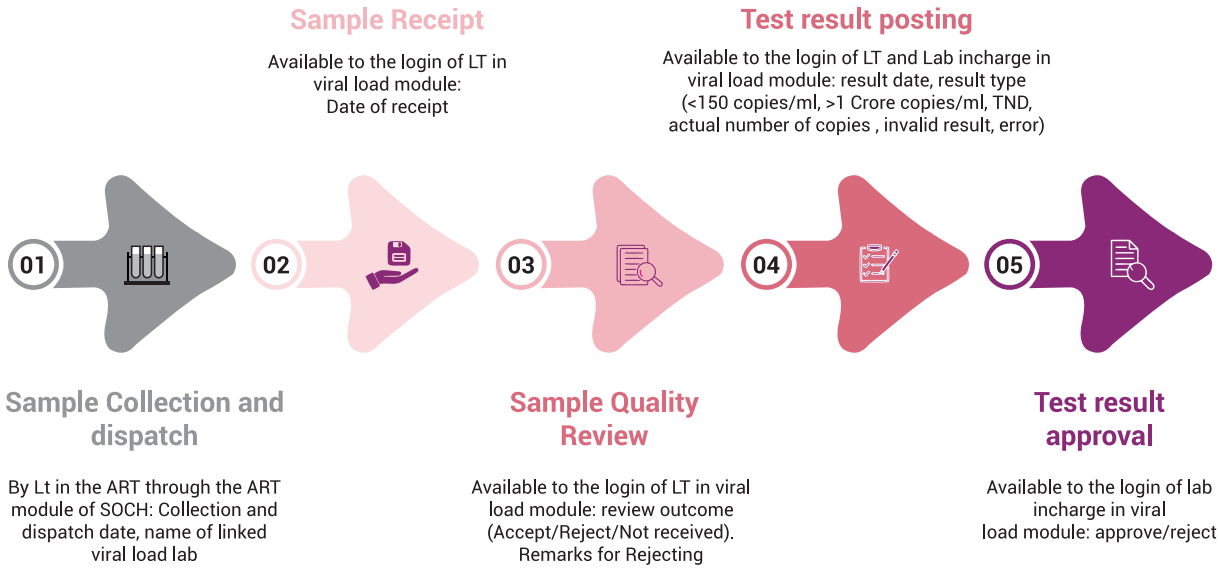
Viral Load Monitoring

Currently, there are 64 viral load laboratories under NACP registered in the SOCH portal. The recording of the data on sample collection for viral load (collection and dispatch date and linked viral load lab) for an eligible PLHIV is done by the ARTC-LT in the ART module of SOCH.

At the linked viral load module, the key is to record the data for receipt of VL samples (received from ART), quality assurance, results posting and results approval. The functions of approving the results are available only in the login ID of the Viral Load Lab in charge.

The progress on viral load testing, as recorded in the VL module of SOCH, is displayed in the ART module suitably. Figure 13.4.11 depicts the Viral load data reporting flow and key data items in the EID module of SOCH.

Figure 13.4.11: Viral load data reporting flow and key data items in EID module of SOCH.



13.5. Data quality assurance system

Ongoing quality data assurance is central to the Strategic Information framework of EVTHS.. Quality data is also one of the four foundational requirements for EMTCT validation.

The MIS systems of HMIS, RCH Portal/ANMOL App, and SOCH, with in-built logical validations, would be fundamental to the quality data from EVTHS perspectives. Reconciliation among data elements generated through these three systems would be crucial. The approach for the data quality system would be bottom-up with district authorities in charge of the data quality assurance system. The ongoing monthly data quality review at the district level would be further supplemented by periodic reviews at State and national levels.

Specifically, the following data elements, to be primarily reviewed by the DISHA/DAPCU team in collaboration with the NHM counterpart, would be key focus areas for reconciliation ensuring correctness and completeness at the facility/district level. More elements may be added to this list as the understanding of the field evolves on the matter.

a. Screening/testing for HIV and Syphilis as reported in HMIS vis-à-vis RCH Portal/ANMOL App (Facility-level)

b. Number reported screened reactive/positive for HIV and Syphilis as reported in HMIS vis-à-vis RCH Portal/ANMOL App (Facility-level)

c. Testing for HIV and Syphilis as reported in confirmatory facilities vis-à-vis number reported in HMIS (Facility-level)

d. Number reported positive for HIV and Syphilis as reported in confirmatory facilities vis-à-vis number reported in HMIS (Facility-level)

e. Number reported screened reactive/positive for HIV and Syphilis in RCH Portal/ANMOL App (Facility-level) vis-à-vis number reflected as inward referral in SOCH (District-level) (Total number and cohort).

Supportive supervision would be a critical element of the data quality assurance system. Cross-checking (comparing the number reported in portals against the source registers); and spot-checking (supervising the real-time delivery of services and its recording in registers/portals) would be core components of the data quality assurance through the supportive supervision.

WHO has specific requirements for quality data as a part of the foundational requirements for EVTHS validation. NACO would undertake an internal assessment of MIS systems given the WHO guidelines to establish a baseline and work out the specific action points for improving the MIS system data vis-à-vis foundational requirements.

13.6. Data management measures

NACP generates considerable amount of data on HIV and AIDS from service facilities across the country through the complementary systems of programme monitoring, surveillance and research. NACO encourages the use of this data for evidence-based programme planning, epidemic monitoring and surveillance, research, etc., at all levels under the programme. NACO also encourages students to use NACP data for their thesis/dissertation work.

In addition to this, many national and international organizations have been involved in HIV and AIDS related work in the country and many of them support respective SACS and/or NACP facilities in various activities. Hence, there is a need for availability of data to all those who are involved in the program.

In compliance with the provisions of the HIV and AIDS (Prevention and Control) Act, 2017, every facility maintaining records of HIV infected and affected population is mandated to adopt adequate data protection measures. Section 11 of the Act ask for maintaining confidentiality of HIV related information of protected person and puts this responsibility on the respective facility to ensure that no data or information is shared without the proper procedure and necessary approvals and consent. (Table 13.6.1)

Table 13.6.1: 'HIV-related information' and 'protected person'

'HIV-related information' and 'protected person'
"HIV-related information" means any information relating to the HIV status of a person, and includes— I. information relating to the undertaking and performing the HIV test or the result of an HIV test; II. information relating to the care, support or treatment of that person; III. information which may identify that person; and IV. any other information concerning that person, which is collected, received, accessed or recorded in connection with an HIV test, HIV treatment or HIV-related research or the HIV status of that person
Protected person" means a person who is— V. HIV-Positive; or VI. ordinarily living, residing or cohabiting with a person who is HIV-positive person; or VII. ordinarily lived, resided or cohabited with a person who was HIV- positive;

In compliance to the provisions of the Act, the facilities offering the EVTHS related services will have following contours in context of the data protection and data sharing.

A. Data Management Committee (DMC)

DMC should be formed at each facility. Concerned DMC is responsible to ensure data security and also to review and provide appropriate recommendation regarding data security measures. Wherever the facility do not have DMC, the head of the facility should be entrusted with the responsibility and function of DMC. Details of composition as well roles and responsibilities at the NACP facility level are given in table 13.6.2

Table 13.6.2: Roles and Responsibilities of Data Management Committee

Composition of DMC At NACP Facility	
Chairperson	Senior and relevant officer of the facility
Members	The committee will have 2 members, one of the members should be representatives from protected person and other from the same facility who deals with the data
Terms of Reference	
• Review of implementation of data protection measures at the respective facility. • Review of data access and data security at the respective facility. • To provide inputs on disposal of physical file/ computer equipment containing HIV related information at the respective facility. • To consider all adverse events related to NACP data reported to the committee. • Any other matter related to NACP data management.	

B. Data protection measures

It is mandatory for every facility that keeps the records of HIV related information of protected persons to adopt all necessary measures to protect the data/information. Data protection measures here include following steps:

- **Protecting information from disclosure of HIV related information:** Confidentiality and privacy is to be maintained while collecting HIV related information. For each facility desirous of collecting the HIV related information, authorized persons or staff should sign an undertaking for data confidentiality.
- **Access to HIV-related information:** Access should be granted only to the authorized persons/ staff after they sign a formal undertaking for confidentiality.
- **Provision for security systems for HIV related information:**
    - There should be secured almirahs or cabinet for physical records like registers, reports etc. which should be carefully locked when not being used.
    - Facility should ensure that computer systems having HIV related information are protected by using appropriate and up-to-date anti-virus and firewall technologies and it is to be kept up- to-date to meet emerging threats.
    - Personal computers or mobiles or tablets or any other hardware with HIV related information should be password protected and should be logged off or 'locked' when not being used.
    - Passwords for hardware, software, databases, etc. should be of sufficient strength. Facilities must also ensure that passwords are changed on a regular basis.
    - A Strong Password must
        - Be at least 8 characters in length
        - Contain both upper and lowercase alphabetic characters (e.g. A-Z, a-z)
        - Have at least one numerical character (e.g. 0-9)
        - Have at least one special character (e.g. ~!@#$%^&*()_-+=)
    - Any software or applications for maintaining the HIV-related information of protected persons in the facility should be explicitly approved by competent authority.
- **Disposal of HIV related information:** Facility should have standard operating procedures (SOPs) in place regarding the disposal of physical and electronic records/files containing HIV related information of protected persons.
- **Accountability and liability** of security of HIV related information should be with Data Management Committees or the head of the concerned facility where DMC is not constituted.

C. Data sharing through shared confidentiality

NACP data is only to be shared by NACO and SACS as per the SOP for NACP data sharing available at NACO website (https://naco.gov.in/sites/default/files/SOP%20for_data_sharing.pdf).

D. Exemption through Shared Confidentiality

- By a health care provider to another health care provider who is involved in the screening/ testing, linkage, care, treatment, support or counselling of HIV and other related disease of such person, when such disclosure is necessary to provide appropriate healthcare to that person

- By an order of a court that the disclosure of such information is necessary in the interest of justice for the determination of issues and in the matter before it
- In suits or legal proceedings between persons, where the disclosure of such information is necessary in filing suits or legal proceedings or for instructing their counsel
- To the officials of the Central Government or the State Government/SACS for the purposes of monitoring, evaluation, and related activities
- If it relates to statistical or other information of a person that could not reasonably be expected to lead to the identification of that person.

In all other scenarios, ***no paper or electronic records containing the HIV-related information*** *of protected persons shall be shared or transferred to other facilities or persons* ***without written informed consent of concerned person or his or her representative.***

E. Monitoring of protected and shared data at facility level

Consistently monitor data access and security, and in case of any concerns or data breach, proactively report them to the Data Management Committee or the Head of the Institution.

The sharing of data between different facilities or organizations must strictly adhere to authorized channels. It is of utmost importance to ensure that shared data is exclusively utilized for healthcare and monitoring purposes and is not disseminated to any unauthorized individuals or organizations. The Dos and Don'ts for NACP Data Management at confirmatory facility and screening facilities are enumerated in table-13.6.3 and table 13.6.4, respectively.

Table 13.6.3: Dos and Don'ts for NACP Data Management at confirmatory facility

Dos	Don'ts
• Grant access to authorized personnel. • Maintain confidentiality during data collection. • All electronic devices should have password protection. • Secure physical records in locked cabinets. • Log off and lock devices when not in use. • Follow SOP for safe physical/ electronic files disposal. • Regularly review of data access/ security; promptly inform the Data Management Committee/ Head of Institution of any issues. • Share NACP data through authorized channels.	• Allow unauthorized personnel to access data/records. • Neglect secure storage and protection measures such as leaving paper/ files accessible to unauthorized individuals. • Use weak passwords not meeting criteria. • Use software/device for NACP data storage without proper approval. • Dispose of data without following the established procedures. • Share data through unauthorized channels. • Neglect to monitor data access regularly.

Table 13.6.4: Dos and Don't for NACP Data sharing at screening facilities

Dos	Don'ts
• Share data for appropriate healthcare between healthcare providers. • Share with Central Government, State Government/SACS for monitoring and evaluation. • Ensure shared data is not further shared with other organizations/individuals. • Maintain responsibility for data security and proper use.	• Share NACP data without proper approval of NACO/ SACS. • Share paper/ electronic HIV-related data with personal information without informed consent, except for healthcare and monitoring purposes.

CHAPTER-14

EVTHS validation framework

EVTHS validation framework

14.1 Background

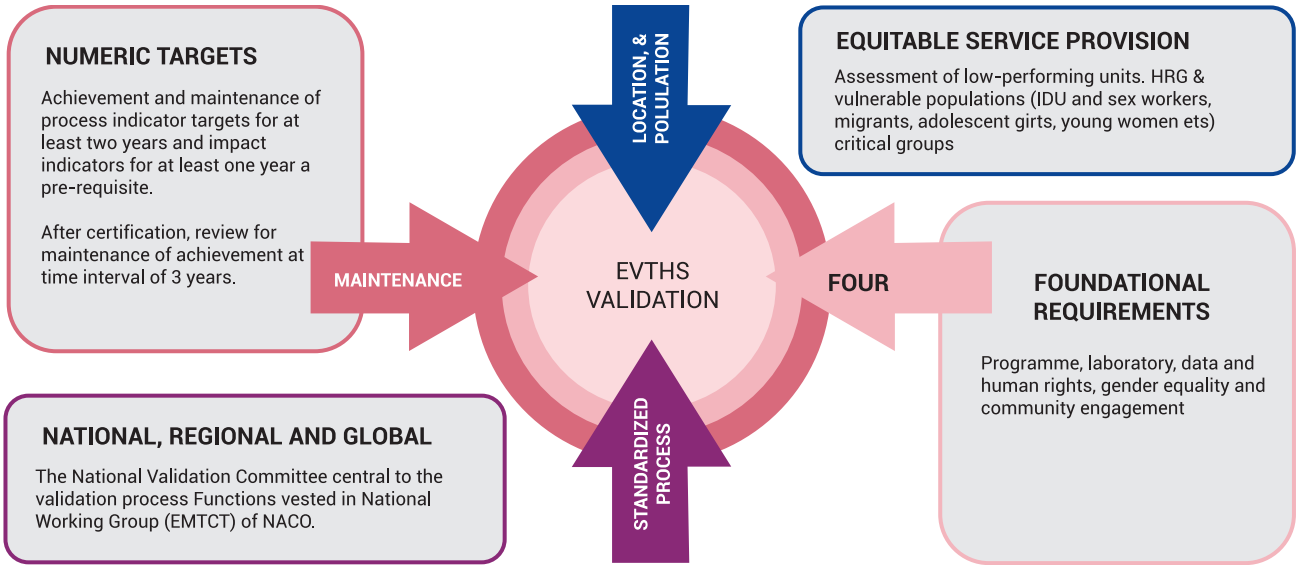
Elimination of the vertical transmission of HIV and Syphilis is the third goal under phase V of the National AIDS and STD Control Programme. The progress towards the attainment of elimination of the vertical transmission of HIV and Syphilis is measured through standard criteria and processes for validation prescribed by WHO in its global guidance. Currently, the third edition of the global guidance, released in 2021, is in implementation[2].

The guidance document has specific processes and impact targets for each of the vertical infections. Evidence of achievement and maintenance of process indicator targets for at least two years and impact indicators for at least one year, at the national level prior is mandatory to submit for EVTHS validation (Figure 14.1.1).

The national-level achievement and maintenance of elimination shall be accompanied by an assessment of low-performing units and of subpopulations with the lowest coverage and access to services. This does not mean that elimination targets are met in the lowest-performing subnational units but there shall be evidence to demonstrate that the low-performing subnational units are being reviewed and substantial efforts are being made to address and improve the service delivery in these units.

[2] https://iris.who.int/bitstream/handle/10665/349550/9789240039360-eng.pdf?sequence=1

Figure 14.1.1: Key elements of EVTHS validation.



High-risk groups (HRG) and vulnerable populations (injecting drug users and sex workers, migrants, adolescent girls, young women, etc.) are critical groups for the attainment of elimination. Women and their partners belonging to these groups may be at higher risk with relatively less access to health care and may be disproportionately represented among pregnant women with late or no ANC. Follow-up in health facilities or the community, including contact tracing, may be challenging, for pregnant women from such groups for various reasons including stigma and mobility. Given the context, the validation process also requires evidence of equitable services provided to key and vulnerable populations.

Once validation is achieved, the maintenance of the same is reviewed periodically to sustain the elimination. For HIV and Syphilis, the review for maintenance of time interval is 3 years. Countries that fail to maintain the prescribed standards on the numeric targets or the foundational requirements may lose their validation status.

14.2 Process and impact targets

The indicators and targets for each of infection has been reproduced in table 14.2.1 below.

Table 14.2.1: Impact and process indicators and targets for EVTHS

Infection	Indicator Type	Indicator	Target
HIV	Impact	HIV mother-to-child transmission (MTCT) rate, and	<5% (breastfeeding populations) OR <2% (non-breastfeeding populations)
		Case rate of new paediatric HIV infections due to MTCT	<50 per 100,000 live births
	Process	ANC-1 coverage (at least one visit)	≥95%
		Coverage of HIV testing among pregnant women	≥95%
		ART coverage of pregnant women living with HIV	≥95%

Infection	Indicator Type	Indicator	Target
Syphilis	Impact	Case rate of Congenital Syphilis (CS)	≤50 per 100,000 live births
	Process	ANC-1 coverage (at least one visit)	≥95%
		Coverage of syphilis testing among pregnant women	≥95%
		Adequate treatment coverage of syphilis-seropositive pregnant women[3]	≥95%

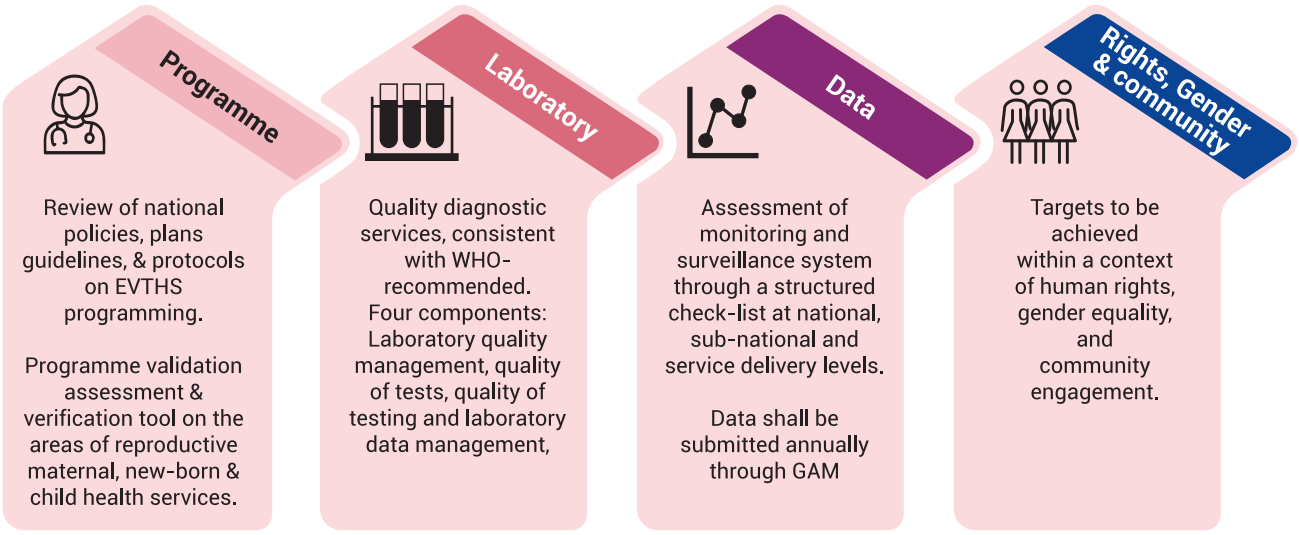
14.3 Foundational requirements

While there are specific numeric targets for EVTHS validation, demonstration of progress on foundational requirements across four thematic areas of programme, laboratory, data and human rights, gender equality and community engagement are a must for validation. The progress on foundational requirements is assessed using standardized tools. These tools are administered to the programme managers, service providers and civil society representatives including women living with HIV to assess the situation at national, sub-national and local/service delivery level. (Figure-14.3.1).

A. **Programme:** The validation process reviews the relevant national policies, plans, guidelines, and protocols on EVTHS programming, assess evidence that services exist in both public and non-public sectors and complete the programme validation assessment and verification tool on the areas of maternal, new-born and child health services (including ANC, maternity care, postnatal care and newborn, child, and adolescent health services). The tool assesses the programme on leadership & governance, financing, human resources, service delivery, medical products and technology and strategic information.

B. **Laboratory:** Quality diagnostic services, consistent with WHO-recommendations, is a mandatory validation requirement. The tools for the laboratory quality assessment have four components covering the aspects of laboratory quality management, quality of tests, quality of testing and laboratory data management.

Figure-14.3.1: Foundational requirements for EVTHS



[3] Syphilis seropositive pregnant women received at least one dose of intramuscular benzathine penicillin G at least 30 days prior to delivery

C. **Data (Monitoring and Surveillance):** A robust monitoring and surveillance system tracking pregnant women/mothers and infants on key services like registration, testing, and treatment with prescribed standards for data privacy and confidentiality is critical for validation of EVTHS. Accordingly, the validation process includes assessment of monitoring and surveillance system through a structured checklist. The checklist reviews the functionality of information systems, indicator definitions and measurement with specific focus on data quality. Population-level estimates, available through nationally representative surveys, models or other mechanisms, should be used to complement programme data on process and impact indicators. One of the components of the data validation is examination of population-level estimates. The data assessment covers the national, sub-national and service delivery level. If the private sector data are not included in the national information management system, then data is also verified in private sectors. The indicators are included in the UNAIDS Global AIDS Monitoring (GAM) system and data shall be submitted annually through GAM to facilitate processing.

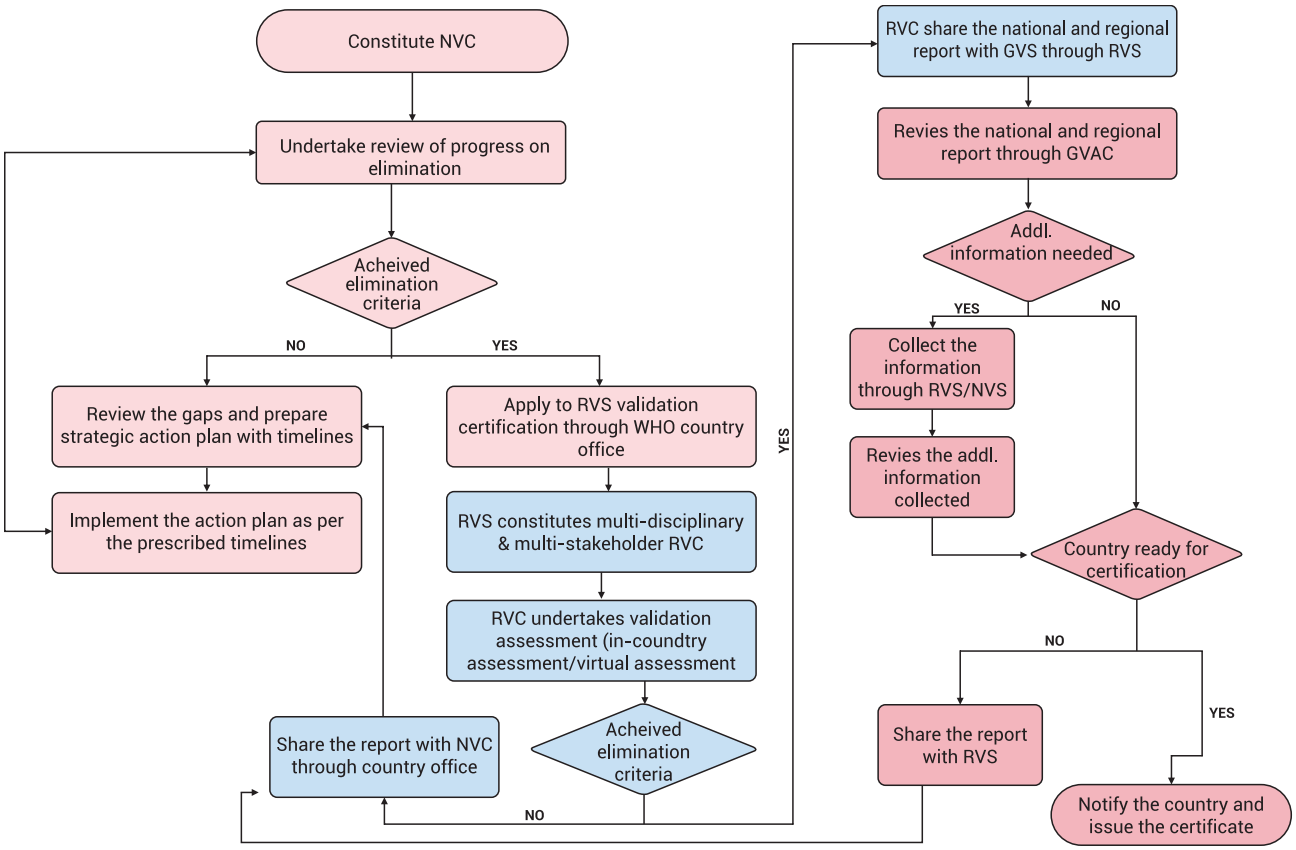
D. **Human rights, gender equality and community engagement:** The validation process requires that vertical elimination targets are achieved within a context of human rights, gender equality, and community engagement as a foundational requirement. Examination of existing laws, policies and services and of their implementation and interviews with human rights stakeholders as well as HIV-infected women are built into the validation tool.

14.4 Action framework for EVTHS validation

The validation of elimination of vertical transmission (HIV and Syphilis) is a rigorous three-level process. The first level is owned and led by ministry of health that includes review of country progress to apply for the validation and then initiating the application for validation through WHO country office if found suitable in internal review. After the application of validation process is initiated by the country, the rest of the activities are undertaken by regional validation secretariat (RVS) and global validation secretariat (GVS) through regional validation committee (RVC) and global validation advisory committee (GVAC) (Figure 14.4.1).

In view of the global guidance, the strategic framework for validation of elimination of vertical transmission of HIV and Syphilis, has been summarized in the paragraph and sections below.

Figure 14.4.1: Steps in validation of elimination of vertical transmission of HIV & syphilis



Establishment of the national validation committee.

Establishment of the national validation committee (NVC) is the first step in the process of validation. This may be a dedicated group created for the specific purpose of validation or one of the technical resource groups (TRG)/ technical working group/sub-group in NACO may be assigned the additional role of the NVC. However, the NVC may also have members from various UN, funding, and implementation partners. NVC shall have multi-disciplinary skills including those having expertise in programme including those in maternal and child healthcare, laboratory, strategic information (epidemiology, monitoring, and evaluation), human rights, gender equity and community engagements. NVC shall also have representation from WLHIV.

Currently, functions of NVC have been vested in the Technical Working Group (TWG) on elimination of mother to child transmission (EMTCT) for HIV and Syphilis under NACP constituted vide office order no T-12015/40/2006-NACO (CTC) PF dated 30th May 2022. The NVC thus constituted will be anchoring the validation process under NACP from initiation of validation process to the stage of certification. Secretarial assistance to the NVC for EVTHS would be provided by the TWG sub-group constituted for M&E and validation framework.

Undertake an internal assessment.

The current progress on numeric process and impact indicators are lower than the target value. However, while shortfall on numeric targets for HIV is well established, same may not be said for the syphilis as the MIS systems for syphilis has scope of improvement. Also, the progress of country on foundational requirements are not well described.

An internal assessment by TWG sub-group constituted for M&E and validation framework, under the guidance of the TWG (EMTCT), of the country progress on elimination of HIV and Syphilis on both numeric targets as well as foundational requirements of programme, laboratory, strategic information, human rights, gender equity and community engagements using WHO recommended tools would be one of the fundamental actions in validation. A report shall be developed for the internal assessment.

Prepare the roadmap.

Based on the internal assessment report, the TWG (EMTCT) shall prepare the roadmap on specific action points for the attainment of the elimination of the vertical transmission with defined timelines. The roadmap shall not only cover the programmatic targets but also address the foundational requirements of laboratory, strategic information, human rights, gender equity and community engagements. It should have also clearly identified the low-performing units in the country and recommended a review mechanism in the low-performing locations. The roadmap shall also address the relevant HRGs and vulnerable population needs if specific gaps are noted in the internal assessment.

Undertake periodic review of progress on roadmap.

The TWG (EMTCT) shall periodically review the progress using the standard checklist focussing on key identified gaps. The TWG (EMTCT) will recommend for initiation of the process for certification for elimination once it is satisfied that globally recommended criteria for the validation have been achieved. This will include the preparation of the national validation report. The TWG (EMTCT) may recommend for the validation for single or double elimination depending upon the progress.

Initiate validation process

Based on the TWG (EMTCT) recommendations, NACO will apply for validation and submit its application to the SEARO's RVS through country office. This will include submission of the national validation report prepared by the TWG (EMTCT) to the RVS.

Coordinate with RSV and support them to undertake validation assessment.

RSV, through its regional validation committee (RVC), will review the national validation report and subsequently undertake the assessment (via in-country mission or virtual assessment). This will be followed by a review by GVS through its GVAC in case of a positive report from regional validation.

The TWG sub-group (M&E and validation framework) will coordinate with the RSV through the WHO country office to coordinate the regional and global validation assessment. This will include responding to the queries that the regional/global team may have during the review process.

Undertake follow-up actions based on the regional/global validation reports.

The RVS or GVS may recommend deferral of the validation with specific action points and communicate the same to the NACO via the proper channel. In such cases, NACO will prepare clarifications in consultation with TWG (EMTCT). This may require the undertaking of specific action points to address the suggestions of RVS or GVS. The clarifications/action points will be submitted back to RVS/GVS through the proper channel. The GVS then take necessary actions for validation.

References for Section-V

1. National AIDS Control Organization (2022). Integrated and Enhanced Surveillance and Epidemiology of HIV, STI and related Co-morbidities Under the National AIDS and STD Control Programme: Strategic Framework. New Delhi: NACO, Ministry of Health and Family Welfare, Government of India. Available at: https://naco.gov.in/sites/default/files/Stretegic_Framework_On_IESE_of_HIV_STD_and_Related_Co_Morbidities.pdf
2. Global guidance on criteria and processes for validation: elimination of mother-to child transmission of HIV, syphilis and hepatitis B virus. Geneva: World Health Organization; 2021. Available at: https://iris.who.int/bitstream/handle/10665/349550/9789240039360-eng.pdf?sequence=1
3. NACP Data Management Guidelines, 2020, are available in public domain at link: https://naco.gov.in/sites/default/files/Draft%20NACP%20Data%20Management%20Guidelines%202020.pdf

ANNEXURES

Annexures

Annexure 1: Medical Eligibility Criteria (MEC) Categories for Contraceptive Use: Guidelines for Interpretation and Application in Clinical Practice

Medical eligibility criteria (MEC) categories for contraceptive use

Category 1	**A condition for which there is no restriction for the use of contraceptive method**
Category 2	A condition where the advantages of using the method generally our way the theoretical or prover risks
Category 3	A condition where the theoretical or proven risks usually away the advantage of using the method
Category 4	A condition which represents an unacceptable health risk if the contraceptive method is used

Interpretation and application of the categories in practice

Category	With good resources for clinical judgment	With limited resources for clinical judgment
1	Use method in any circumstances	Yes (use the method)
2	Generally, use the method	
3	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	No (don't use the matter)
4	Method not to be used	

Source:

Medical Eligibility Criteria for Contraceptive Use. 5th edition. Geneva: World Health Organization; 2015. II, Using the recommendations. Available from: https://www.ncbi.nlm.nih.gov/books/NBK321153/

Annexure 2: A Guide to ARV Drug Safety during Pregnancy

Drug Name	Placental transfer to the foetus	Teratogenicity	Side effects	Consideration in pregnancy
Abacavir (ABC) 300 mg twice daily or 600 mg once daily	High	No evidence	Hypersensitivity reaction in 3 to 5% (can be fatal), fever, rash, fatigue, nausea, vomiting, anorexia, respiratory symptoms (sore throat, cough, shortness of breath); Re-challenging after reaction can be fatal.	The rate of reactions during pregnancy is unknown. Patients should be educated regarding symptoms of Hypersensitivity Reaction.
Lamivudine (3TC) 150 mg twice daily or 300 mg once daily	High	No evidence	Renal toxicity, bone demineralization	If the patient has HBV/HIV coinfection, an HBV flare may occur if TDF is stopped. Renal function should be monitored because of the potential for renal toxicity.
Zidovudine (ZDV) 300 mg twice daily	High	No evidence	Anaemia, neutropenia, bone marrow suppression, gastrointestinal intolerance, headache, insomnia, myopathy, lactic acidosis, skin and nail hyperpigmentation	
Efavirenz (EFV) 600 mg once daily (bedtime administration is suggested to decrease CNS side-effects)	Moderate	The data on more than 7,900 preconception EFV exposures from Botswana rule out a threefold or greater increased risk of NTDs. As a result, the current Perinatal Guidelines do not restrict the use of EFV in pregnant women or in women who are planning to become pregnant.	CNS symptoms (dizziness, somnolence, insomnia, confusion, hallucinations, agitation) and personality change. A rash occurs but is less common than NVP.	

Drug Name	Placental transfer to the foetus	Teratogenicity	Side effects	Consideration in pregnancy
Nevirapine (NVP) 200 mg once daily for 14 days, followed by 200 mg twice daily	High	No evidence	Hepatitis (usually within 12 weeks); sometimes life-threatening hepatotoxicity. Skin rash occasionally progresses to severe conditions, including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Patients who develop severe hepatic toxicity or grade 4 skin rashes should not be re-challenged.	Pregnancy does not appear to increase this risk. A potential increased risk of life-threatening hepatotoxicity exists in pregnant woman with high CD4 counts. Elevated transaminase levels at baseline may increase the risk of NVP toxicity.
Atazanavir (ATV) 300 mg Atazanavir + 100 mg Ritonavir once daily	Low	No evidence	Unconjugated hyperbilirubinemia, lipid abnormality, hyperglycaemia, fat maldistribution, nephrolithiasis, cholelithiasis, PR prolongation	Must be given with RTV boosting in pregnancy. Effect of in-utero ATV exposure on infant Indirect bilirubin levels are unclear. Nonpathological elevations of neonatal bilirubin has been observed in some, but not all clinical trials to date. ATV is not recommended during pregnancy for ARV -experienced patients who are taking TDF and an H2-receptor antagonist.

Drug Name	Placental transfer to the foetus	Teratogenicity	Side effects	Consideration in pregnancy
Darunavir (DRV) 600 mg twice a day (when used with Ritonavir 100 mg twice daily)	Low	No evidence	Hepatotoxicity, skin rash (10%), diarrhea, nausea, headache, hyperlipidemia, serum transaminase elevation, hyperglycemia	Must be boosted with low-dose RTV. Once-daily dosing with DRV/r during pregnancy is not recommended.
Lopinavir Ritonavir (LPV/r) 200 mg Lopinavir/50mg Ritonavir Fixed dose tablet 2 tablets twice daily.	Low	No evidence	Diarrhea, nausea, vomiting, abnormal lipid profiles, glucose intolerance.	Once-daily LPV/r dosing is not recommended during pregnancy.
Dolutegravir (DTG) 50mg once daily+A4	High	No evidence. The most recent data from Botswana indicates the prevalence of NTDs in infants born to pregnant women with HIV receiving DTG at conception is no longer statistically different than in those receiving other antiretrovirals.	Insomnia and headache. Dolutegravir can cause serious, life-threatening side effects. These include hypersensitivity (allergic) reactions and liver problems. People with a history of Hepatitis B virus (HBV) or Hepatitis C virus (HCV) infection or who have elevated results on liver function tests may have an increased risk of developing new or worsening liver problems while taking dolutegravir.	DTG is a Preferred antiretroviral drug for use during pregnancy, irrespective of trimester, and for people who are trying to conceive. To maximize DTG absorption, doses should not be administered within 2 hours of ingesting any preparation that contains such minerals as iron or calcium, including prenatal vitamins.

Drug Name	Placental transfer to the foetus	Teratogenicity	Side effects	Consideration in pregnancy
Raltegravir (RAL) 400mg twice daily	High	No evidence	Rhabdomyolysis, Myopathy, Myalgia, diarrhea, fever, Rash, Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, Hepatitis, and Hepatic failure	There is a case report of markedly elevated liver transaminases with RAL use in late pregnancy. Severe, potentially life-threatening, and fatal skin and HSRs have been reported in nonpregnant adults. To maximize RAL absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals—such as iron or calcium—including prenatal vitamins.
Ritonavir (RTV) 100 mg twice daily (used only to boost another PI)	Low	No evidence	Common-gastrointestinal (diarrhea, nausea, vomiting, abdominal pain (upper and lower), rarely neurological disturbances (including paraesthesia)	

Source: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/safety-toxicity-arv-agents-drug-use-pregnant-full

Annexure 3: Antenatal implications for Antenatal Care of Pregnant WLHIV with Comorbidities

- Pregnancy-induced hypertension and HIV: Older HIV-infected patients on ART have a higher risk of hypertension, making frequent blood pressure monitoring and risk factor identification during antenatal care crucial.
- Preeclampsia and HIV/AIDS: Both conditions are inflammatory and contribute to adverse maternal and foetal outcomes. The impact of HAART on inflammatory cytokine network in women with co-morbid preeclampsia remains unclear.
- Negative Pregnancy Outcomes: While ART use during pregnancy may increase the risk of adverse outcomes such as small for gestational age (SGA) and pregnancy loss, the availability of more effective ART options has led to a reduction in preterm deliveries and an increase in vaginal delivery rates. However, rates of complications such as GDM, pre-eclampsia, preterm contractions, PROM, and postnatal complications are higher in WLHIV compared to the general population.
- Anaemia: Rule out advanced HIV disease and zidovudine-induced anaemia in pregnant women presenting with anaemia. The management of anaemia in HIV-pregnant women should follow national guidelines for non-HIV pregnancy.
- Gestational Diabetes Mellitus (GDM): Early screening for GDM is crucial to reduce its complications related to pregnancy in HIV-infected pregnant women. The risk of GDM is lower with DTG- than with EFV-based ART. However, a dose adjustment of metformin should be considered when starting and stopping co-administration of dolutegravir with metformin.
- Common Mental Disorder: Screening and services to address IPV and mental health are urgently needed for this population. Interventions to prevent, screen, and address IPV and common mental health disorders should be implemented and evaluated.
- Pregnancy-related venous thromboembolism and HIV infection: HIV infection is a significant risk factor for pregnancy-related venous thromboembolism, independent of traditional HIV risk factors. Healthcare providers should carefully consider potential interactions between ART and medications used to prevent or treat thromboembolism when managing HIV-positive pregnant women. Careful consideration should also be given to the use of uterotonic drugs such as oxytocin and ergometrine in women with HIV infection at higher risk of thrombosis. Further research is needed to explore the mechanisms of thrombosis associated with HIV infection.

Annexure-4 ART Patient Booklet

④

Reminder for CD4

	Date	Result	Remarks
AI registration	D D M M Y Y Y Y		
	D D M M Y Y Y Y		
	D D M M Y Y Y Y		
	D D M M Y Y Y Y		
	D D M M Y Y Y Y		

Reminder for Viral Load

Date	Result	Next due Date	Remarks
D D M M Y Y Y Y		D D M M Y Y Y Y	
D D M M Y Y Y Y		D D M M Y Y Y Y	
D D M M Y Y Y Y		D D M M Y Y Y Y	
D D M M Y Y Y Y		D D M M Y Y Y Y	
D D M M Y Y Y Y		D D M M Y Y Y Y	

*Doctor to prescribe date

Reminder

Bring this boked at each follow-up visit.
Take of medicines without missing any dose.
Take of medicines at the right time.
Take the full dose of medicine, DO NOT have medicines with timly, friends or others
Regular treatment can help you to feel better and resume

Normal actives.
Stock to a healthy and reponcible life style.
Bring empty better packets bottle an each follow up visit.
You can 1097 for any informantion on HIV AIDS or query Regarding the servinces

In case of emergency, contact: _____

(Name, address and phone number of hospital health worker): _____

Please come back on (Write date of next appointment)

1	16	31	46
2	17	32	47
3	18	33	48
4	19	34	49
5	20	35	50
6	21	36	51
7	22	37	52
8	23	38	53
9	24	39	54
10	25	40	55
11	26	41	56
12	27	42	57
13	28	43	58
14	29	44	59
15	30	45	60

(May be traslated language as per requirment)

Patient Booklet (Green Booklet)

(To be relained by the patient) ①

Name of ART Centre/LAC/LAC plus): _____

District: _____ State: _____

Patient's name: _____ Age: _____ Sex: _____

Current address(full): _____

Village/town: _____

District: _____ State: _____

ICTC PID No.: _____ Date: D D M M Y Y Y Y

Permanent address _____

Village/town: _____

District: _____ State: _____

HIV Care (Pre ART) registration number: _____ Date: D D M M Y Y Y Y

ART registration number: _____ Date: D D M M Y Y Y Y

Date of ART initiation: D D M M Y Y Y Y

LAC/LAC plus registration number _____ Date: D D M M Y Y Y Y

Name of caregiver/guardian: _____

Phone number of caregirven/guandian: _____

Address of caregiver/guardian: _____

Alternate Contract Number _____

Name of CSC: _____

Address of CSC: _____

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②

Summary

AADHAAR No.: _____

Date of First Pragnancy: D D M M Y Y Y Y

Date of Second Pregnancy: D D M M Y Y Y Y

Date of Third Pregnancy: D D M M Y Y Y Y

Remarks: _____

Patient Photograph

ART Regimen	Start date	Stop date	Reason for stop
	D D M M Y Y Y Y	D D M M Y Y Y Y	
	D D M M Y Y Y Y	D D M M Y Y Y Y	
	D D M M Y Y Y Y	D D M M Y Y Y Y	

	Date	WHO clinical Stage	Weight (kg)	Cd4 count	
				No.	%
AI. 1st visit at centre	D D M M Y Y Y Y				
AI. Start of ART	D D M M Y Y Y Y				
6 months after start of ART	D D M M Y Y Y Y				
12 months after start of ART	D D M M Y Y Y Y				
24 months after start of ART	D D M M Y Y Y Y				
36 months after start of ART	D D M M Y Y Y Y				
48 months after start of ART	D D M M Y Y Y Y				

Summary for Opportunistic infections

Opportunitis tc Intections	Date	Remarks

Counselling/ Clinical Notes ③

Counsellor/Staff Nurse Section	Doctor Section
Date of visit: D D M M Y Y Y Y	Weight: _____ Kg Section
4S ☐ Positive ☐ Negative	Chief Complaint
4 Symptoms ☐ Cough ☐ Fever ☐ Weight loss ☐ Night Sweat	
BP (mmtig):	Clinical Examination
Blood Sugar (F/R/PP):	
No of pills remaring	
adheance:	WHO Clinical Stage: I/II/III/IV Investigation
Counselling notes:	Treatment

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Annexure-5: ART Patient Treatment Record (White Card)

PATIENT TREATMENT RECORD (WHITE CARD)

(To be filled for all patients and to be store in a locked cabinet at the centre, arranged serially by registration number)

(Section 1 to 4 are to be filled by counsellor; other sections are to be filled by SMO/MO)

Name of ART Centre: | PID Code:

ART Centre Code: | UID Code:

HIV Care Registration No.: | ART Registration No.: | Name of LAC/LAC plus:

Date of Registration: D D M M Y Y Y Y | ART Initiation Date: D D M M Y Y Y Y | LAC/LAC plus Registration Number:

1. Identification Data (Write complete information)

Name of patient:

Age: | Date of birth: D D M M Y Y Y Y | Phone No.

Gender: ☐ Male ☐ Female ☐ TG | Treatment status at registration: ☐ On ART ☐ Not on ART

Patient's Current Address:*	Patient's Permanent Address:*
City/Village:	City/Village:
Tehsil/Taluk:	Tehsil/Taluk:
Landmark:	Landmark:
District:	District:
State:	State:

Details of Caregiver/Alternate Contact:	Caregiver's/Alternate Address:
Name:	City/Village:
Relation:	Tehsil/Taluk:
Education:	District:
Mobile No:	State:

Date of HIV Confirmation: D D M M Y Y Y Y | Type of infection ☐ HIV-1 ☐ HIV-2 ☐ HIV1 & 2

* Connsellor has to verify the details and update the same on every visit

Patient On ART Transferred in from: ☐ ART Centre ☐ Private, | Date transferred in D D M M Y Y Y Y

Name and address of preveious Clinic/Centre: .....

.....

2. Personal Details (tick all applicable)

Probable mode of transmission:

☐ 1-Sexual ☐ 4-Mother to child

☐ 2-Injection drug use ☐ 5-Probable unsafe injection

☐ 3-Blood transfusion ☐ 6-Unknown

Education:

☐ Illiterate ☐ Secondary School

☐ Primary school ☐ College & above

**Occupational Status: ☐ (enter Code)

Note: .....

.....

Type of client

☐ 1-General Polulation ☐ 7- Migrant

☐ 2-ANC/Breastfeedubg Mother ☐ 8- Trucker

☐ 3-Men who have Sec with Men (MSM) ☐ 9- Prison and other closed setting

☐ 4-Transgender (TG) ☐ 10- Juvenile Home

☐ 5-Female Sex Worker (FSW) ☐ 11- Others (if any, specify)

☐ 6-Intravenous Drug User (IDU)

For IDUs: Substitution therapy ☐ Yes ☐ No

If 'Yes', Type:

3. Personal and Medical History

A. Alcohol	B. Smoking	C. Tobacco use	D. NCD	E. Drug use
☐ Current/	☐ Current/	☐ Current/	☐ Diabetes	☐ (Oral/injectable/NA)
☐ Habitual/Occasion	☐ Habitual/Occasion	☐ Habitual/Occasion	☐ Hypertension	F. Others: .....
☐ Never	☐ Never	☐ Never	☐ Stroke	.....
☐ Past HIstory	☐ Past HIstory	☐ Past HIstory	☐ Malignancy	.....
Date of last episode:	Date of last episode:	Date of last episode:	☐ Myocardial Infarction	.....

4. Family / Partner History (To be updated as and when new information is available)

Marital Status: ☐ Married ☐ Single ☐ Widowed ☐ Divorcee ☐ Separated ☐ Live-in

Orphan: ☐ Yes ☐ No.

Family members	Age	Sex	Alive Dead	HIV Status (HIV+/HIV-/Unknown)*	If positive, Whether on ART (Y/N)	HIV Care No. / ART No.
Mother						
Father						
Spouse						
Child-1						
Child-2						
Child-3						
Partner-1						
Partner-2						

(*if Spouse/partner is negative, then testing needs to be done & documented every six months)

5. Past Antiretroviral Treatment (ART) History

ARV received in the Past? ☐ Yes ☐ No		ARV Regimen & Dose	Duration
If yes,	☐ PPTCT/ARV Prophylaxis		
	☐ ART		
	☐ PEP		
	☐ PrEP		
Place of ART	☐ Pvt. ☐ Govt. ☐ NGO	(Past ART History) Last VL :	Last Cd4 Count: ..... as %

** Occupation-1. Agricultural labourer2. Non-Agricultural labourer 3. Domestic servant 4. Skilled worker 5. Semi skilled worker 6. Petty business/large business/Small shop/ self-employed 7. Service (Govt/Pvt) 8. Student 9. Truck driver/helper 10. Local transport worker (auto/taxi driver, handcraft puller, rickshaw puller) 11. Hotel staff 12. Agricultural cultivator / landholder 13. Unemployed 14. Retired 15. Housewife.

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6. Enhance Adherence Counselling / Step up Counselling SACEP (Summary)

S No.	VL Testing Result	EAC 1 (dd/mm/yy)	EAC 2 (dd/mm/yy)	EAC 3 (dd/mm/yy)	Repeat VL Test Result	If un-suppress Date of SACEP Referral	SACEP Recommendation
1							
2							
3							
4							
5							
6							
7							

7. Antiretroviral Treatment (Summary)

Regimen	Start Date	Line of Treatment	SACEP Referral (Yes/No)	If 'Yes' Date of SACEP Referral	*Reason for Referral	Date of Stop/substitute/ switch/transition	New regimen

*Reasons for referral

STOP. 1. Toxicity/ side effects:.....

SUBSTITUTE: 1. Toxicity/ side effects, 2. Comorbidities / Coinfection 3. other reasons (specify): .....

.....

SWITCH: 1. Immunological failure, 2. Virologic failure (any one)

8A. Tuberculosis preventive & treatment (To be filled by Staff Nurse/Counsellor)

TPT Regimen: _____ TPT start date: D D M M Y Y Y Y

NIKSHAY ID: _____ TPT comoleted / stop date: D D M M Y Y Y Y

History of TB: ☐ New or ☐ Previously Treated..... (Please attach TB Treatment Card from NTEP)

Detail	Episode 1	Episode 2	Episode 3
Type of TB Case: DS TB or DR TB			
Site of TB: (Pulmonary or Extra Pulmonary)			
Type of TB Diagnosis: (Bacteriological or Clinical)			
TB Regimen			
Date of start of Rx			
Date of Completion of Rx			
Outcome			
CPT provided (yes/No)			
Outcome: Cured/ Treatment Completedc/ Failure / Died / Not Evaluated /LFU/ Treatment Regimen Changed			

*** Functional Status : W - Working= able to perform routine work in or out of the house like harvest , normal activities, for children go to school or playing A-Ambulatory = Able to perform activeties of daily living but not able to work B - Bedridden = Not able to perform activities of daily living

8B. Comorbidities Hepatitis B, Hepatitis C, NCD, Mental Health Kala Azar & Syphilis etc,

Name of Comobidity	1 Hep-B	2 Hep-C	3 HTN	4 DM	5
Date of diagnosis					
Date of treatment start					
Details of treatment					
Date of treatment completed					
Outcome					

Vacaination for Hepatities B: ☐ Yes ☐ No. If Yes 1st Dose D D M M Y Y Y Y

2nd Dose D D M M Y Y Y Y 3rd Dose D D M M Y Y Y Y

9. Outcome / Status (To be updated by Counsellor / Staff Nurse)

Transferred out

Date transferred out: D D M M Y Y Y Y

Name of ART Center: _____

Died:

Date of death: D D M M Y Y Y Y

Reason: _____

Any notes:.....

10. Consent Form

I, (name) ..... (address) .....

.....

CONSENT to share all information pertaining to my/my minor child's health and HIV/AIDS status with the service providers who will be Part of the management of my/my child's health condition.

And

I AGREE to receive Antiretroviral Therapy and other HIV related services 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 will be started at the earlies after readiness assessment and 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.
- I agree to receive care/treatment as per national guidelines.
- That ART requires 100% adherence to drugs, and I shall abide by the same.
- That I understand the adverse 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/my minor childis on ART from outside on a different regimen,i agree to receive the drugs /regimen provded under the national programme.
- In case, I/my minor child want to take ART from other centre or go to other city for livelihood or other reason s, I will inform my ART centre and get a "transfer out" letter before leaving.
- That I may access/update/correct the infornation whichis collected under the programme by visiting concemed NACP facility.
- That all personal information provided will be kept confidential under the programme.
- That receiving ART also involves shared confidentiality with ART staff and other service providers who will be involved in care, supoort and treatment (such as LAC/CSC/positive network/CBO/NGO etc.) who may support my/my child's treatment, retention and other welfare meansures through phone call/ other modes of communications, outreach and home-based care activities at home.

Sign of witness
(Doctor/Nurse/ Counsellor)

Sign of patient with date /
Sign of caregiver with date
D D M M Y Y Y Y

to be printed in local language by States / UTs

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Section-11: PREGNANT WOMEN

Obsteric History

- LMP: D D M M Y Y Y Y EDD: D D M M Y Y Y Y
- ☐ Gravide ☐ Para
- Institute/Place selected for the delivery: ☐ Govt ☐ Private ☐ Home
- Name of the institution planned for delivery _____

Details of Viral Load Testing (32-36 weeks)_____

- Viral Load Testing (32-36 weeks) ☐ Yes ☐ No ☐ Not Applicable
- Viral Load Testing D D M M Y Y Y Y Result:_____
- Category of baby based on Viral Load Testing:(☑ Tick the appropriate)
  - ☐ a) Low Risk → Single Prophylaxis
  - ☐ b) High Risk → Dual Prophylaxis

Delivery Details

- Status of pregnant women at the registration of EVTHS
  - ☐ Already on ART ☐ Newly diagnosed PLHIV ☐ Direct in labor ☐ Post delivery
- Date of Delivery: D D M M Y Y Y Y
- Mode of Delivery: ☐ Normal ☐ Cesarean ☐ Assisted
- Place of Delivery: ☐ Govt ☐ Private ☐ Home
- Name of the institution where delivery: _____
- Pregnancy Outcome : (☑Tick the appropriate)
  - ☐ a) Live birth single ☐ b) Live birth twin ☐ c) MTP
  - ☐ d) Still birth ☐ e) Abortion

HIV EXPOSED INFANT

Birth Details

- Date of Birth D D M M Y Y Y Y
- Birth weight:_____ Kgs
- Selected Infant feeding Option* (☑ Tick the appropriate)
  - ☐ a) EBF ☐ b) ERF ☐ C) Mixed

* To reassess feeding practice at 6 weeks for high-risk infants

- CPT initiation Date: D D M M Y Y Y Y (Ensure CPT initiation at 6 Weeks of age)
- Any other details: _____

ARV prophylaxis

- Date Starting ARV prophylaxis: D D M M Y Y Y Y Date completion D D M M Y Y Y Y
- Name of ARV Drug: (☑ Tick the appropriate)
  - a) Nevirapine - Initiated : (☐ Yes/ ☐ No) Completed : (☐ Yes/ ☐ No)
  - b) Zidovudine - Initiated : (☐ Yes/ ☐ No) Completed : (☐ Yes/ ☐ No)
  - c) Any Other - Initiated : (☐ Yes/ ☐ No) Completed : (☐ Yes/ ☐ No)
- Duration of Prophylaxis : (☑Tick the appropriate)
  - ☐ 6 week ☐ 12 weeks
  - Date of cessation of Breast Feeding : D D M M Y Y Y Y

EID DETAILS OF THE BABY

Details:	6 WEEKS	6 MONTHS	12 MONTHS	> 18 MONTHS
TNA PCR Code: ..... (If Baby found Positive at any EID:)	• Infant feeding Option ☐ EBF ☐ ERF ☐ Mixed • Baby weight :..... Kgs	• Infant feeding Option ☐ EBF ☐ ERF ☐ Mixed ☐ Complementary feeding • Baby weight :..... Kgs	• Breast feeding continued: ☐ Yes ☐ No • Baby weight :..... Kgs	• Breast feeding continued: ☐ Yes ☐ No • Baby weight :..... Kgs • 3 Serological tests D D M M Y Y Y Y • Antibody reactive on all 3 tests ☐ Yes ☐ No • Antibody reactive on 1/2 tests ☐ Yes ☐ No • Antibody non-reactive all 3 tests ☐ Yes ☐ No
ART Centre: .... ART on of the Baby: ..... Date of ART Initiation: D D M M Y Y Y Y	• DBS Collection Date (First): D D M M Y Y Y Y • DBS Result: ☐ +ve ☐ -ve • DBS Collection Date (Second): D D M M Y Y Y Y • DBS Result: ☐ +ve ☐ -ve Notes:	• 3 Serological tests D D M M Y Y • Result: ☐ Reactive ☐ Non-reactive • DBS Date (1st): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative • DBS Date (2nd): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative • DBS Date (3rd): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative	• 3 Serological tests D D M M Y Y • Result: ☐ Reactive ☐ Non-reactive • DBS Date (1st): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative • DBS Date (2nd): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative • DBS Date (3rd): D D M M Y Y • DBS Result: ☐ Positive ☐ Negative	If sero discordance ☑ Tick on test where sample reactive 1 All 3 Rapid Antibody test in parallel ☐ 2 HIV-1 ELISA ☐ 3 Western Blot ☐ 4 Qualitative TNA HIV-1 PCR ☐ 5 Quantitative HIV-1 PCR (Viral Load) ☐ VL Results* ..... (if non-reactive of all 5 tests):

Notes: 1 Please follow EID algorithm as per NACO guildelines *

2. Death of the baby to be recorded & reported if occurred during treatment

3. Final test results at 18 months or at 3 months of CESSATION of breast feeding ☐ Yes ☐ No

* Final test results ☐ Positive ☐ Negative ☐ Indetemrminate ☐ Sero discordance

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12. Investigations								
Test date:	...../...../.....	...../...../.....	...../...../.....	...../...../.....	...../...../.....	...../...../.....	...../...../.....	...../...../.....
Cd4 Count / % *								
Viral Load (Copies/ml)*								
Hb (g/dl)								
Urine R&M								
Blood Sugar (F/R/PP)								
Hb A1c (mg/dl)								
S. Creatinine (mg/dl)								
S. Bilirubin (mg/dL)								
SGOT (AST)								
SGPT (ALT)								
VDRL								
Lipid Profile :								
S. Cholesterol								
S. Triglycerides								
S. HDL								
S. LDL								
Hba Ag								
Anti-HCV IgG								
Pregnancy Test (LMP)								
NAAT for TB								
Pap smear / VIA								
Other*:								
.....								
.....								
.....								
.....								
.....								
BP (mmHg)								
CXR (PA view)	Date & Finding:		Date & Finding:		Date & Finding:		Date & Finding:	
USG (ABD)	Date & Finding:		Date & Finding:		Date & Finding:		Date & Finding:	

* Cd4 and Viral Load results to be updated by counsellor while rest of the details to be updated by Staff Nurse

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Section 13: Monthly follow up (1 to 4, 11 to be updated by Counselor and remaining by Medical Officer)*																		
S No.	1	2	3	4	5	6	7	8						9	10	11	12	13	14
	Date of visit*	Pill Collection In Person/ Procy)	Date of next visit (Due date)	Weight (Kg)	WHO Clinical Stage	Oppor-tunistic Infections (code)#	4S (positive/ Negative)	Drugs prescribed for OI/Prophylaxis						Status of dient (P=Pre-paredmess; N=New initiation; S=Stable; U=Un suppressed)	ART regimen & Dose	Adherence to ART (%)##	ART Side effects -Code$	Remarks/ Referrals	Staff Sginature
								Prophylaxis (8A)			Treatment (8B)								
								CPT (Yes/No)	TPT (Yes/No)	Others (with dose)	TB Regimen	Other (with dose)	Other (with dose)						
1																			
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			
10																			
11																			

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* To be filled preferably by MO/ Counselor, If incase the primary staff is unavailable supportive staff may complete the necessary details

Annexure 6: HIV-1 Viral Load Sample Collection, Processing, Storage, Packaging and Transportation at ART Centre for Pregnant Women

A) Purpose: The purpose is to provide technical guidelines for HIV-1 VL sample collection of pregnant women at the sample collection facility and then dispatched to ART Centre for ID generation and IIMS entries. Thereafter, ART Centre will further dispatch the plasma sample to the linked viral load laboratory. The document aims to ensure that sample integrity is maintained, and no sample is rejected.

B) Activities at the sample collection facility

I. Pre-collection:

1. Laboratory technician at the sample collection facility should ensure that all the necessary materials required for VL sample collection are available.
2. Ensure the TRF is properly filled with a ARTC unique identifier before the sample collection process is started. The blood collection tube should be labelled with the same UID.

II. Sample collection:

1. Standard precautions should be strictly followed.
2. Powder-free gloves are to be used for sample collection.
3. 3 ml of whole blood sample should be collected in a K2 EDTA tube.
4. EDTA tube should be gently inverted 8-10 times to ensure proper mixing of whole blood and prevent clotting.
5. The tubes should be kept upright for 30 minutes at room temperature (15-30˚C).

III. Sample Processing:

1. Plasma should be separated from whole blood within six hours of sample collection by centrifuging at 2000-2500 rpm for 10-15 minutes at the collection facility (LAC/ICTC) only.
2. Using a sterile Pasteur pipette, transfer the plasma to the prelabelled storage vials (2.0 ml polypropylene tube with O ring screw cap)
3. Seal the tube with parafilm to avoid leakage during transportation.
4. Keep the aliquots in storage box for aliquots.

IV. Sample Storage:

1. Separated plasma samples are to be stored in a refrigerator maintained at 2-8°C and sent to the ARTC for ID generation in IIMS.
2. The samples should be sent to the linked ARTC lab at the earliest to the linked ARTC. Samples are to reach the linked Viral Load lab within 5 days from the date of sample collection. (LAC / ICTC lab should coordinate with linked ARTC to know the date of shipment to VL Lab)

V. Sample Packaging and Transportation:

1. Laboratory technicians at the sample collection facility and ARTC will ensure triple packaging instructions are followed as per the national testing guidelines for sample transportation. This is to maintain the biosafety and integrity of the sample.
2. During packaging, it is important to record the temperature inside the box after the ice packs are kept and before sealing. (Refer Annexure 1 for transportation guidelines).

3. The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" should be mentioned.
4. All the waste generated during sample collection, processing and packaging should be disposed of according to institution/ hospital BMW guidelines.

(Note: Sample collection facility to ensure that plasma sample reaches testing laboratory within 5 days of sample collection)

VI. Documentation:

1. Sample collection facility (ICTC/Link ARTC) should duly maintain the records of the samples sent to ARTC.
2. ARTC technician will enter the VL sample details in the viral load register/IIMS at the ART centre.
3. ARTC will initiate the process of dispatching VL samples to the linked VL lab through the NACO IIMS (SOCH) portal.
4. ARTC LT to duly fill the sample transportation sheets for VL samples to be transported.

(Ref: National Guidelines for HIV-1 Viral Load Laboratory testing 2018. Chapters 4 and 5, pg. 15-23.)

Sample Packaging and Transportation Requirements

- Laboratory technicians at the sample collection facility will ensure triple packaging instructions are followed as per the national testing guidelines for sample transportation to maintain the biosafety and integrity of the sample.
- During packaging, it is important to record the temperature inside the box after the ice packs are placed inside and before sealing.

Requirements for triple packaging system:

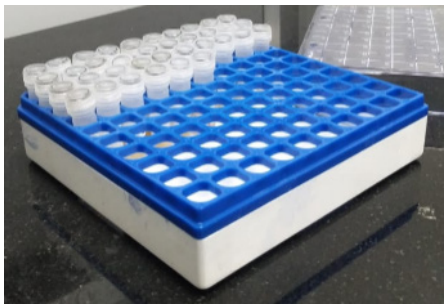
a) Overnight frozen gel packs
b) Labelled and parafilm M-sealed plasma tubes
c) Aliquot storage box
d) Sample Transport sheet
e) Sealable plastic bag
f) Absorbent pad or brown paper
g) Clean sample transport box
h) Biohazard symbol label
i) Label with name, address and contact number of Viral load lab
j) Thermometer

The triple packaging system includes 3 layers:

a) Primary Receptacle

- Tube containing sample for viral load testing
- Tube must be watertight and leakproof
- Must be appropriately labelled

b) Secondary Packaging

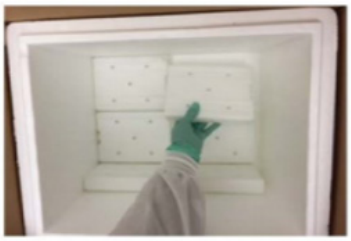


- The aim of this layer is for enclosure and protection of the primary receptacle
- Must be watertight and leakproof
- Aliquot storage box compatible to store 2.0 ml aliquot vials
- Seal the aliquot storage box and keep it in a zip lock bag along with absorbent material.

c) Outer Packaging

- Protects secondary packaging from physical damage while in transit
- Insulated box (sample transport box) or thermocol box
- Should be labelled with biohazard symbol.
- The outside of the third container should remain clean to be easily handled without any need for PPE
- The filled transport sheet should be sent along with the samples shipped.
- The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" should be mentioned. The labelling should include Bio-hazard symbol.

Clean Sample transport Box

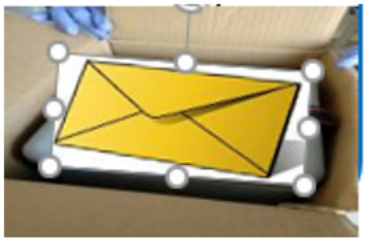


Arrange pre cooled ice pack

Place absorbent material

Keep sample aliquot box in zip lock bag and place in the sample transport box

Cover the lid and label with Biohazard symbol



Keep transport sheet in envelop. Keep the sample transport box and transport sheet in card board box.

Source: National Guidelines For HIV-1 Viral Load Laboratory Testing. New Delhi: National AIDS Control Organization (NACO); April 2018. Available from: https://www.naco.gov.in/sites/default/files/NationalGuidelinesForHIV-1ViralLoadLaboratoryTestingApril2018%20(2).pdf

Annexure-7: Dosage Chart for Infant ARV Prophylaxis

Infant ARV prophylaxis should be started immediately after birth or at their first encounter with health services in all HIV-exposed infants. It can be started even if more than 72 hours have passed since birth, though its efficacy in preventing perinatal transmission will be lower.

Dosage of Syrup Nevirapine (10 mg/ml solution) for infant ARV prophylaxis

Infant age	Daily dosing
Birth* to 6 weeks • Birth weight 2000-2500 g • Birth weight >2500 g	 10 mg (1 ml) once daily 15 mg (1.5 ml) once daily
>6 weeks – up to 6 months#	20 mg (2 ml) once daily
>6 months – up to 9 months#	30 mg (3 ml) once daily
>9 months	40 mg (4 ml) once daily
*Infants weighing <2000 g; the suggested starting dose is 2 mg/kg once daily #NVP dose for older infants is provided for the situation where HIV exposure is identified during infancy, the mother is breastfeeding, and the infant is either HIV uninfected or the status is yet to be determined after taking opinion from SACEP/ PCoE. Any HIV-exposed breastfeeding baby coming beyond 6 weeks of age, will need SACEP/PCoE opinion for dual prophylaxis to be given or not.	

Dose of Syrup Zidovudine (10 mg/ml solution) for infant ARV prophylaxis

Infant Birth Weight	AZT Daily Dosage (in mg)	AZT Daily Dosage (in ml)	Duration
<2000 g	5 mg/dose twice daily	0.5 ml twice daily	6 weeks
2000- 2500 g	10 mg/dose twice daily	1 ml twice daily	6 weeks
≥2500 g	15 mg/dose twice daily	1.5 ml twice daily	6 weeks
Older infants requiring dual prophylaxis may be given syrup zidovudine in a dose of 4mg/kg/dose twice daily			

- In situations where Nevirapine will not be effective for single ARV prophylaxis (for low risk infants) and if Zidovudine syrup is not available, syrup LPV/r should be used after 14 days of birth.
- In situation where dual ARV prophylaxis advised (for high risk infants) and if Zidovudine syrup is not available, syrup Nevirapine should be used for the first 14 days after birth, and then LPV/r should be added after 14 days of birth until 6 weeks in the case of Exclusive Replacement Feeding or 12 weeks in the case of Exclusive Breast Feeding.

Dosage of Syrup LPV/r (80 mg/20mg per ml of solution) for infant ARV prophylaxis

Infant age	Weight of baby	Daily dosing
Birth to 2 weeks	Do not use LPV/r solution for infants aged younger than 2 weeks of age	
2 weeks to 4 weeks	Weight 2000-2999 g	0.6 ml twice daily
	Weight 3000-3999 g	0.8 ml twice daily
	Weight 4000-4999 g	1.0 ml twice daily
> 4 weeks	Weight 3.0 kg-5.9 kg	1.0 ml twice a day
	Weight 6.0 kg-9.9 kg	1.5 ml twice a day

- Syrup Lopinavir/ritonavir is recommended for infant prophylaxis in specific situations and should only be used for infants after 14 days of birth.
- Dosage: Once-daily dosing of LPV/r **is not recommended**.
- Syrup LPV/r must be administered twice daily according to the body weight of the infant
- LPV/r 300 mg/75 mg per m2 of body surface area per dose, given twice daily. This approximates LPV/r 16 mg / 4 mg (both per kg body weight) per dose given twice daily.

Source: National Guidelines on HIV Care and Treatment 2021; available at https://www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment%202021.pdf

Annexure 8: Process Steps for Administering BPG Injection and Management of Anaphylaxis

- Conduct a penicillin sensitivity test before administering BPG.
- Administer the injection into the ventrolateral, dorso-gluteal area of the buttock, or vastus lateralis of the thigh, alternating on each administration. Do not give BPG into the deltoid muscle of the upper arm.
- Deliver the medication at a slow, steady rate over 2-3 minutes.
- Never administer BPG via intravenous administration. Take special precautions to avoid intravascular injection.
- Avoid injecting the suspension near major nerves or blood vessels as it could cause neurovascular damage.
- Observe the patient for signs of anaphylactic shock such as discomfort in breathing, shock, itchy rashes, or hives.

If the patient experiences anaphylactic shock,

- Call for help and contact emergency services if required.
- Assess the patient's airway, breathing, and circulation, and perform CPR if necessary.
- Inject adrenaline intramuscularly (0.5ml for adults, 0.3ml for elderly) and repeat in 5-10 minutes until the response is adequate. The recommended dilution for adrenaline is 1:1000 (1 mg/ml).
- Check the patient's blood pressure and pulse every 5-10 minutes.
- Administer hydrocortisone, 250 mg intramuscularly.
- Administer chlorpheniramine, 10-20 mg, or diphenhydramine, 50-100 mg intramuscularly.
- Transfer the patient to the hospital or nearest emergency ward.
- Repeat adrenaline if necessary.
- Record all details of treatment and give a copy to the hospital as well as the patient.

Source: National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections (2024), NACO, MoHFW.

Annexure 9: Management Of Neurosyphilis, Ocular Syphilis, and Oto-Syphilis In Pregnant Women

Neurosyphilis, ocular syphilis, and oto-syphilis are serious manifestations of syphilis that can affect pregnant women. These conditions require immediate medical attention and management by a team of specialists in a tertiary care centre. All the pregnant women suspected with neurosyphlis, ocular syphilis and oto-syphilis should be referred to a tertiary care centre for specialized care. The following are the guidelines for the management of these conditions in pregnant women.

Neurosyphilis:

Neurosyphilis is a severe form of syphilis that affects the central nervous system. Pregnant women with suspected or confirmed neurosyphilis should be referred to a tertiary care centre for further evaluation and management. The following steps should be followed:

- Evaluation: The patient should undergo a thorough evaluation, including a detailed neurological examination, cerebrospinal fluid (CSF) analysis, and neuroimaging studies.
- Treatment: The treatment of neurosyphilis in pregnant women involves intravenous administration of aqueous crystalline penicillin G every 4 hours for 10-14 days. The dose and duration of treatment should be determined by the specialist team based on the stage and severity of the disease. Refer to latest recommendations for management.
- Monitoring: The patient should be closely monitored during and after treatment to assess treatment response and detect any adverse effects. Repeat CSF analysis may be necessary to confirm the eradication of the disease.
- Follow-up: The patient should be scheduled for regular follow-up visits to assess treatment response, monitor the pregnancy, and prevent any adverse outcomes.

Ocular syphilis: Ocular syphilis is a rare but serious manifestation of syphilis that affects the eyes and can cause permanent vision loss. Pregnant women with suspected or confirmed ocular syphilis should be referred to a tertiary care centre for further evaluation and management. The following steps should be followed:

- Evaluation: The patient should undergo a thorough ophthalmic examination, including fundus examination, optical coherence tomography (OCT), and visual field testing.
- Treatment: The treatment of ocular syphilis in pregnant women involves intravenous administration of aqueous crystalline penicillin G every 4 hours for 10-14 days. The dose and duration of treatment should be determined by the specialist team based on the stage and severity of the disease. Refer to latest recommendations for management.
- Monitoring: The patient should be closely monitored during and after treatment to assess treatment response and detect any adverse effects. Repeat ophthalmic examination may be necessary to confirm the eradication of the disease.
- Follow-up: The patient should be scheduled for regular follow-up visits to assess treatment response, monitor the pregnancy, and prevent any adverse outcomes.

Oto-syphilis: Oto-syphilis is a rare but serious manifestation of syphilis that affects the inner ear and can cause hearing loss. Pregnant women with suspected or confirmed oto-syphilis should be referred to a tertiary care centre for further evaluation and management. The following steps should be followed:

- Evaluation: The patient should undergo a thorough audiological examination, including pure-tone audiometry and auditory brainstem response (ABR) testing.
- Treatment: The treatment of oto-syphilis in pregnant women involves intravenous administration of aqueous crystalline penicillin G every 4 hours for 10-14 days. The dose and duration of treatment should be determined by the specialist team based on the stage and severity of the disease. Refer to latest recommendations for management.
- Monitoring: The patient should be closely monitored during and after treatment to assess treatment response and detect any adverse effects. Repeat audiological examination may be necessary to evaluate the efficacy of the treatment and to monitor any changes in the patient's hearing.
- Follow-up: Pregnant women with oto-syphilis should receive regular follow-up care to ensure that the disease has been adequately treated and that there are no long-term effects on the patient's hearing or overall health.
- Prevention: The best way to prevent oto-syphilis in new-borns is to ensure that pregnant women receive adequate prenatal care and are screened and treated for syphilis during pregnancy. All pregnant women should be tested for syphilis early in pregnancy and at delivery if they are at high-risk of infection. Prompt treatment of syphilis in pregnant women can prevent the transmission of the disease to the foetus and the development of oto-syphilis in the newborn.
- Note: The updated guidelines for management of neurosyphilis, oto-syphilis and oculosyphilis may be referred to guide the treatment. The guidelines are available at:

  National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections (2024), NACO, MoHFW.

Source: Workowski KA, Bolan GA, Centres for Disease Control and Prevention. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021 Jun 4;70(RR-3):1-187. Available from: https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

Annexure-10: EVTHS Syphilis Card

Baby's Card

(To be completed for all babies by Pediatrician)

Follow-up at 6th Month

Date	:		
Click all that apply	: Complications/Congenital Syphilis/others (specify)		
Findings on Clinical Examination	:		
Whether tested for RPR/VDRL	: Yes/No	**If yes, RPR/VDRL titres**	:
Diagnosed with Congenital Syphillis	: Yes/No	**If yes, whether curative treatment provided**	: Yes/No
Treatment Details (Mention details of the drug, duration, and dates of treatment)			
Details on Management of Complications	:		
Any further follow-up needed	: Yes/No If yes, attach further sheets with details		

(The details on immunization, growth monitoring and others can be added as additional sheets)

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EVTHS Card - Syphilis

Pregnant Woman's Card

(to be completed for all pregnant women screened reactive for Syphilis)

Name	:	**PID No./ Mobile Number & DSRC**	:
Age	:	**Case**	: Pregnant Women /DIL
Gravida	:	**Parity**	:
LMP	:	**EDD**	:

Details on Syphilis Screening

Type of test with date of screening	: RPR/VDRL/Dual RDT/ TPHA/ Others (Please Name)		
Whether test for confirmation conducted	: Yes/No	**If yes, test used & results**	:
RPR/ VDRL Titres	: (Mention baseline titres)		

Treatment Details

Injection Benzathine Penicillin	1st Dose (Yes/No)	**Date of treatment**	:
	2nd Dose (Yes/No/NA)	**Date of treatment**	:
	3rd Dose (Yes/No/NA)	**Date of treatment**	:

Treatment Monitoring (Yes/No)

If yes, date of monitoring	:	**RPR/VDRL Titres**	:
Outcome	: Treatment Failure/Successful	If Failure, then Retreatment	:Yes/No/ NA (Date)
Partner Screening and Management	: Yes/No	**Provide details**	:

Details on Delivery

Pregnancy Outcome	: Abortion/MTP/Still Birth/Live Birth	**Date of delivery (NA if Abortion or MTP)**	:
RPR/VDRL Titres (at delivery/ childbirth)	Yes/No	**RPR/VDRL Titres**	:

Page 1

Baby's Card

(To be completed for all babies by Pediatrician)

Name of baby	:	**Date of Birth**	:
Details at Birth			
Click all that apply	: LBW/Premature/ Complications/Congenital Syphilis/others (specify)		
Findings of Clinical Examination	:		
Whether tested for RPR/VDRL	: Yes/No	**If yes, RPR/VDRL titres**	:
Diagnosed with Congenital Syphilis	: Yes/No	**Treatment**	: Prophylactic/Crative
Treatment Details (Mention Details of the drug, duration, and dates of Treatment)	:		
Details on Management of Complications	:		
Date of Next Follow-up	:		

(The details on immunization, growth monitoring and others can be added as additional sheets)

Baby's Card

(To be completed for all babies by Pediatrician)

Follow-up at 14th Week

Date	:		
Click all that apply	: Complications/Congenital Syphilis/others (specify)		
Findings of Clinical Examination	:		
Whether tested for RPR/VDRL	: Yes/No	**If yes, RPR/VDRL titres**	:
Diagnosed with Congenital Syphilis	: Yes/No	**if yes, whether curative treatment provided**	: Yes/No
Treatment Details (Mention details of the drug, duration, and dates of treatment)	:		
Details on Management of Complications	:		
Date of Next Follow-up	:		

(The details on immunization, growth monitoring and others can be added as additional sheets)

Annexure- 11: Cleaning and Disinfection of Labour Room

Cleaning and Disinfection of Labour Room

The labour room along with all equipment and all surfaces should be cleaned every morning and all equipment and surfaces used should be cleaned after every delivery.

Labor table should be cleaned in each shift and after each delivery with:

(a) cloth soaked in clean water (and soap water if required)

(b) cloth soaked in 0.5 % chlorine solution

Cheatle forceps should not be kept in antiseptic, and should be autoclaved daily and kept in autoclaved holder with date and time labelled each day.

Toilet should be cleaned with disinfectant at the start of each shift and after each delivery. The overhead tank supplying water to the labor room should be cleaned at least once a week. (9)

a) Daily at start of the Day

- The floor and sinks should be cleaned with detergent (soap water) or chlorine solution daily in the morning and thereafter every three hours. The floor should be kept dry.
- All the table tops and other surfaces such as lamp shades, almirah, lockers, trollies etc. should be cleaned with low level disinfectant (2% carbolic acid).
- Monitor machines should be cleaned with 70% alcohol.

b) After each delivery

- Table tops should be cleaned thoroughly with chlorine solution or disinfectant (1% carbolic acid).
- Disposable absorbent sheet placed on the labor table should be changed.
- Any spillage of blood or body fluids on the floor should be soaked with chlorine solution for 10 minutes. Should be absorbed in a spillage kit or absorbent paper and then mopped. The soaked absorbent paper should be discarded in appropriate plastic bin.

c) Procedure for mopping

- Prepare 3 buckets with clear water. Pour the disinfectant solution in one of the buckets. (So that you have two buckets of clean water and one bucket containing disinfectant). Clean water buckets should be labelled as 1st, 2nd and 3rd bucket. The 3rd bucket will be containing disinfectant.
- The cleaning begins on the floor starting from inside to outside. Towards the end, all corners and groves have to be cleaned.
- After each sweep of the floor, the mop should be dipped first in the 1st bucket then in the 2nd bucket and lastly in the 3rd bucket containing disinfectant.
- Mops should be cleaned in the dirty utility area and put in the stand under the sun with the mop head upward and tilted, not straight.
- Mopping of floors would be done at least thrice a day and in-between whenever required. Mopping of floors would be done with water with detergent and disinfectant (phenolic based) in Negative Pressure Isolation rooms.

- In case of visible blood/body-fluids spills, the protocol of managing spills would be followed. All soiled mops would be treated as soiled linen and transported likewise in a covered (lid) container.
- At the end of each shift & a cleaning schedule for an area, all soiled mops should be sent, in a hamper, to the laundry for washing.
- Mops should be visibly clean before starting cleaning of an area.
- Mops should be replaced after interim cleaning is done, as and when called for and mops kept in the wringer trolley well squeezed and out of the solution.
- Mops should be changed routinely and immediately following the cleaning of blood, body-fluids secretions and excretions, after cleaning contaminated areas, Operation theatres or isolation rooms.
- Mops should not be left wet.
- Store mops dry in a designated well demarcated utility storage area away from the clean area.
- Mops should be washed in a laundry in a cycle dedicated for mops washing only with 1% Hypochlorite. This should be followed by a non-load disinfectant cycle with 1% Hypochlorite giving an exposure of 20 minutes at least.
- Personnel carrying out the cleaning and transporting the soiled mops would wear adequate PPE (gloves, mask and gown).
- Trolleys transporting mops should be cleaned as per schedule with detergent followed by chlorine solution/ 70% isopropyl alcohol –as per compatibility according to manufacturer's instructions.
- Hand-mops mounted on wipers should be used for the bathroom mopping after putting on gloves.

B Protocol for safe care in the labour room

- In LDR labor rooms, the pregnant woman should be directly sent to the LDR unit after admission. She can be transferred to the postpartum ward 4 hour after the delivery, if the mother and baby are free of complications and there are other cases. If the rooms are free, she should be kept in the same room for as long as possible.
- In case of conventional labor rooms, the pregnant woman should be brought in the labor room in active phase of labor and can be shifted to postpartum ward after 2 hours if there are other cases.
- Pregnant woman should be brought in the labor room/LDR unit after changing into properly washed and dried delivery gown.
- One birth companion of her choice should be encouraged to be present in the labor room for giving her emotional and physical support.
- The duty nurse and doctor should undertake a thorough examination to assess the progress of labor and relevant medical and obstetric history.
- If the woman is in active labor, the partograph should be plotted.
- In the second stage of labor, besides attending nurse one additional support may be required.

C Displays

All essential practices protocols (for example, AMTSL, partograph, essential newborn care, hand washing, IMEP protocols etc.) should be displayed in and around the labor room and clearly visible at appropriate places. Such as, the hand-washing poster should be displayed near the washing station; newborn resuscitation poster should be displayed near the newborn care area, AMTSL and partograph on a wall near the labor table, etc. Following essential practices should be performed in all the delivery cases. The SCC should be used at all relevant check points {on admission, before delivery, just after delivery (within 1 hour), and at the time discharge} to ensure that these practices have been completed in all cases: Following are some of the harmful practices that should not be performed in every case without specific indication. Please remember, induction/augmentation should not be done routinely. Also, whenever needed, augmentation of labor should be done only in centres capable of performing caesarean sections.

Supportive supervision for quality of care in labour room

- The labor room should have a cleanliness checklist for cleanliness assessment that should be completed and signed by every supervisor conducting a visit of the labor room. The facility in-charge should visit the labor room at least twice during each week.
- The OBG/MO (wherever available) in-charge of the labor room should visit labor room twice every day. The nursing supervisor/nurse in-charge should visit the labor room at least once in every shift.
- During every visit, the supervisors should observe the cleanliness in the labor room and mark appropriate responses in the cleanliness (no wet areas) checklist. Further, they should review the availability of essential supplies.
- Every month, a labor room practice review meeting should be organized at each facility. All staff involved in care in labor room, including support and cleaning staff, should participate in this meeting. The group should deliberate upon ways to improve quality in the labor rooms. Feedback of supportive supervision should also be shared during these meetings.

Annexure-12: Clinical criteria for presumptive diagnosis of severe HIV disease in infants and children less than 18 months of age requiring ART in situations where virological testing is not immediately available/report is pending.

A presumptive diagnosis of severe HIV disease should be made in the following situations:

The infant's HIV antibody test is reactive

and

Diagnosis of any AIDS-indicator condition(s) can be made

or

The infant is symptomatic with two or more of the following:*

- Oral thrush
- Severe pneumonia
- Severe sepsis

Other factors that support the diagnosis of severe HIV disease in an HIV seropositive infant include the following:

Recent HIV-related maternal death; or advanced HIV disease in the mother; CD4 in the child <20%.

Confirmation of the diagnosis of HIV infection should be sought as soon as possible.

Notes

*As per IMCI definition:

1. Oral thrush: Creamy white to yellow soft small plaques on red or normally coloured mucosa that can often be scraped off (pseudo membranous), or red patches on tongue, palate or lining of mouth, usually painful or tender
2. Severe pneumonia: Cough or difficult breathing in a child with chest in-drawing, stridor or any of the IMCI general danger signs, i.e., lethargic or unconscious, not able to drink or breastfeed, vomiting and presence or history of convulsions during current illness; responding to antibioticss
3. Severe sepsis: Fever or low body temperature in a young infant with any severe sign such as fast breathing, chest in-drawing, bulging fontanelle, lethargy, reduced movement, not feeding or sucking breast milk, convulsions, etc.

IMCI: Integrated Management of Childhood Illness

Source: Chapter 3.1, Table 3.1.11 of the National Guidelines for HIV Care and Treatment, 2021;
Available at: https://www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment%202021.pdf

Annexure-13: Referral Slip Format

National AIDS and STD Control Program
Linkage/Referral Form (in triplicate)

Copy-1
(to be retained at the facility referring the person)

Referred by: .....

Referred to (Name & Address of facility):

.....

To be filled by the facility referring the person

Details of the person being referred:
PID Number: .....
Name: .....
Age: ..... Sex: ..... Contact No: .....
Any other details:

Date of referral: .....
Purpose of referral:

Details of the staff referring the person:
Name: .....
Designation: .....
Contact No: .....

Feedback from referred Centre

Has the person reached and has received care:
YES ☐ NO ☐
Remarks:

Name of the staff documenting this information:

National AIDS and STD Control Program
Linkage/Referral Form (in triplicate)

Copy-1
(to be carried by the person to the referred facility & to be retained at referred facility)

Referred by: .....

Referred to (Name & Address of facility):

.....

To be filled by the facility referring the person

Details of the person being referred:
PID Number: .....
Name: .....
Age: ..... Sex: ..... Contact No: .....
Any other details:

Date of referral: .....
Purpose of referral:

Details of the staff referring the person:
Name: .....
Designation: .....
Contact No: .....

Feedback from referred Centre

Has the person reached and has received care:
YES ☐ NO ☐
Remarks:

Name of the staff documenting this information:

National AIDS and STD Control Program
Linkage/Referral Form (in triplicate)

Copy-3
(to be retained at the person)

Referred by: .....

Referred to (Name & Address of facility):

.....

To be filled by the facility referring the person

Details of the person being referred:
PID Number: .....
Name: .....
Age: ..... Sex: ..... Contact No: .....
Any other details:

Date of referral: .....
Purpose of referral:

Details of the staff referring the person:
Name: .....
Designation: .....
Contact No: .....

Annexure-14: Agendas for Comprehensive Training on Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) Interventions under NACP V

Agenda-1

Comprehensive Training on Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) Interventions under NACP V

Mode of Training: Virtual/Physical/Hybrid (State/Regional/District)

Participants: NACP Staff at ART, ICTC, and DSRC (Medical officers, Counsellors, Staff Nurse), District Managers from RCH, DAPCU and DISHA representatives.

Time for the Training: 04.00 hours

S. No	Time for the Session	Topic	Content of the Session	Suggested Facilitator/ resource Person (To be decided by SACS)
	-	Welcome & Introduction	• Setting the context	• SACS/State NHM
1	15 min	Introduction to EVTHS services	• Need for EVTHS • Overview of Strategies and Newer Prongs for EVTHS	• BSD, SACS
2	25 min	Primary Prevention of HIV and STI Prevention of Unintended Pregnancies in WLHIV	• Demand Generation and Awareness • Prevention Services for At-risk and High-risk women • ART initiation in WLHIV • Health Timing and Spacing of Pregnancy (HTSP) in Women living with HIV (WLHIV)	• TI/IEC SACS • CST SACS • Family Planning Division, State NHM
3	20 min	Screening and Diagnosis of HIV and Syphilis in pregnant women	• Screening for HIV and Syphilis during Pregnancy • Linkages of HIV reactive and Syphilis reactive case • Confirmation of HIV and Syphilis diagnosis • Index and Partner Testing for HIV and Syphilis	• BSD, SACS • STI, SACS • Lab Services, SACS

S. No	Time for the Session	Topic	Content of the Session	Suggested Facilitator/ resource Person (To be decided by SACS)
	10 min		**Discussion**	Resource Persons
4	35 min	Management of HIV/Syphilis infection in Pregnant Women	• Care Cascade for HIV infected pregnant mother • Care Cascade for Syphilis infected pregnant mother • Management of Women Coming Directly in Labour • Two case scenarios	• STI SACS • CST SACS • Maternal Health, State NHM
5	35 min	Management of HIV exposed Babies including EID	• Care Cascade for HIV exposed baby • Early Infant Diagnosis (EID) • three case scenarios and two quiz questions	• BSD, SACS • Lab Services, SACS • Child Health, State NHM
6	20 min	Management of Syphilis exposed babies	• Care Cascade for Syphilis exposed baby • one case scenario	• STI, SACS • Child Health, State NHM
	10 min		**Discussion**	Resource Persons
7	20 min	Comprehensive and Integrated EVTHS Service Delivery	• Services delivery model of EVTHS • Referrals and Linkages for EVTHS	• State NHM • BSD SACS
8	10 min	Commodities and Supply Chain	• Commodity provisioning and its Source of funding • Responsibility for Supply chain Management	• BSD, SACS
9	30 min	Recording and Reporting for EVTHS Services at State NHM	• Data recording in RCH Portal • Data recording in HMIS • Key indicators as per M&E Framework	• SACS M&E • Officials responsible for SOCH, RCH portal and HMIS
10		Recording and Reporting for EVTHS Services at SACS	• Data flow in SOCH • Key indicators as per M&E Framework	
	10 min		**Discussion**	Resource Persons
		Vote of Thanks		

Agenda-2

Sensitization for Comprehensive Training on Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) Interventions under NACP V

Mode of Training: Virtual/Hybrid (National Level)

Participants: SACS BSD, CST, M&E, Lab services and STI/ State NHM representatives including Maternal Health, Child Health, Adolescent Health, Family Planning

T**ime for the Training:** 03.00 hours

S. No	Time for the Session	Topic	Content of the Session	Facilitator/ resource Person
-	-	Welcome & Introduction	• Setting the context	• NACP/NHM Representative
1	20 min	Integrated EVTHS Strategies and Services	• Need for EVTHS • Overview of Strategies and Newer Prongs for EVTHS • Services delivery model of EVTHS • Referrals and Linkages for EVTHS	• Representatives from RMNCAH+N • BSD Division, NACO
2	10 min	Primary Prevention of HIV and STI	• Demand Generation and Awareness • Prevention Services for At-risk and High-risk women	• IEC Division, NACO • Adolescent Health Division, MoHFW
3	15 min	Prevention of Unintended Pregnancies in WLHIV	• ART initiation in WLHIV • Health Timing and Spacing of Pregnancy (HTSP) in Women living with HIV (WLHIV)	• Family Planning, MoHFW • CST Division, NACO
4	15 min	Screening and Diagnosis of HIV & Syphilis in pregnant women	• Screening for HIV and Syphilis during Pregnancy • Linkages of HIV reactive and Syphilis reactive case • Confirmation of HIV and Syphilis diagnosis • Index and Partner Testing for HIV and Syphilis	• Maternal Health, MoHFW • BSD Division, NACO
5	20 min	Management of HIV/Syphilis infection in Pregnant Women including DIL	• Care Cascade for HIV infected pregnant mother • Care Cascade for Syphilis infected pregnant mother	• CST Division, NACO • STI Division, NACO

S. No	Time for the Session	Topic	Content of the Session	Facilitator/ resource Person
6	30 min	Management of HIV exposed babies including EID	• Care Cascade for HIV exposed baby • Child Health consultations as a high-risk baby • Early Infant Diagnosis (EID)	• BSD Division, NACO • Child Health, MoHFW • Lab Services Division, NACO
7	20 min	Management of Syphilis exposed babies	• Care Cascade for Syphilis exposed baby • Child Health consultations as a high-risk baby	• STI Division • Child Health Division, MoHFW
8	10 min	Commodities and Supply Chain	• Commodity provisioning and its Source of funding • Responsibility for Supply chain Management	• NACO
9	20 min	Recording and Reporting for EVTHS Services at NHM	• Data recording in RCH Portal • Data recording in HMIS • Key indicators as per M&E Framework	• Statistics Division, MoHFW
		Recording and Reporting for EVTHS Services at NACP	• Data flow in SOCH • Key indicators as per M&E Framework	• SI/IT Division NACO
10	10 min	Question and Answer	• All Participants	• All resource Persons/ Facilitators
-	10 min	Guidance for Training Plan and Next steps	• _	• BSD Division. NACO
-	-	Vote of Thanks		

National AIDS Control Organisation

India's response to HIV & Sexually Transmitted Infections

Ministry of Health & Family Welfare, Government of India

www.naco.gov.in

6th & 9th Floor, Chanderlok Building, 36, Janpath, New Delhi - 110001

Email Id: dgnaco@gmail.com

Tel: 011-43509999, 011-23731778, **Fax**: 011-23731746