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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
www.naco.gov.in

National HIV Counselling and Testing Guidelines 2024

September 2024

NACO, MoHFW, GoI, 2024

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For additional Information about National HIV Counselling and Testing Guidelines 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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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
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National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India

Foreword

It gives me immense pleasure to bring forth to you the "National HIV Counselling and Testing Guideline 2024" which has been meticulously prepared for program managers and service providers across the health system, both for the public as well as the private sector. "Break the Silos & Build Synergy" has been the cornerstone strategy for National AIDS and STD Control Programme (NACP) Phase V. Therefore, beholding this vision, the guideline has been prepared in accordance to the newer approaches and policies adopted under the programme, while realigning them as per the provisions under HIV and AIDS (Prevention and Control) Act, 2017.

The key change in the HIV Counselling and Testing Strategy is by expanding access to HIV screening within and beyond health systems, using simple point of care diagnostic tests for HIV or HIV & Syphilis. Efforts are also augmented to maintain and strengthen the quality of HIV & Syphilis diagnosis within the network of laboratories under NACP.

The document focuses on a standardized and uniform 'Terms of Reference' for all NACP Counsellors and client prioritization as well as on high yield strategies such as Index Testing Services, Social Networking Strategies and Mobile Outreach Strategy, etc. These concepts are incorporated in the guideline with the aim for ease of understanding and to bring synergy in the processes while implementing HIV Counselling and Testing Services in diversified settings.

To cover "At Risk" HIV-negative population to prevent emergence of new infection of HIV and STI, Sampoorna Suraksha Strategy through its single window approach provides holistic set of services that are customized as per the client's need. The document, therefore, guide the inclusion of these approaches while providing clarity on operational decisions, ensuring quality care, management of supply chain and implementation of special campaigns.

I take this opportunity to acknowledge the valuable inputs and contribution of the members of the Technical Resource Group and National Working Group as well as representatives from program divisions within and outside of National AIDS and STD Control Programme towards the development and finalization of the content. By integrating these guidelines into practice, we can work collaboratively towards creating future generations of India who are HIV and AIDS free.

I believe that the National HIV Counselling and Testing Guideline, 2024, will serve its purpose as a reference document for all who are involved in policy formation, program designing, planning, implementation and monitoring of the HIV and STI Counselling and Testing Services at various levels and in varied capacities in our overall health system.

(V. HEKALI ZHIMOMI)

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

लता गणपति, भा.प्र.से.
संयुक्त सचिव
Latha Ganapathy, IAS
Joint Secretary

सत्यमेव जयते

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



Message

National AIDS and STD Control Programme in its fifth phase of implementation adopted several newer HIV Counselling and Testing approaches and strategies to attain the Sustainable Development Goals (SDGs) of "Ending AIDS as a Public Health Threat by 2030". NACP-V aims to provide comprehensive services package delivery for "at-risk" and "High-Risk" populations as well as for People Living with HIV (PLHIV) for prevention, treatment and care services.

The objective of achieving the 1st 95 needs a paradigm shift in the implementation of HIV Counselling and Testing Services. The previous HIV Counselling and Testing Services Guideline required necessary revisions and modifications and hence this new updated National HIV Counselling and Testing Guidelines 2024 is being issued. This new guideline, while underlining the time tested effective strategies have also given adequate space and emphasis on the newer and impactful initiatives like Sampoorna Suraksha Strategy, Index Testing Services, Mobile Outreach Services etc.

To achieve the national and global goal of prevention of new infection and reduction in AIDS related mortality by early identification necessitated a focussed approach towards at-risk HIV negative clients and keep them negative through proper counselling and effective cyclical preventive services. In this guideline, adequate weightage has been placed on obtaining informed consent while taking care of maintaining the confidentiality of the client in line of the HIV AIDS (Prevention & Control) Act, 2017. The process of obtaining consent, provisioning of pre and post-test counselling and the risk-assessment helps counsellors to understand their client's risk and educate them to stay HIV negative.

These guidelines have explained in detail, the terminologies and procedures used at different levels to help all stakeholders to develop common understanding. It is expected that this National HIV Counselling and Testing Guidelines 2024 will serve as a reference document for all the personnel engaged in the HIV Counselling and Testing Services at National, State, district or facility level. I am confident that the National HIV Counselling and Testing Guidelines 2024 will serve as guiding framework to ensure access, availability and quality of HIV Counselling and Testing services, contributing to the goal of ending AIDS as a public health threat by 2030.

(Latha Ganapathy)

Room No. 145, 'A' Wing, Nirman Bhawan, New Delhi-110011
Tel. (O) : 011-23063809, E-mail : g.latha@nic.in

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

Under the fifth phase of National AIDS & STD Control Programme (NACP -V), NACO has conceived a paradigm shift in terms of embracing newer approaches and strategies under the HIV Counselling & Testing Services (HCTS) to enhance its effectiveness, not just in terms of expanding the coverage to reach out to those who are HIV infected but are unaware of their HIV status, but also to promote desired behaviour change amongst HIV negative but "at-risk" clients and help them to stay HIV negative throughout their lives by linking them with required and appropriate services through in-facility and out-facility referrals.

NACO had worked consistently under the guidance of the National Working Group for revision of HCTS guidelines and Technical Resource Group-HCTS. The development of this guidelines have been a participatory process. National Working Group was constituted to oversee the development of this guidelines. Members of the NWG were active and di. gent in carrying out the tasks of development of the content of the guideline as well as reviewing it and providing the inputs and feedbacks to make the guidelines more effective and relevant. I am happy that the collective efforts have contributed to the outcome of this very important guidelines.

The guideline will contribute to the two areas of global focus: containing HIV transmission & reaching the targets for 1st 95 and elimination of vertical transmission of HIV and Syphilis. The 95-95-95 strategy is essential for controlling HIV, with the second and third 95s relying on the success of the first 95. Therefore, the role of HIV counseling and testing services is crucial and cannot be overlooked. The primary focus of improved HIV Counselling and Testing Services is to reach out to those who are yet not covered under the HIV testing net but are at the potential risk of contracting and/or spreading the infection. These are the populations and groups who are now emphasized under this guideline for reaching out and covered either by outreach camp approach or through well-coordinated mobile outreach services.

Today I am happy to present you the " National HIV Counselling and Testing Guidelines 2024" which has been built upon all newer approaches and strategies adopted under the NACP - V to help its end user to be familiar with the newer strategic direction taken under the programme to reach the last mile.

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

"HIV Counselling and Testing Services Guidelines 2024" has been developed and released with an aim to incorporate all the newer strategies and approaches adopted under the National AIDS Control Programme Phase V (NACP-V). This guideline has been developed under the supervision of the National Working Group for revision of HCTS guideline, constituted to oversee the process of the development of this guideline. There have been a number of domain experts and specialists who have contributed in furnishing, reviewing and finalizing the content of this document.

Thus, myself on behalf of National AIDS Control Organization (NACO) expresses its profound gratitude to Ms. V. Hekali Zhimomi, IAS, Additional Secretary & Director General, NACO, for her visionary leadership and invaluable guidance in the development of these HCTS guidelines. We extend our sincere gratefulness to Ms Latha Ganapathy IAS, Joint Secretary, NACO, for her unwavering support and direction, which have been instrumental in shaping these guidelines.

We are deeply thankful to Dr. Anoop Kumar Puri, (DDG IEC & MS, NACO), Dr. Uday Bhanu Das, (DDG PMR & Lab Services, NACO), Dr. Chinmoyee Das, (PHS Grade I and HoD CST, SI, IT & SCM, NACO) for their technical expertise and timely inputs, which have significantly enhanced the quality of this guideline. Our gratitude to Dr. Shobini Rajan, (CMO (SAG) and HoD TI, BSD, and STI, NACO), for her conceptualization and leadership in designing and developing this guiding document while ensuring inputs from all concerned divisions of MoHFW. We acknowledge the invaluable contributions, continuous guidance and support of, Dr. Bhawani Singh Kushwaha, (DD CST, PMR, & SCM), and Dr. Bhawna Rao, (DD, IEC & MS, Lab Services & Global Fund, NACO), in the development and finalization of this guideline.

We extend our sincere gratitude to Dr. DCS Reddy, Chairperson, and the members of the Technical Resource Group on HCTC, whose technical guidance has been a cornerstone in the development and finalization of this document. The National Working Group for revision of HCTS guideline was constituted under the Chairpersonship of Dr. Sheela Godbole, Scientist G and Director, NITVAR. Her inputs and guidance have been very critical in finalizing the technical content throughout the journey of the development of this guideline. We are very grateful for the members of the National Working Group who have given their valuable time, expertise and experience in shaping this guideline. I

am thankful to Dr. Suneela Garg, Director Professor & Head Community Medicine Maulana Azad Medical College & Hospital New Delhi, Dr. Manju Bala, Professor & Consultant (Microbiology), Apex Regional STD Center and SRL for HIV, VMMC & Safdarjung Hospital, New Delhi, Dr. Sanjeeva G N, Director, pCoE, Indira Gandhi Institute of Child Health, Department of Pediatrics, Dr. Rohit Chawala Member Prof. MAMC, New Delhi, Dr. Bitra George Technical Expert FHI 360, Dr. Asha Hegde Public Health Expert PATH, Mr. Aditya Singh Executive Director JHU, Dr. Sudhir Chawala Public Health Expert CDC, Dr. Rita Prasad Public Health Expert USAID, Dr. Vanita Gupta Sr. Public Health Expert Ex PD Chandigarh SACS

I, take this opportunity to acknowledge the efforts of Dr Vibhavari Deshmukh (NC-BSD), Dr. Vishal Yadav (Consultant STI), Mr Mubarak Ali Ansari (Consultant BSD), Mr. Murugan Thirunavukkarasu (AC-BSD) , Ms. Hansa Lala (AC-BSD), Ms. Surbhi Srivastava (AC-BSD), Mr. Ajin Ayodh Karayil (AC-BSD,), Dr. Abhishek Royal (Technical Expert-STI), Dr. Rohini Gupta, (Consultant), Mr. Chaitnaya Bhat (Technical Expert-HCTS) and Dr. Payal Sahu (Technical Expert-SSS) for their technical assistance, coordination, and support in drafting this document.

An extreme level of efforts have been put up by many experts through their technical expertise and experience in the development of these Revised HCTS guidelines. The list is exhaustive to be covered in the acknowledgement letter here but would be incomplete without expressing the gratitude and appreciations 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.

We extend our gratitude to I-Tech for their invaluable contributions in designing, editing, and printing of this document.

(Dr. Saiprasad Bhavsar)

Contributors' List HCTS

I. National AIDS Control Organization

- Ms. V. Hekali Zhimomi, Additional Secretary & Director General
- Ms. Latha Ganpathy, Joint Secretary
- Dr. Anoop Kumar Puri, Deputy Director General, (IEC)
- Dr. U.B. Das, Deputy Director General (LS, PMR, GF)
- Dr. Shobini Rajan, Deputy Director General (BSD, STI, and Prevention)
- Dr. Chinmoyee Das, Additional Director General (CST, SI, and IT)
- Dr. Bhawani Singh, Deputy Director (CST, PMR)
- Dr. Saiparsad P. Bhavsar, Deputy Director (BSD, STI, and Prevention)
- Dr. Bhawna Rao, Deputy Director (LS, GF, IEC)

Consultants – NACO

- Dr. Pradeep Kumar, National Consultant-SI
- Dr. Shantanu Purohit, National Consultant-Prevention
- Dr. Vibhavari Deshmukh, National Consultant-BSD
- Ms. Nidhi Rawat, National Consultant-IEC
- Dr. Harsh Hora, National Consultant, CST
- Mr. Ginlianmung Ngaihte, Consultant-Prevention
- Dr. Purnima Parmar, Consultant-CST
- Dr. Shivali Kamal, Consultant-Lab Services
- Ms. Smita Mishra, Consultant, Lab Services
- Dr. Vishal Yadav, Consultant, STI
- Mr. Mubarak A Ansari, Consultant, Basic Services
- Dr. Aniruddha Wani Consultant, Lab Service Division NACO.
- Dr. P Sujith Consultant, SI Division.
- Ms. Hansa Lala, Associate Consultant, Basic Services

- Mr. M. Thirunavukkarasu, Associate Consultant, Basic Services
- Ms. Surbhi Srivastava, Associate Consultant, Basic Services
- Mr. Ajin Ayodh, Associate Consultant, Basic Services
- Ms. Suman Sehrawat, Ex. Consultant, Basic Services
- Mr. Shailendra Gandharva, Ex- Associate Consultant, Basic Services
- Ms. Jyotsna Tiwari, Ex- Associate Consultant, Basic Services

Technical Experts – NACO

- Mr. Chaitanya Bhatt, Technical Expert – Basic Services
- Dr. Abhishek Royal, Technical Expert- STI
- Dr. Rohini Gupta, Technical Expert
- Dr. Payal Sahu, Technical Expert – SSS & OSC
- Mr. Samresh Kumar, Technical Expert, TI
- Ms. Ira Madan, Technical Expert – CSS & Virtual Interventions
- Dr. Sheikh Mohd Saleem, Technical Expert- EVTHS
- Ms. Gunjan Pandye, Technical Expert-Prevention

II. Other National Health Programs

- Ms. Meera Srivastava, Joint Secretary, RCH
- Dr. Govind Bansal, Director, RCH
- Dr. Pawan Kumar, Additional Commissioner I/c. Maternal Health and Immunization
- Dr. Indu Grewal, Additional Commissioner, Family Planning, Aspirational District and Blocks, PC&PDT, CAC
- Dr. Zoya Ali Rizvi, Deputy Commissioner, Nutrition, Adolescent Health Division
- Dr. Sandhya Kabra, Additional Director, NCDC & Deputy Commissioner, NVHCP
- Dr. Divya Valecha, Assistant Commissioner, Family Planning Division
- Dr. Partha Rakshit, Joint Director, NVHCP
- Dr. Preeti Madan, Joint Director, NVHCP
- Dr. Hema Gogia, Assistant Director, NVHCP
- Dr. Dileepan S, Senior Consultant, NVHCP
- Dr. Rajendra Joshi, Ex- Deputy Director General NTEP
- Dr. Sanjay Kumar Mattoo, Joint Commissioner & Additional deputy Director General, NTEP

Consultant, MoHFW

- Dr. Vaibhav Rastogi, Consultant Child Health
- Dr. Tushar Purohit, Senior Technical Officer, Maternal Health

III. Technical Resource Group-HCTS

- Dr. DCS Reddy (Chairperson), Ex Professor & HoD, PSM, IMS, Banaras Hindu University (BHU), Varanasi
- Dr. Suneela Garg, Chairperson Prog Advisory Committee NIHFW, Ex-Head & Professor Community Medicine, Sub-Dean MAMC New Delhi, Member of NWG for revision of HCTS guideline
- 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
- Dr. S. Anuradha, Professor, Dept of Medicine, Maulana Azad Medical College, New Delhi
- Dr. Ramesh Bhosale, Professor, Gynecology and Obstetrics, B.J. Medical College, Pune
- 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. Nilesh Gawde, Assistant Professor, School of Health System Studies, TISS, Mumbai
- Dr. Manisha Kiran, Associate Prof. and Head, Deptt. of Psychiatric Social Work, Ranchi Institute of Neuropsychiatry & Allied Sciences, Ranchi
- Dr. Madhuri R Thakar, Scientist G, ICMR National AIDS Research Institute, Pune
- Mr. Ved Prakash, NACP Counselor, Lal Bahadur Shastri Hospital, Delhi
- Ms. Sunetra Choudhury, NACP Counselor, Medical College & Hospital, Kolkata

IV. National Working Group for revision of HCTS Guidelines

- Dr. Sheela Godbole, Chairperson-NWG & Director & Scientist G, NITVAR
- Dr. A.K. Puri, Co -Chairperson DDG, IEC NACO
- Dr. Shobini Rajan, Member Secretary CMO (SAG) & DDG NACO
- Dr. Manju Bala, Member Professor & Consultant (Microbiology), Apex Regional STD Center and SRL for HIV, VMMC & Safdarjung Hospital, New Delhi
- Dr. Sanjeeva G N, Director, pCoE, Indira Gandhi Institute of Child Health, Department of Pediatrics
- Dr. Rohit Chawala, Member Prof. MAMC, New Delhi
- Dr. Bitra George, Technical Expert FHI 360

- Dr. Asha Hegde, Public Health Expert PATH
- Mr. Aditya Singh, Executive Director JHU
- Dr. Sudhir Chawala, Public Health Expert CDC
- Dr. Rita Prasad, Public Health Expert USAID
- Dr. Vanita Gupta, Sr. Public Health Expert Ex PD Chandigarh SACS

Representative from SACS:

- Dr. Sukhwinder Kaur, JD-BSD, Punjab State AIDS Control Society
- Dr. Shahnaz Zothanzami, JD-BSD, Mizoram State AIDS Control Society

V. Representatives from Development 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, 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
- Mr. G. S. Srinivas Public Health Expert PATH.
- Ms. Sai Subhasree Raghavan - President – SAATHII
- Mr. Rajiv Dua, Chief Executive - India HIV/AIDS Alliance
- Mohammed Asif, Executive Director, PLAN India
- Dr. Rajesh Rana, Director Plan India
- Ms. Divya Gulati, I-TECH India

Abbreviations and Acronyms

Abbreviation	Full form
ACH	Air Changes per Hour
AEB	Accidental Exposure to Blood
AFHC	Adolescent Friendly Health Clinics
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ANHI	Annual New HIV infections
ANM	Auxiliary Nurse Midwife
ANMOL	Auxiliary Nurse Midwife On-line
ART	Anti-retroviral Treatment
ARV	Anti-retroviral
ASHA	Accredited Social Health Activist
ATF	Addiction Treatment Facility
BCC	Behaviour Change Communication
BCG	Bacillus Calmette-Guérin
BPG	Benzathine Penicillin G
CBO	Community-Based Organizations
CBS	Community Based Screening
CCSO	Community Care and Support Officer
CD4	Cluster of Differentiation 4
CDHO	Chief District Health Officer
CDMO	Chief District Medical Officer
CEmONC	Comprehensive Emergency Obstetrics & Newborn Care
CHC	Community Health Centre

CLHIV	Children Living with HIV
CLSI	Clinical and Laboratory Standards Institute
CMHO	Chief Medical and Health Officer
COE	Centre of Excellence
CPLI	Community Peer Led Intervention
CPT	Cotrimoxazole Preventive Therapy
CQI	Continuous Quality Improvement
CRG	Community Resource Group
CS	Congenital Syphilis
CSC	Care and Support Centre
CSF	Cerebrospinal Fluid
CSS	Community System Strengthening
DACO	District AIDS Control Officer
DAPCU	District AIDS Prevention and Control Units
DBS	Dried Blood Spot
DH	District Hospital
DHC	District Health Centre
DHO	District Health Officer
DIL	Direct in Labour
DISHA	District integrated Strategy for HIV/AIDS
DLN	District Level Network
DNO	District Nursing Officer
DPMU	District Programme Management Unit
DRTB	Drug Resistant Tuberculosis
DSTB	Drug Sensitive Tuberculosis
DSD	Differentiated Service Delivery
DSRC	Designated STI/RTI Clinic
DTC	Drug Treatment Clinic
DTG	Dolutegravir
DTO	District TB Officer

Dual RDT	Dual Rapid Diagnostic Test
DVD	Digital Video Disc
EBF	Exclusive breastfeeding
EIA	Enzyme Immunoassay
EID	Early Infant Diagnosis
ELISA	Enzyme-Linked Immunosorbent Assay
EOR	Extended Outreach
EQA	External Quality Assurance
ERF	Exclusive replacement feeding
EVTHS	Elimination of Vertical Transmission of HIV and Syphilis
FEFO	First expiry first out
FHW	Female Health worker
FIDU	Female Injecting Drug Users
FRU	First Referral Unit
FSW	Female Sex Worker
GBV	Gender-based violence
H/TG	Hira/Transgender
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B virus
HBV DNA	Hepatitis B Virus DNA
HCP	Health Care Provider
HCTS	HIV Counselling and Testing Services
HCV	Hepatitis C Virus
HCW	Healthcare worker
Hep B	Hepatitis B
Hep C	Hepatitis C
HIV	Human Immunodeficiency Virus
HIV DR	HIV Drug Resistance
HIV SC1	HIV Source Code-1
HIV SC2	HIV Source Code-2

HIV-1	Human Immunodeficiency Virus type 1
HIV-2	Human Immunodeficiency Virus type 2
HIVST	HIV Self Testing
HMIS	Health Management Information System
HPV	Human Papilloma Virus
HRG	High-Risk Groups
HSS	HIV Sentinel Surveillance
HWC	Health and Wellness Centre
ICMR	Indian Council of Medical Research
ICTC	Integrated Counselling and Treatment Centre
IEC	Information, Education and Communication
IFU	Instructions For Use
IIMS	Integrated Information Management System
IPC	Interpersonal Communication
IPD	In-Patient Department
IRCA	Integrated Rehabilitation Centre for Addicts
ISHTH campaign	Integrated STI, HIV, TB & Hepatitis Campaign
ITS	Index Testing services
IUD	Intrauterine Device
KFT	Kidney Function Tests
KP	Key population
LAC	Link ART Centre
LFU	Loss to Follow-up
LHV	Lady Health Visitor
LT	Lab Technician
LWS	Link Workers Scheme
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MCP	Mother-Child Protection
MMU	Medical Mobile Unit

MPHW	Multi-Purpose Health Workers
MPW	Multi-Purpose Worker
MSM	Men having Sex with Men
NAAT	Nucleic Acid Amplification Test
NACO	National AIDS Control Organization
NACP	National AIDS and STD Control Programme
NCD	Non-Communicable Diseases
NGO	Non- Governmental Organization
NHM	National Health Mission
NISD	National Institute of Social Defence
NITVAR	National Institute of Translational Virology and AIDS Research
NMHP	National Mental Health Program
NRL	National Reference Laboratory
NSEP	Needle Syringe Exchange Program
NTEP	National Tuberculosis Elimination Programme
NVHCP	National Viral Hepatitis Control Program
ODIC	Outreach Drop-In Centre
OI	Opportunistic Infection
OPD	Out-Patient Department
ORW	Out-reach Worker
OSC	One Stop Centre
OST	Opioid Substitution Therapy
OT	Operation Theatre
P&COS	Prison and Other Closed Settings
PCR	Polymerase chain reaction
PE	Peer Educator
PEP	Post exposure prophylaxis
PHC	Primary Health Centre
PHN	Public Health nurse
PITC	Provider Initiated counselling and testing

PIWD	People Who Inject Drugs
PLHIV	Person/People Living with HIV
PM	Program Manager
PMSMA	Pradhan Mantri Surakshit Matritva Abhiyan
PoC	Point-of-care
POCSO	Protection of Children from Sexual Offences Act
PPE	Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
PWUD	People Who use Drugs
QC	Quality control
QMS	Quality Management System
RCH	Reproductive and Child Health
RDT	Rapid Diagnostic Test
RH	Rural Hospital;
RMNCAH+N	Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition
RPR	Rapid Plasma Reagin
RTI	Reproductive Tract Infection
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SACS	State AIDS Control Society
SCM	Supply Chain Management
SDH	Sub-District Hospital
SN	Staff Nurse
SNCU	Sick Newborn Care Unit
SNS	Social Network Strategy
SOCH	Strengthening Overall Care for HIV Beneficiaries
SOP	Standard Operating Procedure
SRH	Sexual and Reproductive Health
SRL	State Reference Laboratories
SSK	Sampoorna Suraksha Kendra

SSS	Sampoorna Suraksha Strategy
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infection
TasP	Treatment as Prevention
TB	Tuberculosis
TCC	Tobacco Cessation Centre
TI	Targeted Intervention
TLD	Tenofovir/Lamivudine/Dolutegravir
TNA	Total Nucleic Acid
TND	Target Not Detected
ToR	Terms of Reference
TPHA	Treponema Pallidum Hemagglutination Agglutination.
TPT	Tuberculosis Preventive Therapy
TTI	Temperature Track Indicator
TV	Television
U=U	Undetectable is equal to Untransmittable
UNAIDS	Joint United Nations Programme on HIV/AIDS
UPS	Uninterruptible Power Supply
VDRL	Venereal Disease Research Laboratory
VHSND	Village Health, Sanitation, and Nutrition Day
WBFPT	Whole Blood Finger Prick Test
WHO	World Health Organization
WLHIV	Women Living with HIV

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Scope of the document

HIV counselling and testing services are key entry points for prevention and testing of HIV infection, and for linking people who are infected with HIV to treatment and care. When availing counselling and testing services, people can access accurate information about HIV prevention and care, and undergo HIV testing in a supportive and confidential environment. People found HIV-negative are supported with information and counselling to reduce risks and remain HIV negative, while people who are found HIV-positive are provided psychosocial support and linked to treatment and care.

Thus, HIV counselling and testing services (HCTS) play a critical role towards achieving the first 95 of the UNAIDS 95-95-95 targets as well as reduction in new HIV infections.

India has achieved significant progress in its efforts to reach the global 95:95:95 targets to end the AIDS epidemic by 2030. The challenge is to increase access to and uptake of HIV testing among the priority population. This warrants different innovative strategic approaches for implementation across different states and union territories of India, as defined under the National AIDS & STD Control Program (NACP) phase-V strategy document.

The present 'National HIV Counselling and Testing Guidelines, 2024' provides extensive details on the different strategic approaches with implementation plans to build convergence of HCTS with the general health system, and to reach the unreached population.

The major changes from the National HIV Counselling and Testing Guidelines, 2016, are as follows:

1. Realignment of HCTS implementation as per the provisions under the HIV and AIDS (Prevention and Control) ACT 2017.
2. Expansion of HIV and Syphilis screening sites with consolidation of confirmation sites
3. Combination HIV Prevention: Pre-Exposure Prophylaxis, Undetectable is equal to Untransmittable (U=U), Elimination of Vertical Transmission of HIV and Syphilis
4. Outreach and mobile based HCTS services for High-Risk Groups (HRG), inmates of Prison and Other Closed Settings and other at-risk population
5. Focused testing strategies such as Index Testing Services, Social Networking Strategies, Self-Testing, and Provider Initiated Testing
6. Sampoorna Suraksha Strategy: Comprehensive and integrated service delivery and person-centered high-impact prevention programming for individuals who are at-risk for HIV and are seronegative
7. Optimization of HCTS implementation under NACP for integration with health systems
    - Innovative HIV Interventions focusing on population interacting on non-traditional platforms, which are; at-risk for HIV transmission such as key population involved in sex work at Spas and Massage Parlours, on virtual platforms and through network operators. (Key population includes Female Sex Workers, Men having Sex with Men, Hijra/Transgender Persons, People Who Inject Drugs, Migrants, Transport Workers and other Vulnerable Population)

The guidelines are primarily intended for use at the following levels:

National Level: It will be a reference document for policy decisions about newer approaches or specific HIV detection campaigns.

State/District Level: It will serve as a reference document for any operational decision involving the planning and implementation of HIV Counselling and Testing Services in private and public facilities, monitoring the standard of care provided under HCTS, maintaining a seamless supply chain process, as well as for implementing any special campaigns.

Facility Level: This document will give medical officers, paramedics, and management with the required guidance to ensure that standard practices are followed while maintaining cold-chain and assuring the quality of services provided.

SECTION I: Introduction and HIV Counselling and Testing Facilities

Section I of the National HIV Counselling and Testing Services (HCTS) guidelines has two chapters.

Chapter 1: The chapter begins with the basics of HIV and AIDS, followed by an overview of the current status of HIV epidemic and the response by National AIDS & STD Control Program (NACP), with specific focus on the strategies of NACP phase V towards ending AIDS as a public health threat. The chapter ends with the description of the drivers of the HIV epidemic in India.

Chapter 2: The chapter on HIV Counselling and Testing Facilities will cover change management under HIV Counselling and Testing Services, explained through the optimization of the HCTS. Thereafter, the framework for the HIV Counselling and Testing Services and Implementing the HIV Screening and Diagnostic Services will be elaborated, with guidance on both facility-based and community-based HCTS services.

CHAPTER-1

Introduction

Introduction

1.1 Basics of HIV and AIDS

The term HIV stands for: **H** – Human, **I** – Immunodeficiency, **V** – Virus.

Human Immunodeficiency Virus (HIV) is a retrovirus which destroys the CD4 cells and weakens the immune system of the human body. As a consequence, a person with HIV infection becomes more vulnerable to common and opportunistic infections. Without adequate treatment, the immunosuppression keeps increasing in the body till the stage where severe life-threatening Opportunistic Infections and Cancers attack the human body. This stage of HIV disease is known as Acquired Immuno Deficiency Syndrome (AIDS). A person with HIV infection is known as HIV-positive person or a Person Living with HIV (PLHIV).

Transmission of HIV

The body fluids like blood, semen, vaginal and rectal fluids, breast milk and Cerebrospinal Fluid (CSF) in an HIV infected person, are the sources of transmission. The modes of HIV transmission can be through unprotected sexual intercourse with an infected partner, vertical transmission from infected mother to her child, sharing of infected needles and syringes among injecting drug users and through transfusion of infected blood and blood products. The virus does not spread through casual contact like social kissing, hugging, sharing utensils and toilets, bite of mosquitoes and ticks etc. The virus cannot be transmitted through sweat, saliva or urine unless they are mixed with the infected blood.

HIV as a virus is very fragile, and many common substances, including hot water, soap, bleach and alcohol can kill the virus. Transmission can occur only from an HIV infected individual's blood/body fluid to another individual. Even though small amount of blood is enough to infect, healthy and unbroken skin prevents transmission of infection. The virus can survive for several days in small amounts of blood that remain in a needle after use. Hence, sharing of such needles between the infected and uninfected individuals can transmit the HIV infection. Table-1.1.1 depicts the Risk of HIV infection through various routes of transmission.

Table 1.1.1: Risk of HIV infection through various routes of transmission

Exposure Route	HIV Transmission Rate
Blood transfusion	>98%
Perinatal (without any intervention)	20-40%
Sexual intercourse	0.1-1%
Vaginal	0.05-0.1%
Anal	0.065-0.5%
Oral	0.005-0.01%
Injecting drug use	0.67%
Needle stick exposure	0.3%
Mucous membrane splash to eye, oro-nasal	0.09%
Comparative risk after needle-stick injury for HBV is 9-30% and for HCV is 1-1.8%	

Source-Table-2.10.2, Chapter-2.10, 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

Signs and symptoms of HIV and AIDS

The symptoms of HIV depend on the stage of infection present in the PLHIV. Though PLHIV tend to be most infectious in the first few months after acquiring HIV, many are unaware of their status until later stages. During the first few weeks after initial infection, individuals may experience no symptoms or an influenza-like illness including fever, headache, rash, or sore throat. As the infection progressively weakens the immune system, an individual can develop other signs and symptoms. Based on the opportunistic infections, WHO has categorized the severity of clinical symptoms and signs into 4 stages *(Annexure 1: WHO Clinical Staging in Adults, Adolescents and Children)*

1.2 Overview of current HIV Epidemic in India

As per 2023 estimation data, the HIV epidemic level continues to be low nationally with adult (15-49 years) HIV prevalence at 0.20%, with estimated 25.44 lakh PLHIV across the country. India has the second largest HIV epidemic in the world, accounting for about 6.3% of all PLHIV worldwide. Annual new infections between 2010 and 2023 declined by 44.23% while annual AIDS-related deaths declined by 79.26% in India. Globally, the annual new infections declined by 38% and AIDS-related deaths declined by 51% during the same period.

HIV Prevalence amongst risk-groups

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 9-43 times the adult prevalence. HIV prevalence was 1.8% among female sex workers (FSW), 1.9% among inmates in central jails, 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). The HIV prevalence was observed to be four times among single male migrants (0.89%) and five times among long-distance truckers (1.0%), as compared to the national adult prevalence. Regional variations occur across India, in terms of annual new HIV infections (ANHI).

As per India HIV Estimates 2023, change % from 2010 to 2023 in ANHI, ranges between 76.1% (Andhra Pradesh) to 524% (Tripura), in the various states across India, implying the need for customized regional strategies. For further reading, refer to *India HIV Estimates 2023, Technical Report*.

1.3 NACP history and response to the epidemic under NACP phase V

Since the detection of the first case of Human Immunodeficiency Virus (HIV) infection in June 1986, the National HIV response in India has come a long way. In response to the challenge of curbing further spread of the HIV infection in India, the National AIDS Committee was established in 1988. During the period 1985 to 1991, the response focused on screening of HIV infection in different population groups and locations, screening of blood prior to transfusion and targeted awareness generation.

The National AIDS and STD Control Programme (NACP) was launched in 1992, moving towards a more comprehensive response to the HIV and AIDS epidemic in India. More than thirty years since the launch, NACP has evolved as one of the world's most successful programs.

The first three phases of NACP, effectively controlled the HIV and AIDS epidemic in the country with adoption of National AIDS Prevention and Control Policy (2002); Scale up of Targeted Interventions

projects (TIs) for High-Risk groups (HRG) and vulnerable risk groups in high HIV prevalence states; Adoption of National Blood Policy; Introduction of counselling, testing, Prevention Parent to Child Transmission (PPTCT) of HIV and Anti-retroviral Therapy (ART) services. In addition, the National Council on AIDS in Delhi, and State AIDS Control Societies (SACS) in all the states were formed to further implement and monitor the program.

The NACP phase III also aimed at scaling up prevention efforts among HRG and general population and integration with Care, Support & Treatment (CST) services. Mainstreaming of prevention and care services with decentralized district level coordination and monitoring was done by introducing District AIDS Prevention and Control Units (DAPCU). The capacities of State AIDS Control Societies (SACS) and DAPCUs were also strengthened.

The NACP phase IV aimed to build on the previous achievements and reduce new infections by 50% (2007 Baseline of NACP III). It also aimed to further strengthen the process of decentralising rollout of services including integrating HIV services with health systems in a phased manner. It also prioritised mainstreaming of HIV/ AIDS related activities with key central/state level Ministries/ departments through leveraging resources of the respective departments. Furthermore, social protection mechanisms for PLHIV were strengthened. NACP IV witnessed the launch of test and treat, differentiated service delivery models for prevention, revamped TI structures, expansion of public sector Viral Load labs; involvement of communities in mapping and population size estimates, HIV and AIDS (Prevention and Control) Act 2017, formation of the first National Community Resource Group (CRG) through Community System Strengthening (CSS) and enhanced community engagement.

Several game changing initiatives were implemented during NACP Phase-IV (Extension) up to 2021. The phase started with the passing of the HIV and AIDS (Prevention and Control) Bill, 2017. The Bill ensured equal rights for the people infected with HIV and AIDS in getting treatment and prevention of discrimination of any kind. The Act came into force in September 2018. (Refer to Annexure-2 for the e-gazette of the HIV and AIDS (Prevention &Control) ACT 2017). The 'Mission Sampark' strategy was implemented in 2017 to bring back People Living with HIV (PLHIV) in to the program to start/restart ART with universal viral load testing for on-ART PLHIV.

NACP phase V Strategy

NACP phase V strategy was dictated by the need for continuous action and vigil in the context of the country's commitment of ending the AIDS epidemic as a public health threat by 2030.

The NACP phase V aims to reduce annual new HIV infections and AIDS-related mortalities by 80% by 2026 from the baseline value of 2010, attain dual elimination of vertical transmission, eliminate HIV/AIDS related stigma while promoting universal access to quality STI/RTI services to at-risk and vulnerable population. Under NACP Phase-V, existing interventions will be sustained, optimized, and augmented. Also, newer strategies will be adopted, piloted, and scaled-up to respond to the geographic and community specific needs and priorities.

Goal and Objectives of NACP Phase V

The five goals of NACP phase V are as follows:

- **Goal 1:** Reduce annual new HIV infections by 80%.
- **Goal 2:** Reduce AIDS-related mortalities by 80%.

- **Goal 3:** Eliminate vertical transmission of HIV and Syphilis.
- **Goal 4:** Promote universal access to quality STI/RTI services to at-risk and vulnerable populations.
- **Goal 5:** Eliminate HIV/AIDS-related stigma and discrimination

The specific objectives of the NACP Phase-V are as below:

1. **HIV/AIDS prevention and control**
    i. 95% of people who are most at-risk of acquiring HIV infection use comprehensive prevention
    ii. 95% of HIV-positive know their status, 95% of those who know their status are on treatment and 95% of those who are on treatment have suppressed viral load
    iii. 95% of pregnant and breastfeeding women living with HIV have suppressed viral load towards attainment of elimination of vertical transmission of HIV
    iv. Less than 10% of people living with HIV and key populations experience stigma and discrimination
2. **STI/RTI prevention and control**
    i. Universal access to quality STI/RTI services to at-risk and vulnerable populations
    ii. Attainment of elimination of vertical transmission of syphilis

1.4 Drivers of HIV epidemics

The determinants or the drivers of health are a range of social, economic and environmental factors that determine the health status of individuals or populations. These are the conditions and circumstances into which people are born, grow, live, work, socialize, and form relationships, and the systems that are in place to deal with health and wellness. These determinants of health play a vital role in people's ability to seek care, support and treatment, particularly when they belong to socially or sexually marginalized groups such as Female sex workers (FSW), Men who have sex with men (MSM), Hijra/Transgender persons (H/TG), People who inject drugs (PWID), etc.

Before we understand the drivers of the HIV epidemic, it is important to consider gender norms related to sexuality, as well as physiological and social vulnerabilities which make certain population more predisposed to HIV transmission. These norms in turn affect different populations in different ways, exacerbating their vulnerability to HIV transmission.

Sex-Gender-Sexuality, Gender Norms, and vulnerability to HIV

Sex refers to the biological make-up of a person, based on external and internal genital-reproductive parts, hormones, tissues and chromosomes. Gender is a social construct. Gender roles and behaviours are assigned by society and are learned rather than innate.

Sexuality refers to someone's sexual feelings, thoughts, attractions and behaviors towards other people. The dominant ideal of masculine behaviour and sexuality promotes men and boys to be assertive, independent and strong. These notions of gender and sexuality make it very difficult for women/girls and men/boys to access reliable information about sexuality and reproductive health services, openly discuss sexual matters, practice safer sex, and promote more gender equitable relations.

Physiological vulnerability

Risk of HIV transmission during sexual intercourse is almost twice for cis-gender woman than cis-gender man because women (being receptive partner) have a larger mucosal surface, for HIV transmission.

Gender based violence (GBV): Increases possible risk of HIV infection

GBV is any act that results in, or is likely to result in, physical, sexual or psychological harm or suffering that is directed against a person because of their biological sex, gender identity or perceived adherence to socially defined norms of masculinity and femininity. It can be experienced by women and girls, men and boys, and transgender and intersex people, of all ages and has direct consequences on health, social, financial, and other aspects of their lives.

GBV increases the risk of HIV infection as sexual violence can lead to HIV infection directly and trauma increases the risk of transmission. Trauma of forced sex of any kind such as rape, dry sex or lack of readiness, with an infected partner increases the risk of transmission. It increases the gender inequalities and is an important cause of 'choice disability'. Victims of childhood sexual abuse are more likely to be HIV infected, and to have high-risk behaviour.

Poverty and migration

Social determinants such as socio-economic factors and the role of migration have direct effects on increasing the HIV related vulnerability. Poverty and the lack of economic opportunities often result in migration of men and women, in search of income and employment, which disrupts stable social and familial relationships. If a person migrates without their family and are not able to visit their hometown often, they take care of their sexual needs locally, often through paid sex. Truckers are mobile as per their profession and have access to sex workers. These population forms the bridge for their spouses and sexual partners at the source and thus are responsible for spread of HIV infection.

Sexual Behaviours

High-risk sexual activity (multiple sexual partners, paid commercial sex, sex without condoms across genders) is a major contributor to the spread of HIV infection in India. More than 84% of HIV transmission occurs through high-risk sexual behaviour.

Injecting Practices

The interface between drug use and sharing of contaminated injecting equipment has fuelled the spread of HIV epidemic among people who inject drugs (PWID). Unsafe injecting practices is the one of the most efficient routes for transmission of HIV.

Additional issues of Female Injecting Drug Users (FIDUs): Studies show that FIDUs have a higher risk of acquiring HIV due to sharing needles and syringes and due to unsafe sex. Apart from all the vulnerabilities that exist for PWID, women drug users are at further risk due to:

- Social factors that add to a woman's vulnerabilities. These could be inequality towards access to education, health care and employment with little or no power status in society, or social expectations.
- Biological factors further making women more vulnerable to HIV.

Virtual Solicitation Practices

With the advent of mobile phones and newer communication technologies, the patterns of sex work have also changed and evolved. Instead of traditional street-based solicitation, the various digital channels are utilized to connect with potential clients, leveraging the reach and convenience of modern technology. The use of mobile phones, various social media platforms and applications are now playing a prominent role in solicitation. Internet based communication is rapidly transforming sexual partner seeking behaviours, negotiation of risk behaviours and network dynamics among populations with high-risk behaviours. Such sexual service providers, not soliciting in the physical domains often remain unreached by the program as they are not congregating at any physical hotspots. The freely accessible dating apps, simplify and speed up the process of sifting through potential dating partners, chatting, flirting, and potentially meeting or becoming sexually involved.

This changing pattern of networking and solicitation by HRG and at-risk populations, operating through virtual platforms, has added a new dimension to the HIV epidemic.

CHAPTER-2

HIV Counselling and Testing Facilities

HIV Counselling and Testing Facilities

2.1 Change management under HIV Counselling and Testing Services under NACP

Context:

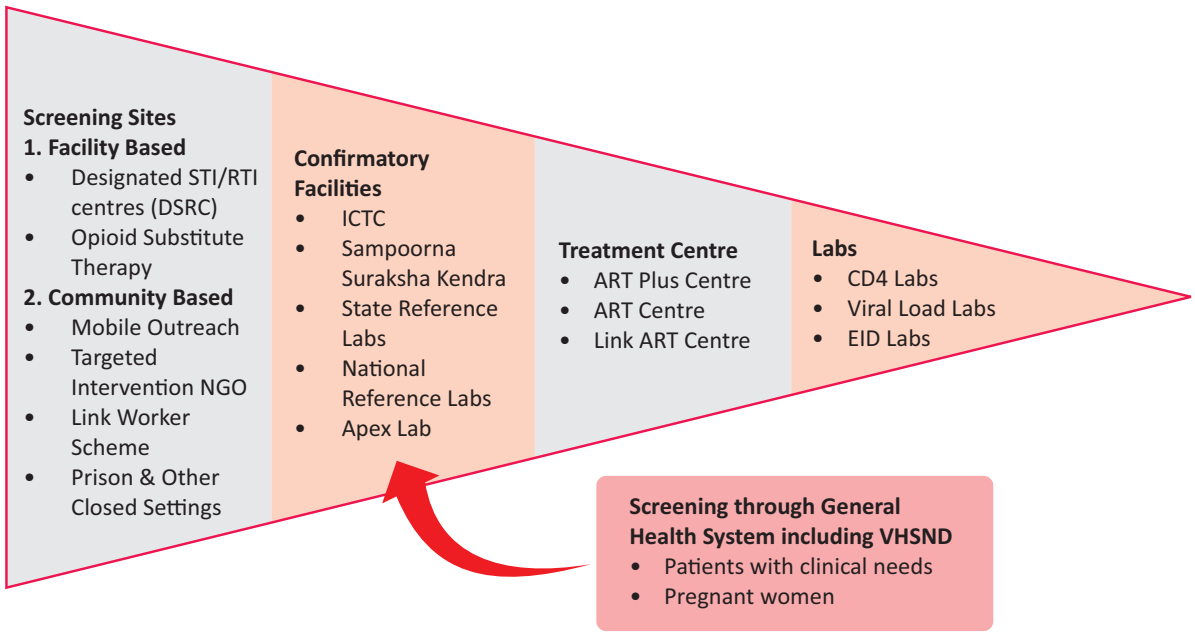
HIV counselling and testing services started in India in 1997 under the NACP phase I. The NACP in its phase II launched the treatment services in 2004 where patients were initiated on Anti-Retroviral Treatment (ART) based on their CD4 counts. In this phase, the major role of Integrated Counselling and Treatment Centre (ICTC) was provision of counselling and testing services and further management of the patients till they were linked to ART Centre for care and treatment based on the CD4 count.

Under NACP phase III, with the objective of increasing access to counselling and testing services, the program introduced HIV Counselling and Testing (HCT) outreach services and Mobile ICTCs, in 2007. The strategic scale up of the testing services under the program was undertaken in the NACP phase IV i.e. from 2012-17, when program scaled up through Facility based screening services for HIV counselling and testing. Thus, the major load of screening of at-risk, high-risk groups as well as provider-initiated testing was further decentralized from confirmatory centres to screening centres under general health system and in community settings.

The Test & Treat Policy under the program was implemented in 2017 under NACP phase IV. With the launch of Test and Treat Policy in 2017, while all the patients were linked to ART Centre for initiation of treatment irrespective of their CD4 count, the impetus of the HCTS was to focus on prevention counselling and strategic testing and confirmation with ensuring linkages to treatment. The HCTS Service Delivery Model under NACP-V, is depicted in Figure-2.1.1

a) **HCTS Service Delivery under NACP-Phase V**

Figure 2.1.1: HCTS Service Delivery under NACP-V



Guiding principles of optimization of services under the NACP phase V

i. Scale-up efforts through prioritization, reorganization, resource optimization, building capacities and leveraging partnerships

ii. Improve collaboration with National Health Mission (NHM) on HIV and STI/RTI service provision and reporting

iii. Maintain and augment convergence with National Tuberculosis Elimination Programme (NTEP) and engage with National Viral Hepatitis Control Program (NVHCP) to explore delivering of an integrated package of services

iv. Rationalize and optimize the resources through synchronizing and bringing together different aspects of high-impact service delivery management

As per the India HIV Estimates 2023, the current adult HIV prevalence in the country is at 0.20%, thus 99.8% of the adult population in the country is HIV free. The optimization and conversion of ICTC to screening sites will continue to support the program while undertaking the HIV screening tests through a system approach in facility or community settings. The screened HIV reactive cases will be linked to the nearest confirmatory ICTC where the services for confirmation of HIV diagnosis are provided. As detailed above, the major thrust of the HIV screening for the majority of the population is integrated with the general health system by undertaking HIV screening at the HIV Screening Sites, through facility or community-based testing approach.

The human resources under NACP are to be optimally and efficiently used such that their capacities are best utilized for achieving the overall objectives of the program. Since screening facilities can be expanded through health system convergence, support under NACP will focus on confirmation of diagnosis for those screened HIV reactive and their linkage and retention on treatment.

NACP will also continue to focus on the clients identified as at-risk on the basis of risk-assessment and whose HIV test result is negative. These clients will be linked to the comprehensive prevention services under the program like Sampoorna Suraksha Strategy (SSS), Targeted intervention projects, Link worker scheme, etc.

Priority population for HCTS include the following:

1. High-risk Group Populations including Prisons and other closed settings (P&OCS)
2. Self-walk-in clients at ICTC with risk behaviour
3. Social and sexual networks of self-initiated clients / individuals
4. HIV negative partners of PLHIV Index case including partners with unknown HIV status
5. Clients motivated from National AIDS helpline 1097/ IEC material/ virtual outreach, etc.
6. At-risk youth and adolescents
7. STI/RTI clients
8. Individuals in casual sexual relation with regular/non-regular partner/s
9. Screened reactive referrals for confirmatory test and screened reactive from Blood Centres
10. Provider initiated referral with high index of clinical suspicion for HIV and AIDS

11. Social network Partner/s of high-risk and at -risk population
12. HIV Exposed babies
13. Pregnant Women

2.2 Framework for HIV Counselling and Testing Services

Context:

HCTS are essential primary entry points for accessing HIV testing, prevention, care and treatment services across the country. Under NACP phase V, maintaining and expanding quality assured laboratory services along with quality counselling services is one of the key strategies for reaching the goals of 1st 95. HIV counselling is important to ensure that individuals have the information, support, and resources they need to make informed decisions about HIV testing, protecting themselves from HIV transmission, and coping with the emotional and social challenges of living with HIV. Similarly, the quality of HIV tests is essential for ensuring accurate diagnosis.

In India, HIV Counselling and Testing Services are provided through following implementation framework:

1. **Screening Services** (HIV screening facilities and HIV/Syphilis dual screening facilities)
2. **HIV Confirmatory Services**

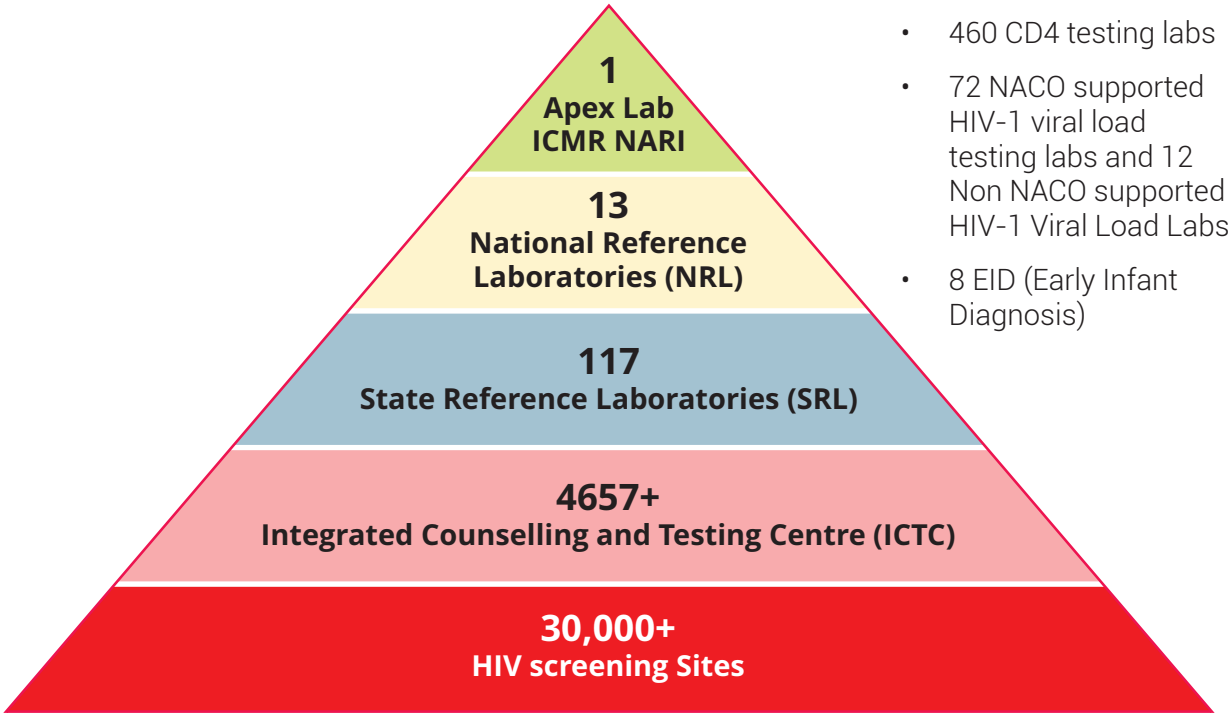
HIV screening and HIV confirmation are two distinct processes. HIV screening involves initial testing to detect the presence of HIV antibodies or HIV antigens in a person's blood using rapid diagnostic kits which provide quick results, often within 20-30 minutes along with brief group/individual counselling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

Currently, there are more than 4400 ICTC centres which provide HIV confirmation services. Additionally, HIV screening services are available across various public and private facilities as well as are provided through outreach services such as community-based screening. The Dual Rapid Diagnostic Test (RDT) strategy for HIV and Syphilis was introduced to address the gaps in testing and elucidated under the NACP phase V strategy to improve efficiency and coverage for both HIV and Syphilis testing for certain population groups including high-risk groups (HRG), Inmates of Prisons and other closed settings, STI attendees, at-risk population, pregnant women screened at field locations.

Dual Rapid Diagnostic Test (RDT) strategy is envisioned to partially replace the Whole Blood Finger Prick (WBFP) tests for the aforementioned populations. For pregnant women, NHM will provide Dual RDT kits for field level testing whereas NACP will provision HIV and Syphilis testing kits for facility as well as field level testing for other priority populations. Dual kits are not envisaged as an addition to single HIV test kits but as a phased replacement of Whole Blood Finger Prick HIV test kits.

The screening and confirmatory laboratory structure under the National AIDS & STD Control Program are categorized into five tiers, as depicted in the Figure-2.2.1 below.

Figure 2.2.1: Five-tiered Laboratory services under NACP



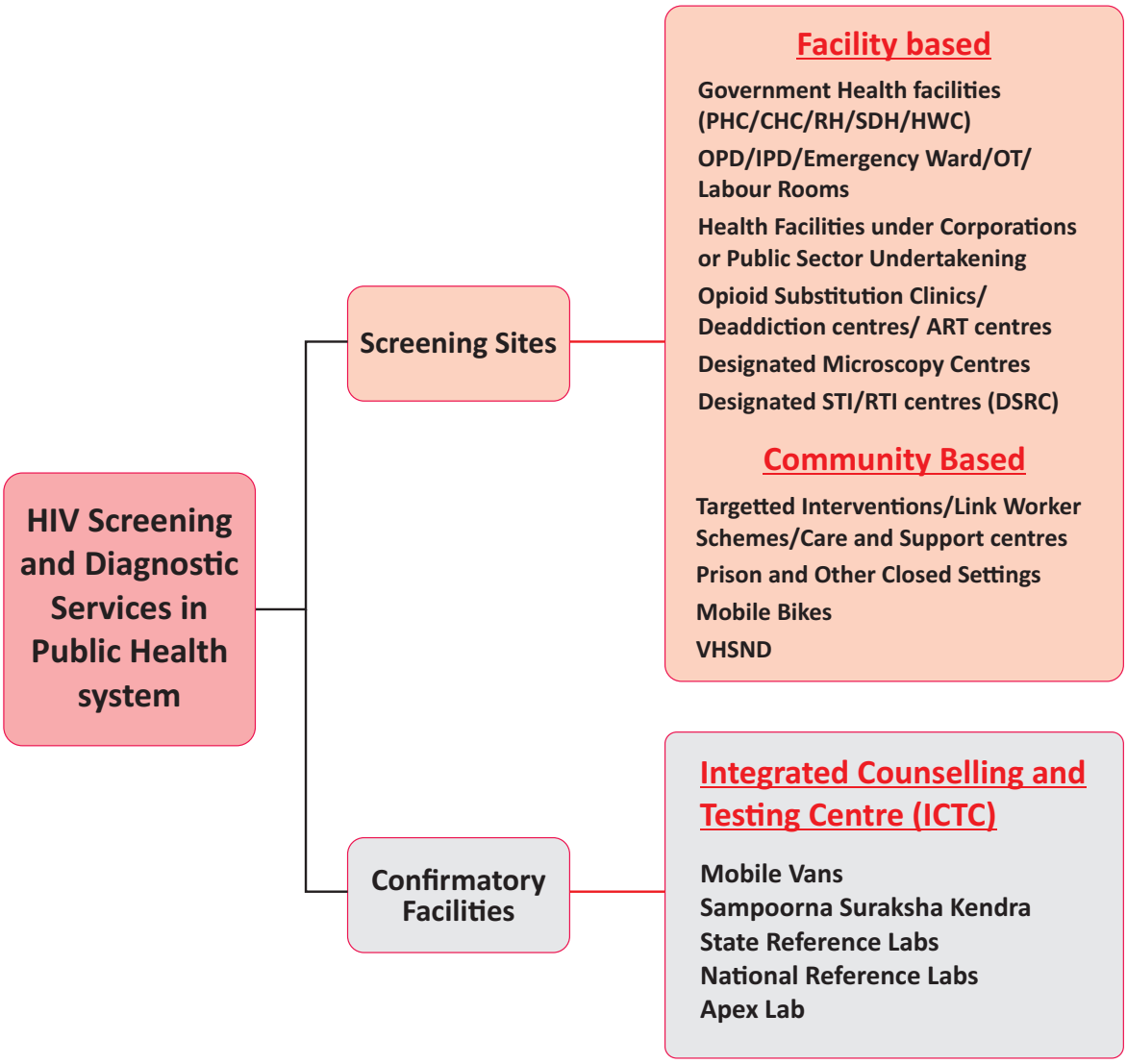
Quality assurance of Laboratory services under NACP is provided through the top three-tiered network. ICMR-NITVAR is the Apex Laboratory providing External Quality Assurance (EQA) to the testing facilities in coordination with the National and State Reference Laboratories. NACP focuses on quality laboratory services through NABL accreditation of their labs. For further details, refer to Chapter-10.2.

For HIV serology, there are 13 National Reference Laboratories (NRL), 117 State Reference Laboratories (SRL) and more than 4657 Integrated Counselling and Testing Centres (ICTC). These are confirmatory testing sites under the program and are engaged in confirmatory diagnosis of HIV 1 & 2 while ensuring the implementation of External Quality Assurance (EQA) for providing accurate results as per the testing principles, detailed in the subsequent chapters of the guideline.

Screening services under the program are provided through more than 30,000 HIV screening sites which are based in the hospital settings or in community settings.

Besides the above, there are more than 460 CD4 testing laboratories and 72 HIV-1 viral load testing laboratories for treatment monitoring of PLHIV and 8 EID (Early Infant Diagnosis) laboratories for testing infants below 18 months for HIV infection. Figure-2.2.2 depicts the Framework of HIV Screening and confirmatory Services both within and outside of NACP.

Figure 2.2.2: Framework of HIV Screening and Diagnostic Services



PHC- *Primary Health Centre;* ***CHC-****Community Health Centre;* ***RH-****Rural Hospital;*
SDH-*Sub-District Hospital;* ***HWC-*** *Health and Wellness Centre;* ***VHSND-*** *Village Health, Sanitation, and Nutrition Day*

A. HIV Confirmatory Facility

Confirmatory testing service for HIV is conducted in Integrated Counselling and Testing Centres (both static and mobile), the Sampoorna Suraksha Kendras, and the National/ State Reference Laboratories.

Integrated Counselling and Testing Centre (ICTC)

Integrated Counselling and Testing Centres are set up to act as HIV confirmatory facilities under the NACP. Their numbers are optimized to balance out access and quality of HIV confirmation and facilitate immediate linkage to HIV treatment as per the Test & Treat policy.

Institutions where ICTCs can be established:

ICTCs can be located in Government healthcare facilities under Central, State and corporation administration of the level of medical college, tertiary hospitals, general hospital, district hospital.

They may also be set up at select sub-district hospitals and community health centres (CHC), and in certain instances at PHC level, the health facilities under public sector undertakings. All private medical colleges providing ART services shall be deemed to be confirmatory facilities and expected to comply to the NACO guidelines.

ICTC will also act as a nodal point for all the screening sites in the catchment area/ assigned geographic area of that ICTC. The DISHA officer will assign the Screening Sites in the taluka/ block to the ICTC. The Nodal ICTC will be responsible for coordination, supportive supervision, capacity building and monitoring stocks of commodities for the linked HIV screening sites.

Aligned with the above, the available limited resources and the intention of bringing efficiencies in the program towards achieving the larger objectives of 95-95-95, it is determined that ICTC should ideally be located in facilities qualifying in any one of the following criteria:

a. Co-located with ART Centre

b. Facilities which may also function as a Link ART Centre

c. At district hospitals and above (even when facility may not be co-located with ART/Link ART Centre)

d. Facilities with a high load of direct "walk-in" clients (average 2 to 3 direct walk-in clients per day) or above 700 per year, positivity is => 1% or with more than 12 positive clients in a year

e. Facilities with the client load of pregnant women of >2000 per year and positivity is =>1% or more than 12 new pregnant women detected positive

f. In far flung areas where the static or mobile facility may function as a confirmatory ICTC and a nodal centre, providing confirmatory testing support to screening sites in the vicinity

g. Any other criteria that justify the efficiency of the facility for identification of confirmed new cases, as deemed appropriate by the respective State AIDS Control Societies.

Package of services:

- Pre and post-test counselling, informed consent, risk assessment of the clients
- HIV testing and sharing of test result and disclosure
- Testing for Syphilis
- Index Testing, Social Network Testing, Provider Initiated Counselling and Testing
- Early Infant Diagnosis (EID)
- Referral to TI-NGO, Sampoorna Suraksha Kendra, DSRC
- Linkage to social welfare schemes
- Outreach activity including through Mobile vans
- Follow-up and repeat testing and counselling of eligible clients
- Nodal point for coordination, supportive supervision, capacity building and monitoring stocks of commodities for linked HIV screening sites
- Screening for STI/RTI, TB and other co-infections

- Linkages to care and treatment and other health services
- Function as Link ART Centre, Sampoorna Suraksha Kendra
- Need based testing or referrals for testing for Hepatitis B and C
- Demonstration, distribution and availability of condoms
- Display of the relevant IEC material for HIV and STI.

Physical infrastructure

The ICTC facility should be located at an easily accessible place with proper signages to direct and guide people to the location. The ICTC facility should consist of two distinct areas, one for counselling and the other for testing.

a. Counselling room

The counselling room should be at least 15'X15' in size (225 sq. ft.) with ventilation standards of 6 –12 air changes per hour (ACH) to reduce the risk of air-borne infection to the staff and individuals accessing HCTS. The room should ensure audio-visual privacy. This room should be furnished with a desk and chair for the counsellor, another 10 –15 chairs for group counselling sessions, a lockable filing cabinet for keeping records, and a desktop computer with a computer table along with UPS, printer and internet facility. It should preferably be located in the OPD area for ease of access to walk in clients and their families.

It should be equipped with the following communication and educational aids:

- TV and DVD player in a lockable stand
- Wall-hanging posters and information materials for display
- Flip charts and penis model for demonstration of condom use
- Leaflets/pamphlets as take-home material

b. Blood collection and testing room

The blood collection and testing room should be at least 10'x10' in size (100 sq. ft.), furnished with a desk, chair and a workstation, and should preferably be co-located with the counselling room. The testing room should also have a comfortable seating (waiting area) arrangement for the individual accessing HCTS. The laboratory should be equipped with one refrigerator with voltage stabilizer, thermometer, centrifuge, needle destroyer, micropipette and colour-coded waste disposal bins with disposable polybags, etc as detailed in the Chapter 9 of this guideline.

Staffing of the ICTC

ICTC is provided with minimum of a Counsellor and a Lab Technician under NACP with the primary responsibility of provisioning of HIV Counselling and Testing Services for the clients accessing the ICTC

i. Counsellor

Counsellor should be appointed on a contractual basis. The counsellor reports to the Nodal Officer of the ICTC and is supervised by the Clinical Services officer of DISHA and SACS officials. The ToR of an NACP counsellor is placed at Annexure 3.

ii. Lab Technician (LT)

LT should be appointed on a contractual basis. The LT reports to the Nodal Officer of the ICTC and is supervised by the Technical Officer of the State Reference Laboratories, DISHA and SACS officials. The TOR of LT of ICTC is placed at Annexure 4.

iii. Nodal Officer of ICTC

The Nodal Officer is from the Hospital where the ICTC is located and is to be nominated by the administrative head of hospital. The testing and reporting of the facility will be under the purview of the laboratory in-charge of the facility, whereas the work of all the counsellors including ICTC, DSRC and ART will come under the purview of the ART Centre in-charge wherever co-located and the STI in-charge where there is no ART centre. In case the ICTC is not co-located with the ICTC or DSRC, the Laboratory -in-charge will look after the work of ICTC Counsellor.

The roles and responsibilities of the laboratory in-charge are to ensure the following:

1. HIV testing procedures are as per National HIV Testing Protocol including Provider initiated counselling and testing
2. Syphilis testing as per NACO guidelines
3. Any other tests included in the scope of ICTC including collection of samples for Viral load, EID, and Hepatitis screening, etc
4. Validated and signed laboratory reports are provided on the same day to individuals who test HIV-positive or Syphilis-positive
5. Smooth supply chain management of commodities from SACS and sufficient availability of kits and related commodities
6. Maintenance of all the equipment in the ICTC
7. Regular monitoring, review and on-site hand holding of ICTC laboratory technician
8. Provision of administrative support to ICTC laboratory technician
9. Daily maintenance and validation of ICTC testing records
10. Supportive supervision of the linked HIV screening sites

The roles and responsibilities of the In-charge of ART/ DSRC are to ensure the following:

1. Active engagement of the NACP Counselor for prevention, counselling and risk assessment
2. Mobile and Outreach activities
3. Deputation for field activities
4. Ensure Index testing and social network testing
5. Provision of administrative support to the NACP Counsellors
6. Provision of supportive supervision to the linked HIV screening sites
7. Regular monitoring, review and on-site hand holding of ICTC counsellors
8. Referral and linkages
9. Overall record maintenance and reporting in SOCH

Sampoorna Suraksha Readiness Facilities

Further to the implementation of the SSK, the existing facilities such as ICTC/ DSRC will be assessed for implementing the Sampoorna Suraksha Strategy and will be remodelled as Sampoorna Suraksha Ready Centres. Such Sampoorna Suraksha Ready Centres will be managed by the existing Counsellor and Lab Technician of the facilities for implementation of Sampoorna Suraksha Strategy. The comprehensive package of services to be provided in SSK ready facilities, will be similar to services provided in SSK. Services provisioned under mobile and outreach-based modality should also be aligned to the principle of single window service delivery in collaboration with health systems.

For further details on SSK, refer to Chapter-11.2.

Screening Facilities

Breaking the silos and Building Synergies:

NACP phase V recognizes opportunities available within the general health system to catalyse progress on stated goals of ending of the AIDS epidemic as a public health threat by 2030. The guiding principle of 'Breaking the silos and building synergies', will promote efficient and coordinated actions, through single window service delivery systems along with functional and measurable referral and linkages, within NACP and across other national health programmes and related sectors.

While the Adult (15–49 years) HIV prevalence in India has declined considerably since 2000, falling from 0.56% in 2000 to 0.32% in 2010 and further declining to 0.20% in 2023, the focus of NACP phase V is to identify at-risk negative population and keep them negative in addition to early identification of HIV infection. This has necessitated a shift in the approach of provision of HIV counselling and testing services. In order to bring efficiencies under the program and towards optimal utilization of existing health resources, the screening for pregnant women, high-risk group individuals, prison inmates, all TB detections, STI clinic attendees, Provider Initiated Screening has been scaled up to HIV Screening Sites by further integration with the General Health System. Integrating HCTS into the general health system will ensure sustainability, cost-effectiveness and facilitate mainstreaming of HCTS.

As per the India HIV Estimates 2023, the current adult HIV prevalence in the country is at 0.20%, inferring that 99.80% of the adult population in the country is HIV-free, wherein the screening sites will support the program by undertaking HIV screening tests in the facility or community-based settings, through a systems approach. Screened HIV reactive clients will be linked to the nearest confirmatory ICTC, where they will be provided services for confirmation of HIV diagnosis. Clients who screened Syphilis reactive using dual RDT kits, should be linked to nearest ICTC for RPR testing.

Facilities where the HIV screening sites can be established

The HIV Screening sites can be located in the general health system like Government Health facilities, OPD/IPD/Emergency Ward/OT/Labour Rooms of the hospitals, health facilities under Corporations or Public Sector Undertaking, Private Medical Colleges, Private health facilities, Designated Microscopy Centres, testing Centres under NVHCP and other health program, and provide HIV rapid tests using serum/plasma or whole blood-based screening.

Designated STI and RTI Clinics, Mobile Vans and Bikes supported under NACP, VHSND supported under NHM, TI/ Link Workers Scheme (LWS)/ Opioid Substitution Therapy (OST)/ Prison and Other Closed Settings, Sampoorna Suraksha Ready and Sampoorna Suraksha Kendra shall provide dual screening for HIV and Syphilis using Dual RDT.

All the Screening sites will be linked to a Nodal ICTC. The DISHA officer will assign the Nodal ICTC for the Screening sites in the taluka/ block. It is essential for a coordination process to be built in between the Screening Sites and the Nodal ICTC for smooth functioning of the HCTS.

Staff in Screening Site

The Lab Technician (LT) of the health facility will conduct the HIV and Syphilis testing. However, in case of non-availability of LT, an existing paramedical staff in the health facility can be trained and designated for HIV and Syphilis screening, as no additional staff will be provided by NACP for the same. For mobile outreach, outreach and field-based settings, any designated programme or project staff trained on conducting community-based screening can provide the services for HIV and Syphilis screening.

The head of the institute/hospital, where the HIV and Syphilis screening site is located will nominate a Nodal Officer who will be responsible for overseeing all the activities pertaining to the HIV/Syphilis screening at the site.

All mobile outreach services under NACP will be coordinated through SACS and DISHA approved plans for conducting camps and outreach activities.

Package of services at HIV/Syphilis Screening Sites

- Pre and post-test counselling, obtaining informed consent, conducting risk assessment
- HIV screening, referral of HIV screened reactive cases to confirmatory facility and sharing of test result, disclosure while maintaining confidentiality.
- Syphilis screening and sharing of test result
- Screening for STI/RTI, TB and other co- infections
- Linkage for HIV confirmation to ICTC
- Linkage to DSRC for treatment of syphilis/STI
- Referral to TI NGO, LWS, Sampoorna Suraksha Kendra, or other health facilities as per the need
- Demonstration, distribution and availability of condoms and
- Display of the relevant IEC material for HIV and STI.

Roles and Responsibilities of staff in Screening Site

1. Ensure HIV and syphilis screening of all pregnant women, at-risk individuals or individuals with high-risk behaviour attending the health facility
2. Ensure that every negative HIV screening laboratory report is signed and provided to the client on the same day as the test
3. Refer for confirmation of diagnosis of every reactive case for HIV and Syphilis
4. Refer for treatment of syphilis reactive cases to nearest treatment facility
5. Ensure smooth supply, logistics and cold chain management of kits and other commodities
6. Use screening kits such as Whole Blood Finger-Prick test kits for HIV/ Dual Test kit for HIV & Syphilis/PoC test kit for Syphilis etc.

7. Ensure regular supply of need-based quantities of these test kits by either the ICTC or through the health system.
8. Ensure Cold chain management: the test kits should be stored between 2°C to 8°C in the refrigerator available at the health facility.
9. Monitor the temperature track indicator (TTI) regularly for any change in colour
10. Ensure that kits that show a change in colour in the TTI are not used. Dispose generated bio-waste as per the infection control guidelines practiced in the health facility.

Community Based Screening approach

Community Based Screening (CBS), introduced during NACP phase IV, brought revolutionary change in the arena of providing accessible HIV Counselling and Testing Services closer to the community. It is an important approach for improving early diagnosis by reaching out to at-risk and vulnerable people and groups with primary screening services to identify the individuals who are HIV-positive but are not aware of their status. Linking these HIV screened reactive individuals for confirmation and subsequent care and treatment services as well as other social and economic welfare services will support in motivating the community to get themselves tested and avail other services critical for them to address factors contributing to their vulnerability. CBS is offered under diverse programmes and settings. CBS has taken the screening process out of the laboratory setting and enabled the programme to organize/ customize HIV and syphilis screening as per the convenience and in the vicinity of the community. In remote locations which are difficult to access, the SACS may facilitate confirmation of HIV diagnosis and related services within the community setting, through mobile vans.

The groups, programmes and facilities where HCTS through the CBS strategy are offered are as below;

1. NACP staff such as HIV confirmatory facility staff or TI NGO or LWS NGO or CBO staff in their geographies
2. Non NACP staff such those under the general health system offer HIV and Syphilis testing at VHSND for pregnant women or during health melas. Private health care providers also provide HIV testing during their community services.

To enhance the reach and coverage of the at-risk populations and Pregnant Women, following para-medical and nursing functionaries (but not limited to) from the mainstream health services can be identified to offer CBS

a. Public Health Nurse (PHN)
b. Lady Health Visitor (LHV)
c. Auxiliary Nurse Midwife (ANM)
d. Counsellors
e. Pharmacist
f. Multi-Purpose Health Workers (MPHW) – Male

Approaches for Community Based Screening

Community based screening is available under the National AIDS & STD Control Program as well as under the larger umbrella of General Health System to improve HCTS access and coverage, which are carried out through various approaches, such as;

(1) Community Based Camps or Outreach activity

(2) Outreach through Mobile Vans or Motor Bikes

(3) Mobile Medical Units/ Outreach Camps

(4) Screening by Ancillary health-care providers, such as at VHSND

(5) Screening by Targeted Interventions projects, Link Worker Schemes/ Opioid Substitution Therapy centres under NACP

(6) HIV screening for Prison inmates and clients in Other Closed Settings

(7) HIV screening at the workplace

References for Section-1:

1. Strategy document titled National AIDS and STD Control Programme Phase-V (2021-2026) at https://naco.gov.in/sites/default/files/NACP_V_Strategy_Booklet.pdf.
2. Sankalak: Status of National AIDS Response, Fifth Edition, 2023. https://naco.gov.in/sites/default/files/Sankalak%20Booklet.pdf
3. India HIV Estimates 2023: Technical Report. New Delhi: NACO, Ministry of Health & Family Welfare, Government of India; available at https://naco.gov.in/sites/default/files/HIV%20Estimates%202023%20Factsheets.pdf
4. National Guidelines on HIV Care and Treatment, 2021; available at http://naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment_2021.pdf

SECTION II:
HIV Counselling and Prevention

Section II of the National HCTS guidelines has four chapters.

Chapter 3: The chapter on Combination HIV Prevention explains in detail the various modalities of HIV Prevention, such as Condom, Pre-Exposure Prophylaxis (PrEP), Post Exposure Prophylaxis (PEP), Treatment as Prevention (U=U), Harm Reduction and HIV Prevention and Elimination of vertical transmission of HIV and Syphilis, Counselling and Communication, Prevention and treatment of sexually transmitted infections.

Chapter 4: The chapter Risk Assessment and Client flow focuses on the process of risk assessment of clients, to identify at-risk population. Further, the client flow at ICTC is described.

Chapter 5: The chapter on Counselling for HIV/STI, covers the guidelines on Counselling for HIV and STI in the context with HIV and AIDS (Prevention and Control) ACT 2017. The chapter details the five "Cs" for HIV Testing, obtaining informed consent prior to HIV testing, Pre and Post test counselling messages (for different result scenarios) and the follow up counselling messages. The chapter ends with steps of sharing HIV test results in context of HIV and AIDS (Prevention and Control) ACT 2017.

Chapter 6: The chapter on Counselling in special contexts covers the additional counselling messages for specific clients. The specific clients include the following:

- Client with Indeterminate HIV Test Result
- At-risk Adolescent and Women in Reproductive age-group
- Blood donor with HIV reactive result
- Spouse or Partner of PLHIV, advised Index Testing
- High-risk groups
- HIV-positive pregnant women and her HIV exposed child
- Victims of sexual violence and POCSO
- PLHIV with TB co-infection
- Hepatitis B or C screened positive client or PLHIV co-infected with Hepatitis B/C
- Clients diagnosed with STI
- Client interacting on National AIDS helpline 1097 and on other virtual platforms

CHAPTER-3

Combination HIV Prevention

Combination HIV Prevention

Context

The prevention of HIV transmission is one of the vital aims of HCTS services as HIV transmission can be prevented through risk reduction and behaviour change. One-to-one counselling on tailor-made methods for HIV prevention is essential as it ensures dialogue on sensitive aspects of a person's life that might increase risk for HIV infection and provides the counsellor with an opportunity to reduce risk and prevent the spread of infection through behaviour change and communication.

The aims of prevention counselling are as follows:

- To assess whether the lifestyle of an individual places him/her at-risk for acquiring HIV
- To work with an individual so that he/she understands the associated risks
- To help in identifying and understanding of high-risk behaviour
- To help in defining the true potential for behaviour change
- To work with the individual to achieve and sustain behaviour change

The prevention counselling is tailored to specific needs, vulnerabilities and behaviours of the clients and entails active listening, providing assistance and determining the client specific approaches for prevention. The prevention counselling primarily consists of risk reduction counselling and behaviour change. The risk reduction strategies are mentioned below:

Information, education and communication: This component involves awareness generation and dissemination of information and education.

Behaviour change communication: This component involves understanding and assessing individual and group practices and behaviours that can pose a risk of acquiring HIV infection. It includes development of context-specific strategies and activities to address the risk of infection through peer counselling and creation of an enabling environment to reinforce safer practices.

All at-risk and high-risk negative clients should get HIV prevention counselling during every visit.

3.1 Condom

A condom is a sheath-shaped barrier device used during sexual intercourse to reduce the probability of pregnancy and HIV and STI.

- There are two types of condoms (Figure-3.1.1: Male and Female Condom):
  - (i) External condoms, worn on the penis – also called the male condoms
  - (ii) Female condoms (also known as femidom), worn inside the vagina



Figure 3.1.1: Male and Female Condom

- Female condom empowers a woman to prevent unintended pregnancies by simultaneously reducing the risk of HIV and STIs, even without considering her partner's opinion.
- Male condoms can be made of latex, polyisoprene, and polyurethane. The female condom is made of polyurethane, which eliminates allergic reactions connected with latex.
- Condoms are lubricated to make them easier to use, but additional lubricant (lube) should also be used for better sexual experience and reducing the chances of condom failure. This is particularly advised for anal sex to reduce the chance of condom failure.
- The instructions for using a male and female condom are given in Figure-3.1.2 and Figure 3.1.3.

Figure 3.1.2: Instructions for use of Male Condom

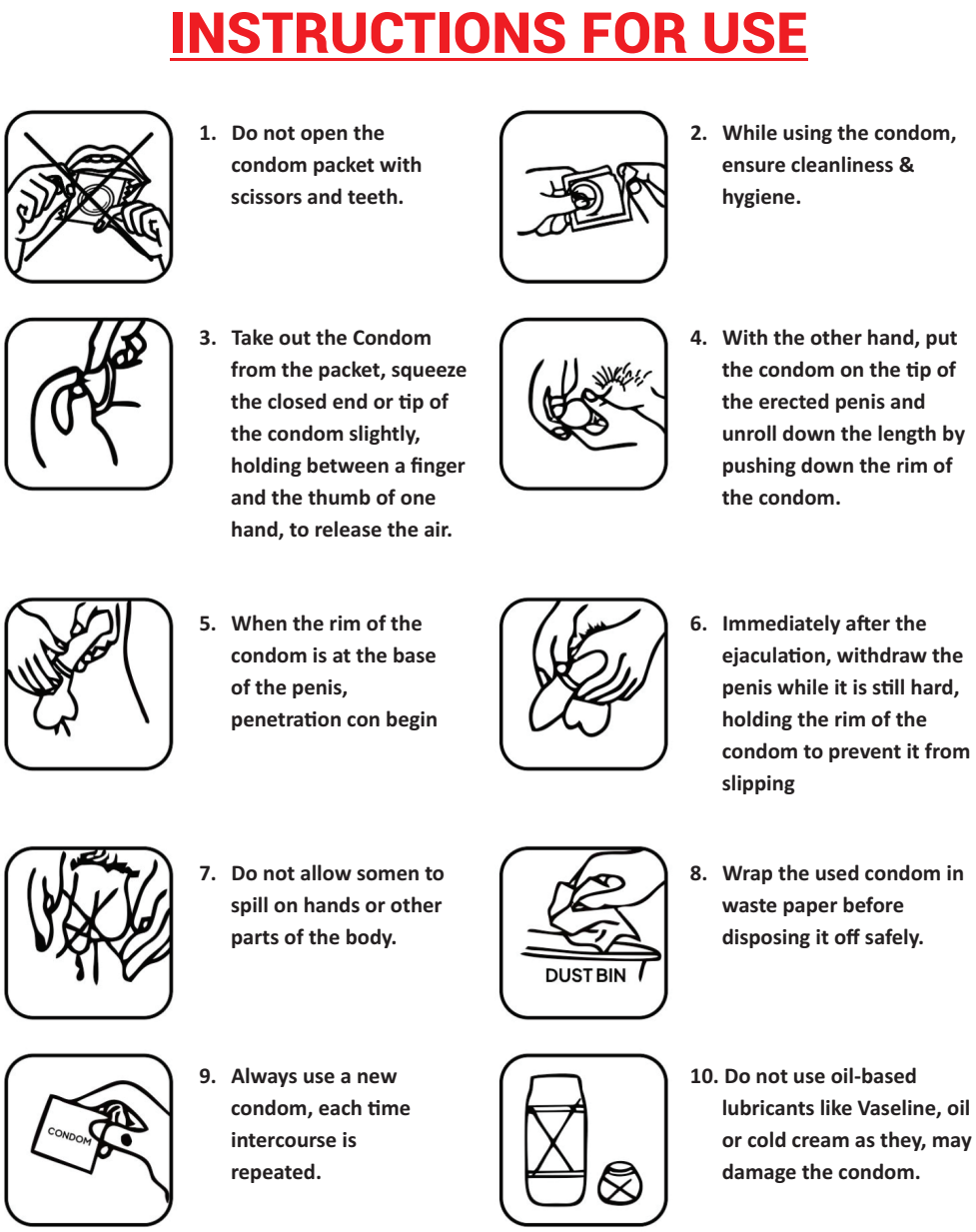
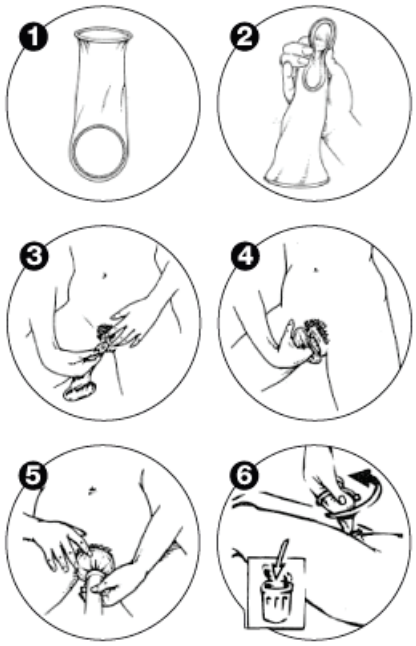


*Figure 3.1.3: Instructions for use of Female Condom**

Instructions for use of female condoms



- Put yourself in a comfortable position, either lying, sitting, or standing with one foot resting on a chair.
- Open the individual female condom pack and take it out carefully, especially be careful not to damage the lining if you are wearing jewelry or have long nails.
- Make sure that the inner ring is at the bottom of the condom. Hold the female condom by this ring by squeezing it with your thumb and index finger.
- Without letting go, insert the ring inside the vagina and push it as far as possible.
- Next, place your index finger inside the female condom and push the femidom to the back of the vagina by pushing on the ring. When the female condom is in place, the external ring must be outside the vagina.
- To remove the female condom, turn the external ring to close the opening completely and to stop the sperm from pouring out. Now pull it gently.
- Put the used female condom back in its pack and throw it in the bin. Do not throw it down the toilet.

***Note:** The female condoms should not be re-appropriated for use in the anal sex.

Use of lubricants with Condoms

Only water-based lubricants are recommended for use with the condoms. A small amount of lubricant can be applied on the outer surface of the condom, once the condom is placed over an erected penis. The use of excessive amount of lubricant should be avoided as it creates a slippery sensation that may interfere with sexual pleasure/activity and reduces the effectiveness of the condom.

The use of water-based lubricant is recommended for several reasons as mentioned below:

1) Compatibility with latex: Water-based lubricants are safe to use with latex condoms, as it doesn't degrade latex. Using oil-based or silicone-based lubricants with latex condoms can cause the condom to weaken, break or tear leading to condom failure. The instructions to be followed in case of condom failure are mentioned in Table-3.1.1.

2) Reducing friction: Lubrication can enhance sexual pleasure by reducing friction, making intercourse more comfortable and enjoyable for both partners. This is particularly important if one or both partners experience dryness and/or discomfort during sex.

3) Easy to clean: Water-based lubricants are easy to clean off the body and sex toys, as they are soluble in water.

4) Safe for most people: Water-based lubricants are generally considered safe for most individuals. They are hypoallergenic and less likely to cause irritation or allergic reactions. However, the product label should be checked or a healthcare professional should be consulted if there are any specific concerns or allergies.

The actions to be taken if a condom fails are compiled in Table-3.1.1.

Table 3.1.1: Actions to be taken if a Condom Fails

What to do if a condom fails?
It is very rare for a condom to break when it is used properly. However, in incidents when a condom splits/breaks/slips off during sexual activity (condom failure), the following steps should be taken: • The penis should be withdrawn immediately, and semen can be removed (as much as possible). • The external genitalia should be washed gently. The washing of internal genitalia including vagina or anus (including douching) should be avoided as it is associated with irritation and can increase the chances of infection. • In case of vaginal sex, instant urination is advised to flush out any semen from vagina. • In case of oral sex, the semen should be spitted out and the mouth should be rinsed with water. • If the female was not using any other contraceptive to prevent pregnancy, emergency contraception should be provided to prevent pregnancy. This should be done within 72 hours of the sexual intercourse. • The eligibility for non-occupational post exposure prophylaxis (PEP) should be assessed.

Some of the common myths and misconceptions associated with condoms (not an exhaustive list) are discussed in Table-3.1.2.

Table 3.1.2: Myths and Misconceptions associated with condoms

Myth	Fact
Condoms are unreliable and can break or slip off easily.	If used properly (as mentioned in the description above), the chances of condom failure are almost negligible.
Sex does not feel as good with a condom.	Condoms do not interfere with sexual pleasure. There are variety of condoms commercially available in the market which can provide a range of sexual pleasure.
Two condoms are better than one.	Use of two condoms simultaneously may lead to rupture (as result of friction) or slippage of condoms
Female condoms are reusable.	The female condoms are for one-time use only and should be discarded appropriately after use.
Female condoms can get lost inside the women's body.	The female condoms can be easily pulled back from vagina and discarded. There are no chances of loss of female condoms from vagina into women's body.
Condoms do not fit.	Condoms are available in multiple sizes. The condoms supplied through public health facilities are appropriate as per the average size of penis in the country. The commercially available condoms can be purchased in multiple size and material.
Condoms are indicative of sexual promiscuity by people who use them	Consistent and correct condom use is a sign of responsible sexual behaviour. The practice is associated with safe sexual and healthy behaviour.

3.2 Pre-Exposure Prophylaxis (PrEP)

Pre-Exposure Prophylaxis (or PrEP) for HIV refers to the use of anti-retroviral medication by people at substantial risk of acquiring HIV infection to reduce the chances of getting infected. PrEP is the method of prevention for HIV-negative persons while those already infected should be linked immediately to HIV care and treatment services. Please note that PrEP is not currently available under NACP for dispensation. However, counsellors should provide the information related to PrEP as a method for HIV prevention.

Eligibility for PrEP

PrEP shall be offered to sexually active HIV-negative individuals who are at substantial risk of acquiring HIV infection. It is important that a careful evaluation is done for assessing the risks and benefits before prescribing PrEP for HIV.

To be eligible for PrEP, persons must meet all the following criteria:

- **Confirmed HIV-negative**, using rapid antibody testing, following the HCTS algorithm.
- **At substantial risk** of acquiring HIV infection (criteria listed below)
- **No contraindication** to the use of any PrEP medication
- No current or recent (within the past one month) illness suggestive of **acute HIV infection** along with history of probable exposure for HIV
- **Ready to adhere** to PrEP and willing to attend follow-up evaluations including repeated HIV testing and monitoring

Substantial risk:

Following are some factors putting people at substantial risk of HIV infection:

- HIV-negative partner in sero-discordant couple when the HIV-positive partner is:
    - Not on ART
    - Not virally suppressed
    - Not adherent to ART
- Engaging in anal or vaginal sex, either receptive or penetrative, with multiple partners with inconsistent or no use of condoms in last six months
- Engaging in transactional sexual activities
- People unable to negotiate condom use during intercourse with partner of unknown HIV status
- History of any STI in the last six months by laboratory testing or self-reporting or history of syndromic management of STI
- History of repeated use of non-occupational PEP (described later in this chapter)
- A person having perceived risk of HIV infection and demanding PrEP

- History of frequent sex under the influence of alcohol or recreational drugs
- Intravenous drug use
- Sero-discordant couples trying to conceive (PrEP for safer conception)

Benefits of PrEP

The major advantage of PrEP is that it adds another effective option of HIV prevention to the bucket of prevention strategies. It is not to be consumed lifelong, rather, can be started during periods of higher risk and stopped during lower risk periods.

In addition, it can be extremely useful to provide an additional method to help protect people, who are unable to negotiate condom use with their partner(s) or, people, who inject drugs but, are not able to obtain new injection equipment, or people, who do not use condoms or new injection equipment consistently (for reasons not cited above).

Cautions while using PrEP

PrEP does not eliminate the risk of HIV infection and it does not prevent STIs or unintended pregnancies. It should, therefore, be offered as part of a combination prevention package that includes risk reduction counselling, regular HIV testing, consistent use of condoms, and lubricants, regular STI screening and treatment, contraception, needle exchange and opioid substitution therapy as needed.

Important Considerations:

- Consistent and correct condom use should be promoted along with PrEP to prevent STIs/ unintended pregnancy.
- PrEP should be initiated only after eligibility assessment.
- It should be taken as prescribed by the doctor. If the client is not willing to take PrEP as per the advice, the health care provider (HCP) can choose not to provide PrEP
- PrEP can be used to reduce the risk of HIV transmission in high-risk sexual encounters and injecting drug use. It may also be used for safer conception in HIV discordant couple.
- The follow-up should be continuous and as per the advice of the doctor. Regular investigations (e.g., HIV screening, KFT, etc) should be ensured for continued prescription.

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

3.3 Post Exposure Prophylaxis (PEP)

Post Exposure Prophylaxis (or PEP) for HIV refers to comprehensive management instituted to prevent the transmission of HIV following a potential exposure.

The potential exposure can be broadly categorized in to the following:

1. Occupational Exposures such as exposure to blood-borne infections (HIV, Hepatitis B & C) during performance of job responsibility in workspaces

Occupational exposures include percutaneous injury (with needle-stick or cut with a sharp instrument), contact with mucous membranes of mouth/eyes and non-intact skin (chapped skin or dermatitis) with blood and body fluids of an HIV-infected person. Therefore, adequate implementation of Standard Workplace Precautions is important to mitigate the risk of exposure to HIV.

For further reading on Standard Workplace Precautions, refer to National Guidelines for Infection Prevention and Control in Healthcare Facilities, Jan 2020; weblink: https://www.mohfw.gov.in/pdf/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf

2. Non-occupational exposure of HIV refers to the exposures outside the healthcare service delivery settings and may include unsafe and risky sexual exposures/ injection exposure. This includes high-risk exposures (condom less sexual encounters/condom failure/injection exposure) with virally unsuppressed PLHIV or persons with unknown HIV status. This also involves consensual high-risk sexual exposures or exposures during sexual assault.

The risk of exposure from different body fluids is mentioned in Table 3.3.1.

Table 3.1.1: Risk of exposure from different body fluids

Exposure to body fluids considered `at-risk'	Exposure to body fluids considered 'not at-risk,' unless these fluids contain visible blood
Blood, Semen, Vaginal secretions, Cerebrospinal fluid, Synovial, pleural, peritoneal, pericardial fluid, Amniotic fluid Other body fluids contaminated with visible blood	Tears, sweat, urine & faeces, saliva, sputum, vomitus (Unless these secretions contain visible blood)

Average Risk of Acquiring HIV, Hepatitis B and Hepatitis C

The average risk of acquiring HIV infection following different types of occupational exposure is low compared to the risk of acquiring infection by Hepatitis B virus (HBV) or Hepatitis C virus (HCV). In terms of occupational exposure, the important routes are needle stick exposure (0.3 % risk for HIV, 9 - 30 % for HBV, and 1 - 1.8% for HCV) and mucous membrane exposure (0. 09% for HIV). However, the risk of HIV transmission during unsafe sexual intercourse ranges from 0.1 to 1.0% while the risk from injecting drug use has been reported to be 0.67%. The HIV risk is higher through anal sex due to higher chances of mucosal damage, than by vaginal sex. There is lower risk of HIV transmission through oral sexual encounters.

Standard of care for individuals exposed to HIV

Certain work practices increase the risk of needle stick injury such as recapping needles (most important), transferring a body fluid between containers, handling and passing needles or sharps after use, failing to dispose of used needles properly in puncture-resistant sharps containers, and poor healthcare waste management practices etc.

Management of the Exposed Person

PEP includes first aid, counselling, risk assessment and relevant baseline laboratory investigations and depending on the risk assessment, the provision of short term (28 days) of antiretroviral drugs, with follow up and support including maintaining confidentiality.

A trained doctor must assess the risk of HIV, HBV and HCV transmission following an Accidental Exposure to Blood (AEB). This evaluation must be made rapidly, so as to start any treatment as soon as possible after the accident. This assessment must be made thoroughly (as every AEB might not require prophylactic treatment).

The first dose of PEP should be administered ideally within 2 hours (but certainly within the first 72 hours) of exposure and the risk evaluated as soon as possible. If the risk is insignificant, PEP could be discontinued, if already commenced. The management of exposure site (First Aid) in case of occupational exposure is mentioned in Table-3.3.2.

Table 3.3.2: Management of Exposure Site-First Aid for Occupational Exposure

<table>
<tr><td colspan="2">• Do not panic.
• PEP must be initiated as soon as possible, preferably within 2 hours</td></tr>
<tr><td>For skin: If the skin is pierced by a needle-stick or sharp instrument.
• Immediately wash the wound and surrounding skin with water and soap and rinse
• Do not scrub.
• Do not use antiseptics or skin washes.
• Don't use bleach, chlorine, alcohol and betadine.
• Do not put pricked/ cut finger in the mouth</td><td>For the eye
• Irrigate exposed eye immediately with water or normal saline.
• Sit in a chair, tilt the head back and ask a colleague to gently pour water or normal saline over the eye.
• If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it. Once the eye is cleaned, remove the contact lens, and clean them in the normal manner. This will make them safe to wear again.
• Do not use soap or disinfectant on the eye</td></tr>
<tr><td>After a splash of blood or body fluids and for unbroken skin
• Wash the area immediately.
• Do not use antiseptics</td><td>For Mouth
• Spit fluid out immediately.
• Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times.
• Do not use soap or disinfectant in the mouth</td></tr>
<tr><td colspan="2">• Never re-cap the needles
• Always use protective gear/Consider all blood samples as potentially infectious.
• Follow universal precautions Practice/Practice safe handling of sharp instruments/Use needle destroyers.</td></tr>
</table>

Source: Chapter-2.10; 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

Establish eligibility for PEP

The exposed individual should undergo confidential counselling and assessment by a trained physician. The exposed individual should be assessed for pre-existing HIV infection as PEP is intended for people who are HIV-negative at the time of their potential exposure to HIV. Exposed individuals who are known or discovered to be HIV-positive should not receive PEP. They should be offered counselling and subsequently linked to comprehensive HIV care and treatment services.

Counselling for PEP

For an informed consent, exposed persons (clients) should receive appropriate information about what PEP is and the risk and benefits of PEP. It should be clear that PEP is not mandatory. The client should understand the details of window period, baseline investigations, drugs that are used, their safety and efficacy and issues related to these drugs during pregnancy and breast-feeding. They should be counselled on safer sexual practices till both baseline and 3 months of HIV test are found to be negative.

Psychological support: Many persons may feel anxious after exposure. Every exposed person needs to be informed about the risks and the measures that can be taken. This will help to relieve part of the anxiety, but some may require further specialized psychological support.

Expert opinion may be obtained for the following situations (for deciding the eligibility of PEP, choosing the regimen, or providing additional services)

- Delay in reporting exposure (> 72 hours)
- Unknown source: use of PEP to be decided on case-to-case basis after considering the severity of exposure and the epidemiologic likelihood of HIV transmission. Do not delay PEP initiation if indicated
- Known or suspected pregnancy: do not delay PEP initiation
- Breastfeeding issues in the exposed person: do not delay PEP initiation
- Source patient is on ART or possibly has HIV drug resistance: refer/consult as soon as possible, do not delay PEP initiation.
- Major toxicity of PEP regimen: minor side effects may be managed symptomatically. Refer to expert if non-tolerance or non-adherence
- Refer/ consult if in doubt or complicated cases (e.g., major psychological problem)

Assessing Need for PEP and Prescribing PEP

The decision on the need for PEP for HIV (following an occupational exposure in healthcare worker) will depend on the exposure, the source person's HIV status and the extent of disease if the source has been confirmed positive. It is decided based on exposure code and source code. Under NACP in India, programme managers and medical staff are undergoing training to assess the exposed person and the source person as detailed in the following two algorithms (Figure-3.3.1 & 3.3.2) (Source: National guidelines for HIV Care and Treatment, 2021)

Figure 3.3.1: HIV exposure codes

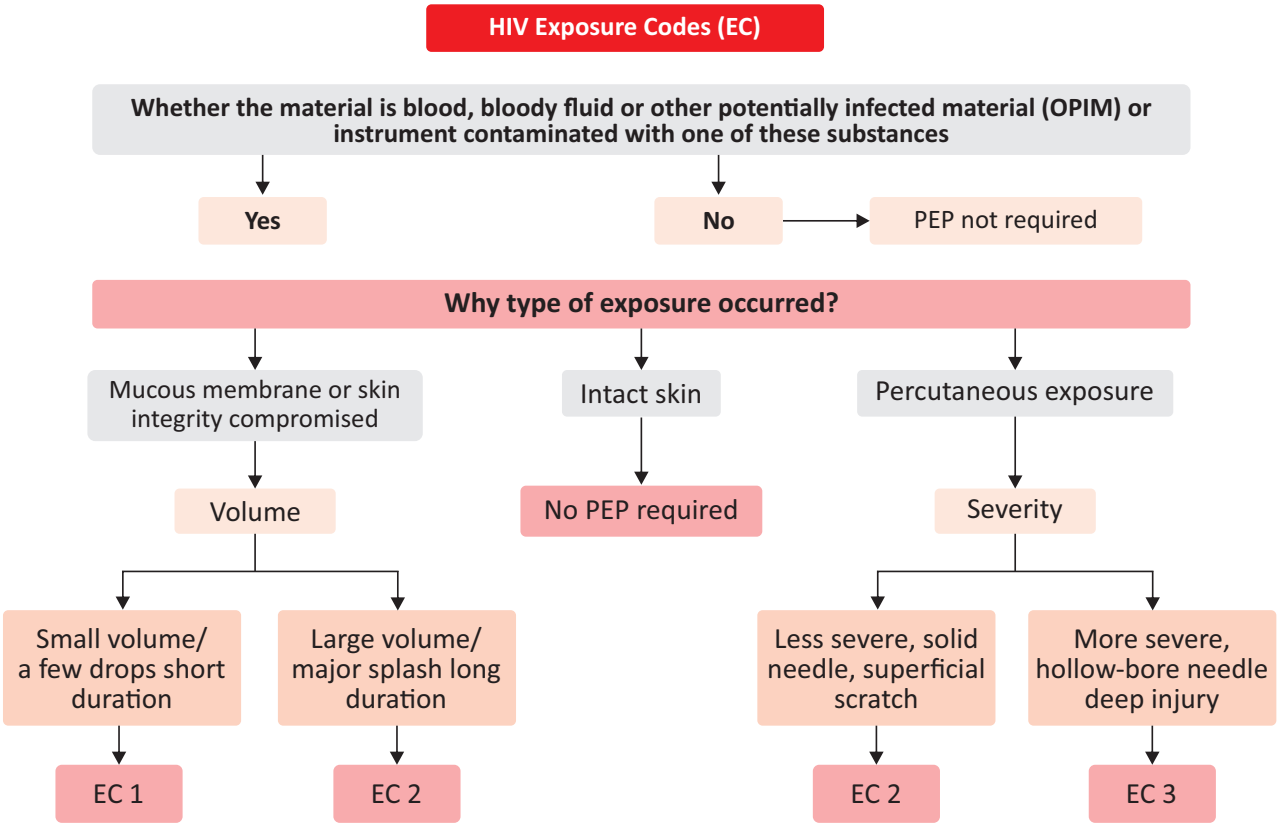
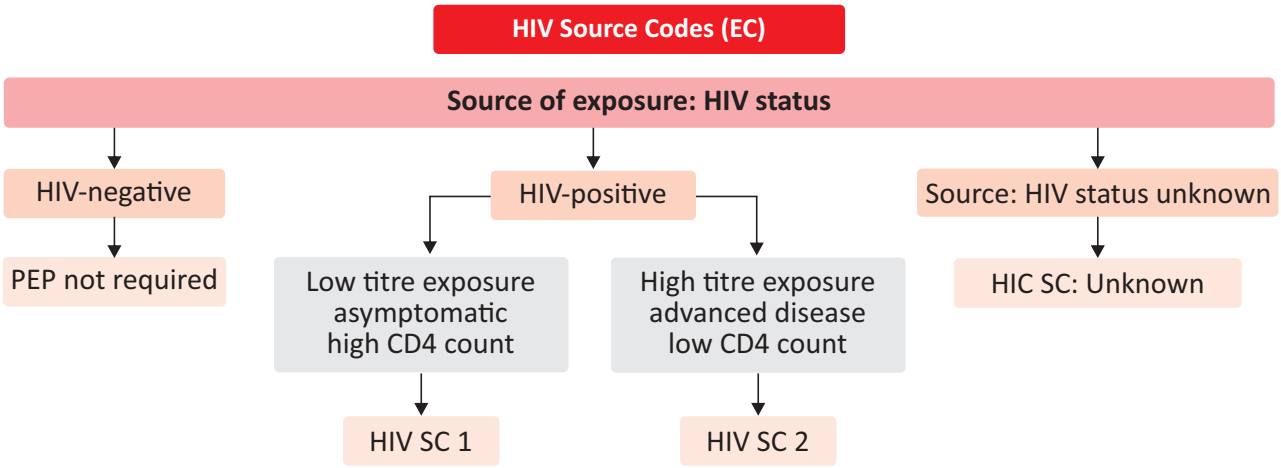


Figure 3.3.2: Source codes



Source-Chapter-2.10; 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

Depending on the exposure and source codes, the decision to offer or defer PEP should be considered as provided in figure 3.3.3.

Figure 3.3.3: Recommendations for PEP for healthcare personnel based on exposure

Exposure Code	Source Code	Recommendation for PEP	Duration
1	1	Not warranted	
1	2	Recommended PEP	PEP is recommended for 28 Days
2	1		
2	2		
3	1 or 2		
2/3	Unknown	Consider PEP if HIV prevalence is high in given population in the region and risk categorization	28 days

Source: Chapter-2.10; 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

In cases of sexual assault, **PEP should be given to the exposed person** as a part of the overall package of post sexual assault care.

Recommended baseline laboratory investigations

The HIV, Hepatitis B and C testing of exposed person within 6 days of an exposure is recommended to know the baseline serostatus. A positive HIV status at baseline may indicate the need to discontinue PEP and referral for HIV treatment. The decision whether to test for HIV or not, should be based on the informed consent of the exposed person. In addition to these, pregnancy testing, serum creatinine and liver function test should be done. However, PEP should be offered even when lab tests are not available. Do not delay administration of PEP while waiting for lab results.

Referrals for Treatment:

As PEP for HIV has its greatest effect if it is initiated within 2 hours of exposure, it is essential to act immediately. Client should be referred to the medical officer of the nearest emergency facility or the medical officer of the nearest ART centre. All clients who are advised PEP should be counselled to complete the four weeks (28 days) course of medication. Exposed clients also to be referred for Hepatitis B vaccination. The ART regimen should be prescribed as per National Guidelines for HIV care and Treatment, 2021. Sexual assault cases are regarded as medico-legal cases and should be dealt accordingly.

Follow-up of an Exposed Person

Clinical monitoring:

- Monitor for acute seroconversion illness, within 3–6 weeks after exposure. If suspected, refer to ART centre.
- Avoid Blood donation, Breastfeeding, Pregnancy.
- Person should use precautions during sexual relationship (condom protection).

- Adherence and adverse drug reaction counselling.
- Follow-up laboratory monitoring (during and after PEP)
- For persons taking PEP (standard regimen):
- **Weeks 2 and 4:** Complete blood count (for patients on zidovudine, this is particularly useful), Fasting blood sugar/Random blood sugar (for patients on Dolutegravir), Serum creatinine
- **Week 6, Week 12 (Month 3), Week 24 (Month 6):** HIV-Ab

Note: It is important to remember that the person exposed to the risk of transmission of HIV is also at-risk of getting infected with HBV and HCV. Hence, that too needs to be addressed.

Exposed persons not taking PEP should be counselled for repeat testing of HIV, HCV, anti-HBsAg at 6 weeks, 12 weeks and 24 weeks from date of exposure.

For further details on Post Exposure Prophylaxis, refer to Chapter- 2.10, National Guidelines for HIV care and Treatment, 2021.

Considerations for non-occupational exposures

In a situation of non-occupational exposure, PEP should be given to the exposed person as part of the overall package of post sexual assault care. Exposed person with history of unsafe sexual or injecting exposure, should be evaluated for eligibility of PEP and advised PEP if eligible. In addition, they should also be evaluated for STI and managed according to the guidelines. The victims of sexual assault should additionally receive following services:

- Emergency contraception for non-pregnant women
- Tetanus toxoid for any physical injury of skin or mucous membranes
- Referral to appropriate authority (medico-legal case)

For further reading, refer to National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections, MOH, FW, 2014.

3.4 Treatment as Prevention (U=U)

If taken as prescribed, antiretroviral therapy (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 the immune system. Adherence to prescribed ART causes HIV viral load to become so less, that it cannot be detected through the viral load test (reported as target not detected [TND]). 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 as **an undetectable viral load.** This helps in keeping PLHIV healthy as well as prevent transmission of HIV to their sexual partners and children (through vertical transmission). This concept is known as Undetectable = Untransmittable or U=U.

PLHIV cannot pass HIV through sex when they have undetectable viral load. This prevention method is very effective as long as PLHIV takes ART without missing doses and the HIV viral load remains undetectable. This is referred to as **treatment as prevention (TasP).**

3.5 Harm Reduction and HIV Prevention

Harm reduction is a public health and rights-based approach for effective HIV prevention among People Who Inject Drugs (PWID) and their sexual and injecting partners. This approach prioritizes short-term pragmatic goals over long-term idealistic ones. The primary aim of harm reduction is to mitigate the transmission of HIV by addressing the immediate risks associated with high-risk behaviors, such as sharing needles, syringes and drug preparation equipment as well as engaging in unsafe sexual practices.

To reduce the harms resulting from injecting drug use particularly transmission of HIV and other blood borne infections, the National AIDS and STD Control Programme (NACP) provides comprehensive Harm reduction services for people who inject drugs. Harm reduction services are delivered through Targeted Intervention projects and OST centres. These services also include HIV and STI counselling, screening and management.

The following Harm reduction services are provided under the Targeted Intervention projects:

- Needle Syringe Exchange Program (NSEP) including Overdose Prevention and management
- Opioid Substitution Therapy (OST)
- Targeted IEC and BCC for PWIDs and their sexual partners
- HIV counselling, testing and ARV treatment, index testing of HIV positive cases
- STI screening and treatment and Condom promotion for PWIDs and their sexual partners
- Prevention, diagnosis, and treatment for Tuberculosis (TB)
- Vaccination, diagnosis and treatment for viral hepatitis B and C

Needle Syringe Exchange Program

Needle and syringe exchange programmes (NSEP) are highly effective in reducing HIV and Hepatitis B and C transmission through injecting drug use. A key goal of the needle syringe programs is to reduce the transmission of HIV, Hepatitis C and other blood-borne infectious diseases by providing new sterile needles for each injecting episode and minimize reuse and sharing of infected equipment. The needle syringe exchange program is implemented at the Targeted Intervention (TI) NGO facility under the NACP. The services are provided through both outreach as well as at the TI drop-in centre (DIC). For further reading refer to Revamped and Revised Elements of Targeted Intervention for HIV Prevention and Care Continuum among Core Population, Strategy Document, NACO,2019; available at: https://naco.gov.in/sites/default/files/TI%20Strategy%20Document_25th%20July%202019_Lowres.pdf

Risk Reduction Counselling

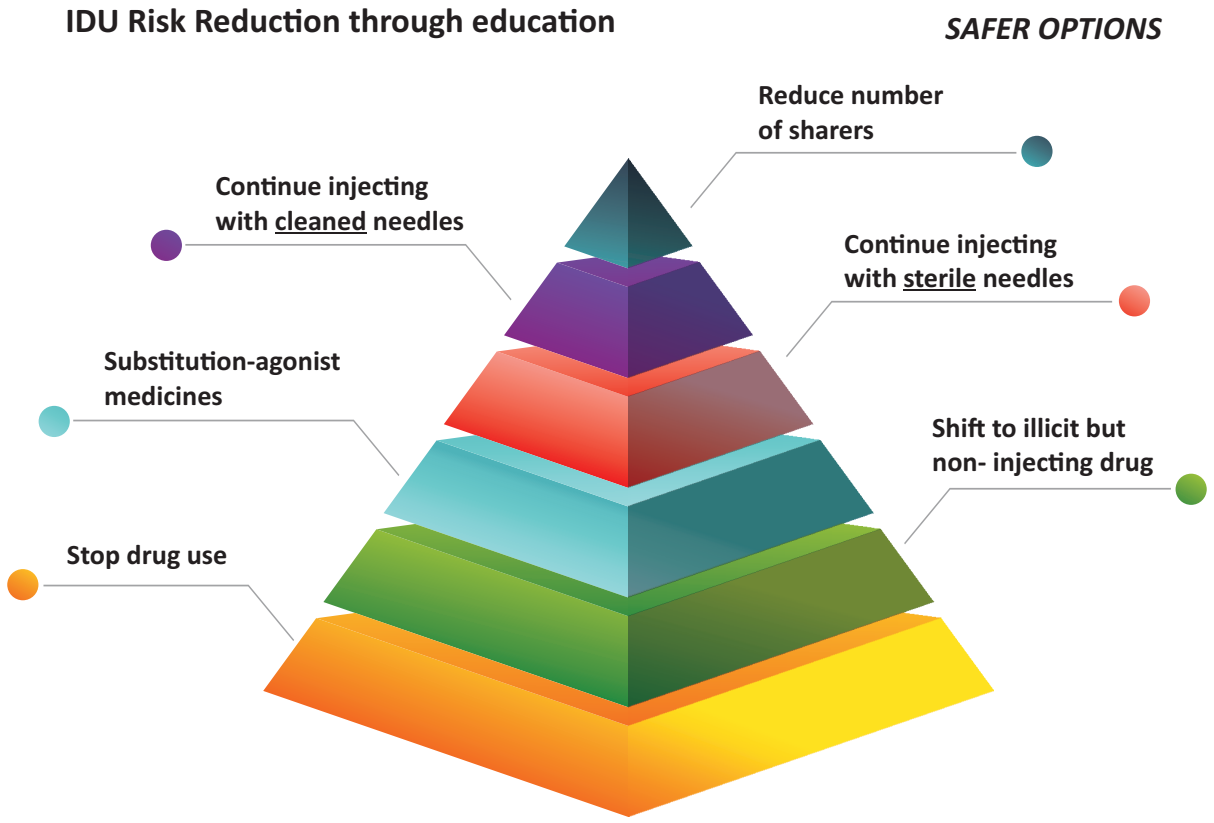
As part of Risk Reduction Counselling, the counsellor explains the complications that can arise due to injecting practices among people who inject drugs (PWIDs). The physical complications of intravenous drug use are compiled in table-3.5.1.

Table 3.5.1: Physical complications of intravenous drug use

Physical complications of intravenous drug use
• Blood Borne Infections such as HIV, Hepatitis B and C, etc. • Local infections called as 'abscesses' and 'ulcers'. • Loss of veins (Sclerosis of veins): Repeated injury to the vein by repeated injections leads to scarring in the vein with subsequent sclerosis. This leads to blockage of the vein. • Scarring of tissue due to repeated injections at one site: Repeated injections and seepage outside the vein due to faulty injection leads to scarring of tissue. • Injection into artery: Leading to severe pain, swelling, spasm of arteries leading to loss of blood flow into the limb where the artery supplies blood. This leads to gangrene of the tissue. • Infection of internal organs: Passage of microorganisms to other organs in the body such as the heart, brain, lungs, etc. which leads to infection in the particular organ. This is especially true if unsafe veins such as the veins of neck, thighs, breast, etc. are used for injections. • Overdose: Drug overdoses can be fatal and is one the most common reason for deaths among PWIDs

The strategies for Risk Reduction for PWIDs are depicted in Figure-3.5.1

Figure 3.5.1: Strategies for PWID Risk Reduction



The Counsellor can provide guidance for reducing risks using a hierarchal approach for clients injecting drugs. Counsellor should provide counselling on the following issues:

- Educate the client on the risks of sharing needles/syringes during injecting.
- Educate the client on the risks associated with the reuse of used needles/ syringes.
- Educate the client on how to inject safely and prevent abscesses and other complications.
- Inform the client regarding the needle/syringe exchange programme and link the client with the concerned PE and ORW of the Targeted Intervention Project for PWID.
- Educate the client on risks of overdose and management
- In case, the client is motivated and ready to stop injecting but is not able to do so due to cravings and withdrawals, the client should be referred to the nearest Opioid Substitution Therapy Centre.

Opioid Substitution Therapy (OST)

Opioid Substitution Therapy (OST) is an integral component of harm reduction services for PWIDs under the National AIDS and STD Control Programme. OST involves treatment of PWIDs who are dependent on opioids with a substitution i.e. a long-acting opioid agonist medication administered through the sublingual route for a prolonged duration of time under the direct supervision of a trained medical officer and nurse. The philosophy of OST is to replace the illicit substance of abuse with a safer, legal and long-acting alternative which effectively minimizes cravings and withdrawals and enables the patient stop to injecting and to lead a normal productive life. The counsellor can provide assistance to the drug user by sharing the benefits of enrolling in the opioid substitution therapy programme.

Benefits of Opioid Substitution Therapy: The benefits accrued from OST range from HIV, Hepatitis B and C prevention to treatment of opioid dependence, and improvements in the well-being at the individual, family and society levels. Some of the benefits include the following:

a. Reduction in injecting behaviour (able to stop injecting)

b. Improved adherence for other treatment, especially treatment for HIV, tuberculosis, and viral hepatitis

c. Reduction in illicit opioid use

d. Reduced overdose related deaths

e. Reduction in criminality

f. Reduction in domestic violence

g. Improved childcare and family ties

h. Improved productivity and gainful employment

For further details, refer to Standard Operating Procedure (Third Edition): Buprenorphine based Opioid Substitution Therapy under National AIDS Control Program, Ministry of health and Family Welfare, Government of India, 2021.

3.6 Elimination of Vertical Transmission of HIV and Syphilis (EVTHS)

Vertical transmission of HIV can be prevented through successful ART treatment of HIV-positive pregnant women in achieving sustained viral suppression and provisioning of appropriate prophylaxis and interventions for the HIV-exposed children.

The interventions for pregnant women and their children are discussed in detail in the National Guidelines for Elimination of Vertical Transmission of HIV & Syphilis (EVTHS), 2024

3.7 Counselling and Communication

All at-risk negative clients should be informed about free access to voluntary HIV testing and counselling. Studies show that early HIV diagnosis and treatment leads to better survival and lesser morbidities and infections. Late HIV diagnosis has higher mortality and morbidity due to presence of advanced HIV disease and severe opportunistic infections. Therefore, counselling the at-risk clients regarding prevention interventions and regular screening for HIV and STI, once every six months, becomes essential.

Virtual strategies should ensure continuity across the entire HIV cascade, supporting linkages from awareness, to prevention, testing, treatment and ongoing follow-up for health-promoting behaviours. The virtual platform providing information on HIV services, if itself does not offer services across the cascade, it should integrate referrals to other resources for service continuity. Messages and services promoted through online channels should be tailored and specific to the population group they are intending to reach. Online outreach workers can be powerful motivators and tools to support client to adopt health promoting behaviours and link clients to either online, National AIDS Helpline-1097 or NACP facilities.

3.8 Prevention and treatment of sexually transmitted infections

Sexually transmitted infections, particularly those that cause genital ulcers, increase the risk for transmission and acquisition of HIV. Early diagnosis and treatment of such infections should therefore, be part of HIV prevention and all the at-risk clients should be counselled on STI prevention, diagnosis and treatment. *For further reading, refer to the National Technical Guidelines on Sexually-transmitted infections and Reproductive tract infections, 2024.*

CHAPTER-4

Risk Assessment and Client flow

Risk Assessment and Client flow

4.1 Risk Assessment

At the confirmatory facilities, all direct referrals are prioritized and assessed for risk of HIV while all provider referral clients are fast tracked. However, counsellors may administer risk assessment to provider referral clients at the time of pre-test or post-test, if they feel the need, based on their interaction with client. The Risk Assessment is to be documented in SOCH (NACP Online Data Management Portal).

All the clients identified as at-risk on the basis of their risk-assessment and whose HIV test result is negative will be linked to the comprehensive prevention services under the program like Sampoorna Suraksha Kendra (SSK). In case the client could not be linked to SSK for any reason, the client should be followed up at the existing ICTC for prevention services.

The risk assessment questionnaire and their respective risk categorization is depicted in Table-4.1.1.

Table 4.1.1: Risk assessment Questionnaires and risk categorization

Questions	Risk assessment questions	Interpretation basis on Response
Q1	Do you have the habit of using/sharing injecting drugs? (Response: Used/ Shared/ Refusal to answer*)	If "Used and Shared" or "Shared" >> High-Risk If "Used" >> Moderate-Risk For Other scenarios >> Not At-Risk
Q2	What kind of sexual partner(s) you have? (Response: Male/ Female/ H/TG No sexual partner/ Refuse to answer*)	If Client is Male and Sexual Partner is Male >> High-Risk If Client is Male and Sexual Partner is H/TG >> High-Risk If Client is H/TG and Sexual Partner is Male >> High-Risk If Client is H/TG and Sexual Partner is H/TG >> High-Risk For other scenarios >> Not At-Risk
Q3	Do you have any sexual relationship beyond your spouse/partner? (Response: Yes/ No/ Refusal to answer*)	If "Yes" >> High-Risk For other scenarios >> Not At-Risk
Q4	Have you bought sex in the past from a man, woman or H/TG using money, goods, favours, or benefits? (Response: Yes/ No/ Refusal to answer*)	If "Yes" >> High-Risk For other scenarios >> Not At-Risk

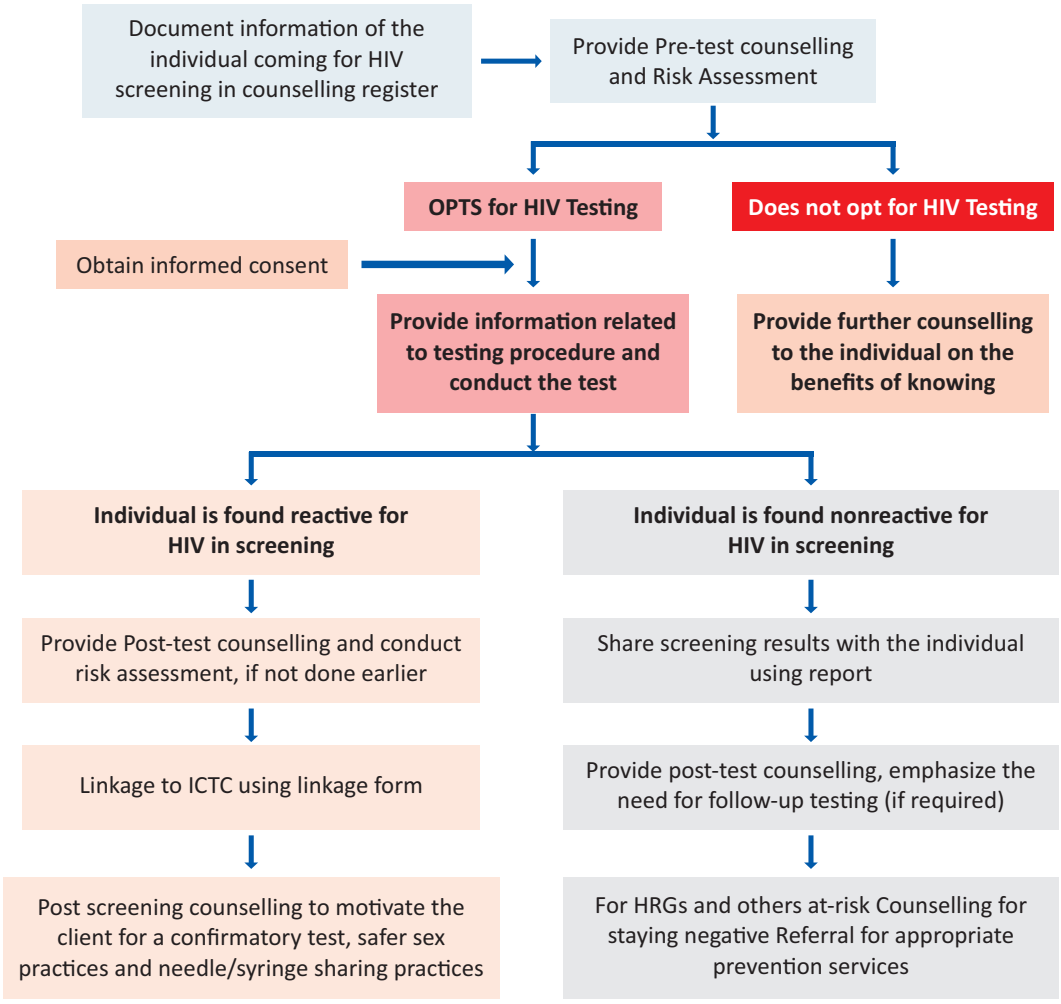
Q5	Have you provided sex in the past in exchange for money, goods, favours, or benefits? (Response: Yes/ No/ Refusal to answer*)	If "Yes" >> High-Risk For other scenarios >> Not At-Risk
Q6	Any STI symptoms in last three months? (Response: Yes/ No/ Refusal to answer*)	If "Yes" >> Moderate-Risk For other scenarios >> Not At-Risk
Q7	Is your spouse or partner, a PLHIV? (Response: Yes/ No/ Refusal to answer*)	If "Yes" >> High-Risk For other scenarios >> Not At-Risk

***NOTE:** If a client "refuses to answer" any of the Risk Assessment Questions, it is the responsibility of the counselor to probe further in order to accurately assess the client's risk level.*

4.2 Client flow

The client flow at HIV screening and confirmatory facilities is devised to focus on identifying at-risk clients and provision of a customised holistic basket of prevention services, while ensuring strengthened follow-up and outreach to continuously engage with at-risk clients and their partners. The client flow at Screening facility is depicted in figure no-4.1.1

Figure 4.1.1: Client flow at Screening Facilities

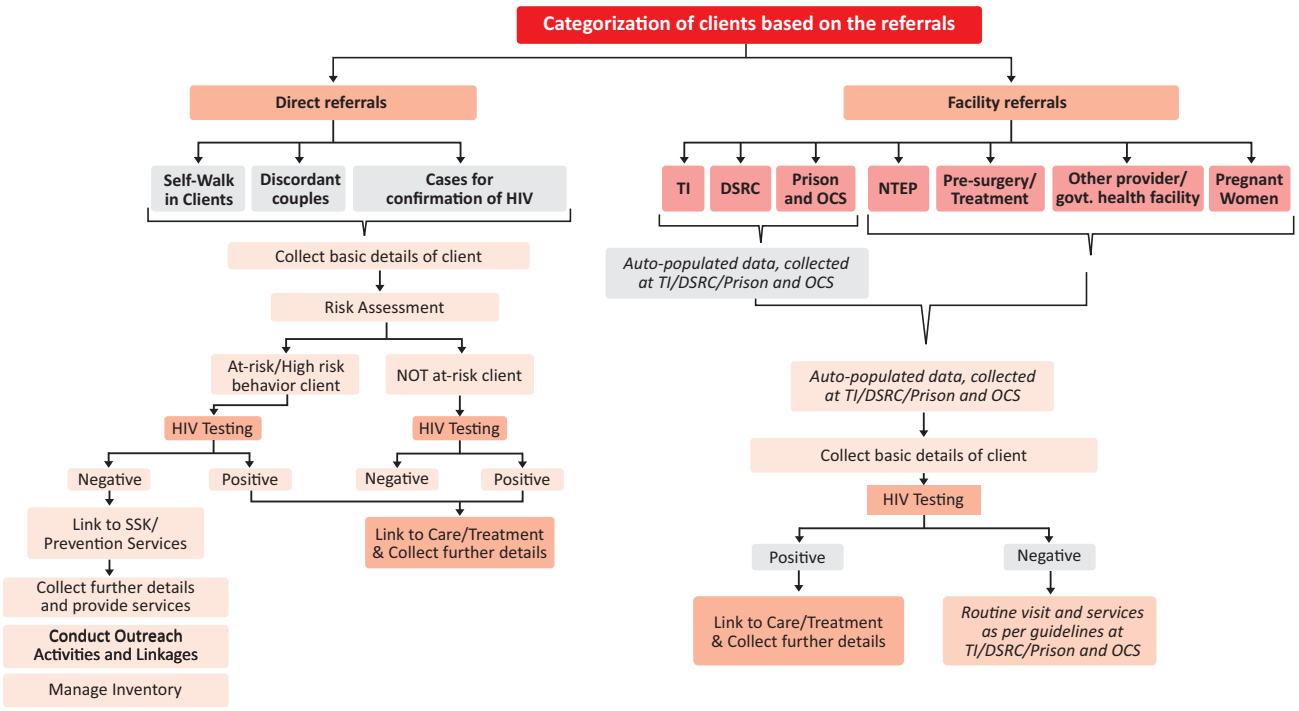


In case of HIV confirmatory facility, the client flow focuses on self-walk-in clients and other direct referrals. Thus, every client arriving at the facility (for the first time) will be identified on the basis of referrals, i.e., Direct Referrals or Facility Referrals.

Clients from Facility Referrals receive routine HCTS services. Risk assessment will be performed for all the clients identified from Direct Referrals.

The client flow at Confirmatory facilities is depicted in Figure-4.1.2

Figure 4.1.2: Client flow at ICTC



CHAPTER-5

Counselling for HIV and STI

Counselling for HIV and STI

5.1 Basics of Counselling

Definition of counselling: Counselling is a confidential dialogue between an individual and a counsellor. Counselling is a professional relationship between a client and a counsellor, empowering them to find the best solution from available options. Counsellors facilitate exploration and guide/support the individual in decision-making, encouraging in-depth discussion and root cause identification. They develop action plans to help individuals to cope with issues and improve their behaviour, beliefs and emotional distress levels.

HCTS aims to provide information on HIV and AIDS and STI to bring about behaviour change in the individual. It also enables the individual to take a decision regarding HIV and Syphilis testing and to understand the implications of the test results.

Counselling also aims to assess the HIV and STI risk, facilitate preventive behaviour, and provides coping mechanisms for HIV-positive persons. It addresses the individual's physical, social, psychological, and spiritual needs, which is crucial for HIV screening and confirmation under HCTS. Counselling creates awareness, prepares individuals for seropositive and seronegative status, addresses stigma and mental health issues, provides information about the services available under the program and ensure linkages to the further care cascade.

The principles of counselling include acceptance, individualization, non-judgmental attitude, confidentiality, empathy, controlled emotional involvement, communication, expression of feelings and self-awareness. Basic communication skills should be employed to convey clear and simple messages. Counsellors should create a comfortable environment for clients to relax, trust and open up about thoughts or emotions. During counselling, audio-visual privacy and confidentiality should be ensured. Preferably, each individual should be counselled separately, particularly at-risk individuals and HIV-positive clients. Pre and post-test group counselling, may be provided for clients who are not at-risk, such as surgical cases and pregnant women.

5.2: Five Cs for HIV Testing

The five Cs are essential for all HIV testing services, including Consent: which is obtained from the persons undergoing testing in order to access testing and counselling services.

i. **Confidentiality:** refers to the non-disclosure of discussions between the health care provider and the client to any other person until the client has given his consent to do so. The guidance in context with HIV and AIDS (Prevention and Control) ACT, Section 8: Disclosure of HIV status, is provided below.

   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.

ii. **Counselling:** is a confidential dialogue between an individual and a counsellor. It's aim is to educate people about HIV/AIDS and to contribute to their behaviour. It also allows the individual to make an informed decision about HIV testing and to comprehend the implications of the test results.

iii. **Correct:** HIV testing providers should strive to provide high-quality testing services, and quality assurance mechanisms should ensure that people receive the correct test result of HIV diagnosis, preferably on the same day.

iv. **Connection**: to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support.

v. **Consent:** Informed consent remains one of the essential 5Cs and should always be obtained individually and in private. Even if pre-test counselling is provided in a group setting, each individual should give informed consent for testing with an opt-out option. The following section provides the definitional and operational details on administering informed consent prior to screening and testing.

5.3 Informed consent

Definition– "Informed consent" means consent given by any individual or his/her 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/her trusted witness or legally authorised 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 .

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.

5.4 Pre-test counselling

The Guidelines in the context of HIV and AIDS (Prevention and Control) ACT 2017, were notified by the Government of India on 4th July 2022. This document provides guidance on the manner of Pre-test counselling prior to HIV testing, which is detailed below.

Manner of conducting Pre-test counselling:

1. Pre-test counselling is provided to the individual before HIV testing. Counsellor should use

posters, flip charts, brochures and short video clips or any other communication means available, so as to prepare him or her for the HIV test and to address myths and misconceptions regarding HIV and AIDS

2. Pre-test counselling may be done in two ways – (a) one-on-one counselling and (b) group counselling.
3. Group counselling can be done when the counsellor is addressing a group, such as, pregnant women at Ante Natal Clinic.
4. The contents of pre-test counselling should include providing information on HIV or AIDS, window period, route of transmission, prevention message, care, support and treatment services.
5. Pre-test counselling should include:
    i. discussion on HIV, risk factors and prevention methods;
    ii. explaining the meaning of positive and negative test results and their implications;
    iii. assessing the patient's personal and social supports;
    iv. determining the patient's readiness to cope with test results;
    v. discussing disclosure of test results to others; and
    vi. advising the patient for HIV status disclosure to the healthcare provider if required.
6. The benefits of HIV testing, right of individual to opt out of HIV testing without affecting access to any other health services should be explained to individuals.
7. During pre-test counselling along with risk assessment, information should be provided on importance and benefits of spouse or partner testing.
8. An opportunity shall be given to the individual to ask and clarify their doubts.

Pre-test counselling is provided to the individual before HIV testing, where counsellor should use posters, flip charts, brochures, etc., so as to prepare them for the HIV test and to address myths and misconceptions regarding HIV and AIDS.

This can be done in two ways – (a) one-on-one counselling and (b) group counselling. One-on-one counselling should be done for all individuals accessing HCTS services where risk has been elicited. Group counselling can be done when the counsellor is addressing a group such as pregnant women at ANC clinics.

At screening facilities, prescribing physicians or any paramedical staff designated for HIV screening (e.g. PHN/ LHV/ANM/MPW male/pharmacist/LT /ORW/SN /ASHA or any other trained paramedical staff), shall provide pre-test counselling for all provider referred clients. However, at ICTC all priority clients shall be provided pre-test counselling by the counsellor after administering risk assessment.

Content of pre-test counselling is compiled in table-5.4.1.

Table 5.4.1: Content of Pre-Test Counselling

a. Provide information on HIV and AIDS: what is HIV, what is AIDS, window period, route of transmission, prevention message, care, support and treatment services

b. Explain the benefits of HIV testing and risk assessment

c. Assure the individual that the test result and any information shared will be kept confidential

d. Explain that the individual has the right to opt out of HIV testing and this will not affect their access to any other health-related services

e. Implication of a positive test result, including availability of free treatment at government hospitals and identified private hospitals

f. Implications of a negative test result including preventive services

g. Disclosure if positive

h. Provide information on importance of Index Testing Services (spouse/sexual/injecting partner/ biological children testing) with consent and confidentiality.

i. Provide information on genital, menstrual and sexual hygiene

j. Demonstrate the use of a condom using any IEC material e.g. penis model, etc.

k. Extend the opportunity to the individual to ask and clarify doubts related to HIV and AIDS, if any.

l. Provide customized services for clients accessing HCTS services through virtual interventions.

m. In addition, explain to all pregnant and breastfeeding women regarding EVTHS

n. Additional counselling of patient who has declined the test:

- That they can return at any time for further information and or testing
- Other health facilities that can offer HIV counselling and testing services
- Information that can be used in prevention and risk reduction for that individual
- That declining the test does not affect any other health service provision

Additionally, the following points should be covered in pre-test for Viral Hepatitis:

- All clients should be assessed by the counsellor for the presence of the risk factors of both Hepatitis B and C.
- Risk factors:
  - Child of HBV positive mother; history of injecting drug use; needle stick injury; recipient of transfusion of blood/blood product; history of repeated tattooing; occupational exposure to blood/bodily fluids; client received dental treatment; history of surgery; high-risk sexual behaviours; history of receiving unsafe injection
- All clients (direct walk-in and referred) must be informed that testing for HBV and HCV at the ICTCs or any other facility in health system is conducted through a simple, easy-to-do rapid diagnostic test that provides the result within 30 minutes.

- HCV is a curable disease and HBV is a vaccine preventable disease and can be managed with lifelong treatment.
- Inform that HBV and HCV diagnosis and treatment services are available at the government health facilities free of cost under the National Viral Hepatitis Control Program (NVHCP).
- Informed consent must be obtained for testing.

5.5 Post Test Counselling:

The Guidelines issued in July 2022 on the HIV and AIDS (Prevention and Control) Act 2017, provides guidance on Post Test Counselling for HIV and is detailed below.

Manner of conducting Post-test counselling:

1. Post-test counselling should prepare the individual to understand and cope with the HIV test result.
2. Individual post- test counselling should be conducted irrespective of whether the result is HIV reactive, HIV-negative, HIV Indeterminate or HIV-positive.

Post-test counselling should include:

i. informing the patient about the results and meaning of the test results

ii. providing education about avoiding risks of sexual and injection drug exposures and, for patients who test reactive/positive

iii. assessing the impact of test results for the patient and family

iv. explaining treatment options

v. discussing partner counselling and disclosure of test results to others

vi. an explanation of test results and initiating a support and treatment plan

vii. risk reduction counselling, information about window period and retesting

viii. risk assessment and importance and benefits of index testing

All efforts must be made to provide test results on the same day and post-test counselling to all those accessing HIV services at the HCTS facilities. Post-test counselling helps the individual to understand and cope with the HIV test result.

Individual post-test counselling must be conducted for all HIV reactive/ indeterminate/ positive at ICTC and whenever risk has been elicited irrespective of whether the result is HIV non-reactive/reactive at screening facility. The HIV-negative clients who are not at-risk, can be provided group counselling for messages on HIV prevention for maintaining their HIV-negative status.

- At screening facilities, any trained paramedical staff designated for HIV screening in the health facility should provide the post-test counselling
- At ICTC, the counsellor should provide post-test counselling.

Content of the post-test counselling for HIV is detailed in table-5.5.1.

Table-5.5.1: Content of the post-test counselling for HIV

HIV result	Content of post-test counselling
All result (Screening as well as confirmatory sites) including negative/non-reactive	• An explanation of the test result. • Assessing the impact of test results for the patient and family • Explaining treatment options • Risk reduction counselling, condom demonstration and information on availability of condoms. • Information regarding the window period, re-testing for clients found negative and follow up testing for clients with indeterminate results, should be emphasized wherever applicable. • Contact elicitation by informing the importance of knowing the HIV status of contacts and biological children less than 19 years of age. • Focus on HIV screening/ testing of contacts and biological children less than 19 years of age, for clients identified as HIV-positive or at-risk HIV-negative. • Information on genital, menstrual and sexual hygiene. • Screening for any signs and symptoms of TB (cough ≥ 2 weeks, fever, haemoptysis, chest pain, breathlessness etc). Refer to subchapter 12.4 for definition of Presumptive TB case. • Linkages to TB/STI/ANC/Viral Hepatitis services, TI programmes, other relevant health programs, etc. • An opportunity for additional counselling of the individual, clarification on myths and misconceptions regarding HIV and AIDS. • Woman in reproductive age group should be counselled on the importance of family planning
Negative (ICTC and at-risk clients)	• Importance of safe practices and preventive measures • Importance of follow up services and re-testing at prescribed intervals • Information regarding window period, re-testing to all those found negative and follow up testing to indeterminate results as applicable, should be emphasized • The details of their social/sexual/injecting partners to be elicited to generate awareness around HIV and STIs and encourage their partners to access NACP services.
Reactive (screening site)	• Emphasize that this is only a screening test for HIV. With this result, it is not possible to confirm the HIV status. • Explain the need for confirmation of HIV diagnosis at an ICTC and the process followed • Explain the process followed at the ICTC for test confirmation • Fill the referral form as "refer to ICTC" and provide directions for reaching the nearest ICTC. • Information on safe sex and needle sharing practices. • Ensure that: the client found reactive for HIV on screening is promptly linked to ICTC for confirmation of HIV diagnosis

HIV-Positive (ICTC)	• Explain the test results and diagnosis • Avoid information overload • Listen and respond to needs (the patient may be overwhelmed and hear little after being told the positive result) • Discuss the immediate implications and treatment options, if patient is ready for the information • Provide clear information on free and nearest ART services (where it is offered, when ART will start, for how long it has to be taken, how many times it has to be taken, who will provide ART, what tests are required for starting ART, etc.), reducing the risk of HIV transmission and the positive impact of ART on health. • Taking into consideration the patient's priorities and convenience, a desirable ART centre should be recommended to the PLHIV. • Review immediate plans and support required. • Assess and address concerns, denial, fear, risk of suicide, depression and other mental health issues. • Assess for support system in the family. • Discuss possible disclosure of the result and encourage index testing • Emphasis on the importance of knowing the status of partners and biological children and offer Index Testing for sexual or needle and syringe sharing partners/biological children • Assess the risk of violence by partner/spouse and discuss existing support system to help such individuals, particularly women, who are diagnosed HIV-positive • Linkages to STI/TB/Viral hepatitis /NCD services including Mental Health • Link to District Level Network (DLN)/Peer support groups

5.6 Follow up Counselling:

Priority follow-up counselling is required for clients who have not accepted their HIV-positive report, have not been linked to prevention services (at-risk negative) or care, support and treatment services (HIV-positive) and those in need of legal and socio-economic welfare services.

Follow up counselling is recommended for the below mentioned clients:

- **For HIV-positive clients:** as per National Guidelines on HIV Care and Treatment, 2021.
- **For at-risk negative clients:** All clients to be followed as per the guidelines provided for SSS under Chapter 11.2.

Schedule for follow-up repeat HIV testing is provided in table-5.6.1

Table 5.6.1: Schedule for Follow up repeat HIV testing

Follow up testing timeline from the baseline HIV testing	Individuals who require follow-up counselling and HIV testing
After 2 weeks	• Donors found HIV reactive in the Blood Bank and found non-reactive at ICTC • Clients found HIV reactive by screening test and found non-reactive at ICTC • Any person with indeterminate HIV test result at ICTC
6 weeks	• Individuals exposed to HIV infection irrespective of PEP Status
After 3 months	• Individuals exposed to HIV infection irrespective of PEP Status • Individuals who are victims of sexual assault • Individuals with high-risk behaviour (to exclude the possibility of window period) • HIV-negative partner of a known HIV-positive individual
Every 6 months	• HIV-negative partner of a known HIV-positive individual • Priority population groups: o HIV-exposed child, as per the EID algorithm o Individuals with continued high-risk behaviour o FSW o MSM o H/TG o PWID o Discordant couple with continued exposure o Inmates in P&OCS (annual testing or as per latest NACP guidelines) • Individuals exposed to HIV infection irrespective of PEP Status
Note: "PLHIV already on treatment at ART Centre should not be re-tested."	

5.7 Sharing of HIV test results

The Guidelines issued in July 2022 on the HIV and AIDS (Prevention and Control) Act 2017, provides guidance on the manner of "sharing of HIV test results", as detailed below.

It is important to maintain utmost confidentiality of personal information shared by individual including his or her HIV result. However, in the following circumstances, the HIV result of an individual may be shared, namely:

(a) in order to protect the health of a partner, the counselor may share a person's HIV result with the person's partner or partners with or without the expressed consent of the index partner;

(b) in the medical interest of the individual, their result may be shared with other health care provider(s) involved in the treatment and care of the individual; and

(c) the person with HIV has the right to privacy and the right to exercise informed consent, however, in certain circumstances when disclosure of an individual's HIV status to another person is required, by law or ethical considerations, the HIV results may be shared.

CHAPTER-6

Counselling in special contexts

Counselling in special contexts

Post-test counselling and follow-up counselling sessions should be customized to the patient being tested and should always be responsive and tailored to the unique situation of each individual or couple. Certain clients require additional counselling messages based on their specialized context. These are described below:

6.1 Client with Indeterminate Test Result

All individuals with an indeterminate test result should be encouraged to undergo follow-up testing in two weeks to confirm their HIV status. Information regarding window period, re-testing in clients with indeterminate results need to be explained in detail and emphasized. The counsellor should assess for potential barriers present for the client returning for repeat testing and address them immediately. The client should be supported for dealing with any immediate concerns he/she may have regarding the importance of re-testing and the confirmation of the HIV infection. All clients with indeterminate results should be thoroughly assessed for depression and other mental health consequences following the diagnosis of HIV infection. Health care provider should use the two screening questions and thereafter, the Patient Health Questionnaire 9 (PHQ-9) for the assessment. (Refer to chapter-5.5 and section 5.5.5, of the National Guidelines for HIV Care and Treatment, 2021)

Maintaining a list of clients with Indeterminate Test Result, tracking their follow-up result and tracking their follow-up re-testing is essential.

6.2 At-risk Adolescents and Women in reproductive age group

Adolescents should undergo risk assessment and be assessed for history of engaging in high-risk behaviour for HIV and STI. Those classified as at-risk Adolescents would need additional counselling support. The at-risk adolescents should be educated through age-appropriate IEC materials and counselled regarding various aspects of adolescent health, including HIV and STI.

At-risk women in the reproductive age group require counselling for family planning, safe sex practices and regular screening of HIV and STI.

Counselling for both these populations should include customised messages as per their needs and situations.

Counselling should focus on safer sex practices, positive and healthy living and prevention of HIV and Syphilis transmission. Ensuring access to prevention services such as HCTS, contraceptives and family planning services is crucial. They should be provided with referrals to SSK, health facilities, de-addiction centres and clinics for non-communicable diseases as and when required.

Regular clinic visits, phone calls or home visits may help maintain their engagement with the healthcare system and adherence to preventive measures. HPV vaccination should be advised if applicable and available.

6.3 Blood donor with HIV reactive result

A blood donor with HIV reactive result will need to be explained that this is only a screening test for HIV. They should be explained the need for confirmation of HIV diagnosis at an ICTC and the subsequent linkage process. Counselling regarding safer sex and to avoid blood donations in the future should emphasized. Any individual with a screened HIV reactive result should be referred to ICTC for confirmation of HIV diagnosis. For further reading, refer to Guidelines for Blood donor selection and Blood donor referral, 2017, available at: *https://naco.gov.in/sites/default/files/Letter%20reg.%20%20guidelines%20for%20blood%20donor%20selection%20%26%20referral%20-2017.pdf*

6.4 Index Testing for PLHIV

The spouse or partner of a person living with HIV may be counselled before HIV testing using posters, flip charts, brochures and other job aids and IEC materials so as to prepare them for the HIV test as well as to address myths and misconceptions regarding HIV and AIDS. The need for follow-up visits and counselling for prevention and screening of HIV and STI should be emphasized. Counselling should focus on safer sex practices, positive and healthy living, and prevention of HIV and Syphilis transmission. For further details refer to guidelines- chapter-7.1.

6.5 High-risk groups including inmates in Prisons & Other Closed Settings

High-risk groups include female sex workers (FSW), men who have sex with men (MSM), hijra/ transgender persons (H/TG), people who inject drugs (PWID) and inmates in prisons and other closed settings.

High-risk clients should be assessed for type of risk behaviour, as more than one type of risk behaviour may be present. Thereafter, appropriate counselling should be given as per the risks identified. The need for follow-up visits and counselling for prevention and screening of HIV and STI should be emphasized. Counselling should focus on safer sex practices, positive and healthy living, risk reduction and prevention of HIV and Syphilis transmission.

TB services such as systematic screening, testing and linkage to NTEP services are also provided to HRGs and inmates in prisons and other closed settings.

Ensuring access to prevention services such as HCTS, barrier contraceptive services is crucial. They should be provided with referrals to TI projects, health facilities, de-addiction centres and clinics for non-communicable diseases, when required.

Regular clinic visits, phone calls, or home visits may help maintain their engagement with the healthcare system and adherence to preventive measures.

Information on social protection schemes and services from support structures as applicable, should be shared with high-risk clients. Linkage to Targeted Interventions projects or link workers scheme (LWS) is essential if they are not already linked. Those HRGs who are not registered at TI projects, should be referred to SSK or One Stop Centre (OSC).

6.6 HIV-positive pregnant women and her HIV-exposed child

After screening and diagnosing pregnant women living with HIV (WLHIV), it is crucial to ensure they receive optimal HIV care, support and treatment. Pregnant WLHIV should be counselled on importance of institutional delivery for complete antenatal care.Pregnant WLHIV should be assessed for her tentative place of delivery for further delivery planning. The details of post-natal location/address should be explored by the counsellor. Pregnant WLHIV should be linked to ART centres and provided with information regarding importance of HIV testing of spouse/partners/biological children. They should be counselled on the comprehensive clinical and laboratory evaluation that they will undergo to assess their baseline status at ART centre. Additionally, they should be informed that 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.

Counselling should be provided to ensure that the positive pregnant woman understands the benefits of treatment, the importance of adherence and the potential side effects. The counsellor should also provide repeated counselling throughout the pregnancy and breastfeeding on drug adherence to reduce the risk of HIV transmission to the baby. Counselling should also be provided on the care of her breasts and nipples. All pregnant WLHIV should be counselled regarding viral load testing at 32 to 36 weeks of pregnancy, regardless of the duration of ART, to know the risk of HIV transmission to her baby.

Caregivers/ parents of HIV-exposed infants should be counselled on the following parameters:

I. Immediate care at birth
II. ARV prophylaxis
III. Infant Feeding
IV. Early infant diagnosis
V. Cotrimoxazole preventive therapy (CPT)
VI. Immunization and vitamin-A supplementation
VII. Monitoring growth and development
VIII. Regular follow-up for clinical evaluation till 18 months or 3 months after complete cessation of breastfeeding

For further reading, please refer to the National Guidelines for Elimination of Vertical Transmission of HIV and Syphilis, 2024

6.7 Victims of sexual violence and POCSO

All victims of sexual violence should be counselled on the need for baseline testing for HIV, STI and pregnancy. Further, the victims should be counselled regarding the importance of taking post-exposure prophylaxis (PEP) for HIV and STI and the need for treatment adherence. Counselling for emergency contraception should be advised in women and adolescent victims. Counselling for follow-up testing for HIV, Hepatitis B and C, as per protocol should be reinforced.

All paediatric sexual violence cases are required to be notified to the concerned authority/ nodal officer in that state/city (as per the POCSO Act, 2012).

Sensitive handling and empathetic counselling skills are essential to support victim to cope with the physical and psychological trauma, and referral to a psychologist for counselling and follow up may be helpful.

Referral to appropriate agencies for further assistance (e.g., Legal support services, shelter services, etc) is essential and is part of package of care given to victims of sexual violence.

For further reading refer to Guidelines and Protocols for Medico-legal care for survivors/victims of sexual violence, 2014, MOH, FW, Govt of India. Available at: https://main.mohfw.gov.in/sites/default/files/953522324.pdf

6.8 PLHIV with Tuberculosis (TB) co-infection

All PLHIV with TB should be fast tracked within the confirmatory and ART centre. The Integrated 10-point counselling tool for TB and Drug-Resistant TB should be utilized while counselling a PLHIV with TB co-infection. (Refer to Annexure-5)

The following counselling messages should be included for PLHIV:

Tuberculosis (TB) is the most common Opportunistic Infection (OI) in people living with HIV (PLHIV) and is the leading cause of death in PLHIV.

- TB is an infectious disease caused predominantly by Mycobacterium Tuberculosis. The infection occurs most commonly through droplet nuclei generated by coughing, sneezing, etc., inhaled via the respiratory route. TB usually affects the lungs, but may affect other parts of the body as well.
- An HIV negative person infected with TB has a 10% life-time risk of developing TB disease.
- HIV increases the risk of progression from TB infection to TB disease and PLHIV have a 60% lifetime risk of developing TB disease.
- All PLHIV should regularly be screened for TB using the 4S screening tool for TB(four clinical symptom-based screening tool), at every visit to a health facility or at every contact with a health-care worker.
- Cure from TB can only be ensured by taking complete and regular treatment. Without correct and complete treatment, a patient can become very ill or develop Drug Resistant TB.
- A newly diagnosed PLHIV with TB, should be linked to ART services at the earliest. Cotrimoxazole preventive therapy should be provided to all HIV-TB co-infected patients to prevent opportunistic infections.
- Anti TB drugs are provided as Fixed Dose Combinations (FDCs) as per weight band, at the ART centre.
- An HIV-TB co-infected patient should be referred to nearest NTEP certified Culture and Drug Sensitivity Laboratory facility/CBNAAT facility for diagnosis of Drug-Resistant TB (DRTB).
- DRTB cases will be managed as per latest guidelines on "Programmatic management of Drug-Resistant TB in India under NTEP; available at https://tbcindia.mohfw.gov.in/wp-content/uploads/2023/05/8368587497Guidelines-for-PMDT-in-India.pdf.

- The client's information should be kept confidential and should not be furnished under any circumstances to any person except as per 'Shared confidentiality' with the treating physician and public health provider for better case management and to get benefit of available options for prophylactic treatment.
- All TB/Drug resistant TB patients should maintain cough hygiene (putting a cloth on nose and mouth while coughing or sneezing) to prevent transmission of TB/DRTB.

6.9 Hepatitis B or C screened positive client or PLHIV co-infected with Hepatitis B or C

The client should be explained the meaning of the antibody positive HCV test or antigen positive HBV (HbsAg) test and be counselled on the need for quantitative HBV DNA and HCV RNA testing as well as the need for further investigations for staging and management of the disease. Client should be provided with the basic information regarding Hepatitis B and C disease, prevention and treatment. All clients screened positive for Hepatitis B and C are required to be linked to treatment sites (treatment centres/model treatment centres) under the National Viral Hepatitis Control Program (NVHCP).

The Hepatitis B screened positive client should be explained that Hepatitis B is manageable with lifelong treatment and all clients who test positive may not require treatment. Further, the client should be counselled regarding the screening of first degree relatives: mother, siblings, spouse and children. Hepatitis B vaccination for children, if not already completed, should be advised.

The Hepatitis C screened positive client should be counselled that they may be chronically infected or have cleared the virus in the past. In addition, there is a need to explain that Hepatitis C is curable with treatment of 12 weeks (84 days), and treatment may be extended in complicated cases. The client should be counselled and encouraged for Hepatitis C testing among family members in case of history of unsafe injection practices from unregistered medical practitioners. They also need to be explained the importance of minimizing risk behaviours to avoid transmitting the infection to others, and encourage notification and screening of all needle sharing contacts.

PLHIV co-infected with Hepatitis B or C, need to be linked to treatment centres for further disease management and should be counselled on healthy life practices, including abstinence from or reducing alcohol intake. The client should be explained that co-infection of HIV with Hepatitis B or C may cause deterioration of their health despite taking adherent ART. They should also be informed the possibility of rapid deterioration in the liver function. The client should be linked with ART centre, if not initiated on ART and further explained that the ARV regimen may require modification due to co-infection. Information regarding infection control practices to prevent the spread of infection to other household members should be shared with the client.

6.10 Clients with STI

Clients with STI/RTI should be given information regarding STI, in detail with the symptoms, mode of spread, consequences of STIs and the link between STI and HIV infection. Further counselling is required on STI treatment, importance of follow-up visits and partner referral and treatment.

Prevention counselling for STI should include education and counselling messages on HIV and STI risk reduction, correct and consistent condom usage, limiting the number of partners and alternatives to penetrative sex.

Pregnant women diagnosed with STI should be informed regarding the negative consequences of STI on pregnancy and the increased risk of vertical transmission to the baby. In addition, they should be counselled on the adverse impacts on the foetus as well as the infected baby. Pregnant women should be informed about the importance of appropriate and adequate STI treatment and regular follow-up along with partner management. *For further detail, refer to National Technical Guidelines on Sexually-transmitted infections and Reproductive tract infections, 2024.*

Clients interacting on National AIDS helpline 1097 and other virtual platforms

Online platforms are changing how people communicate, seek information and identify sex partners. Young individuals, between the ages of 16-29 years, spend the most amount of time on the web in India, compared to other age groups. Many persons interact with the numerous counsellors on the National AIDS helpline 1097 on a daily basis. This then presents an opportunity for the counsellors to counsel these persons on HIV prevention and care services, which are available free of cost in the country.

With the advent of mobile and newer communication technologies, the patterns of sex work, partner seeking and socialization has changed. Mobile phones act as tools for networking and soliciting. Under the program, numerous virtual interventions have been implemented to reach out to this population and the at-risk persons who use virtual tools for fulling their sexual needs. High risk groups for HIV are increasingly using virtual channels to find sexual partners as well as to build and maintain communities. Linking virtual population to comprehensive HIV services tailored to the needs of communities is essential.

Hence, counselling messages should be customized as per the need of the interacting Individual on the National AIDS helpline and other virtual platforms. Counselling messages provided through the helpline/ virtual platform should be aligned with the current guidelines and designed to generate awareness on HIV prevention, care and treatment service options.

For further reading, refer to Standard Operating Procedures for Reaching out to the Unreached HRGs operating at Spa/Massage Parlours, through Network Operators and at Web-Based Platforms; available at: https://naco.gov.in/sites/default/files/National%20Consultation%20on%20SoP%20for%20SPA%EF%80%A2Massage%20Parlours%2C%20Network%20Operators%20and%20Web-based%20platforms%20under%20NACP_8-9%20June%202023.pdf

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SECTION III:
Strategies to enhance early detection

Section III of the National HCTS guidelines has two chapters

Chapter 7: The chapter describes in detail the HCTS through Priority Focused Strategies, and provides guidance on modalities of Index Testing, Social-Networking Strategies, Provider Initiated Testing and Counselling and Self testing.

Chapter 8: The chapter details provision of HCTS through Mobile Outreach, covers modalities of Mobile Outreach Services, Community Engagement and Collaboration, and HIV testing for the inmates of the Prison and Other Closed Settings.

CHAPTER-7

HCTS through Priority Focused Strategies

HCTS through Priority Focused Strategies

7.1 Index Testing Services

Over the various phases of NACP, HIV counselling and Testing Services have been scaled up to reach vulnerable populations towards provision of timely HIV prevention and treatment services as per the client's need. One of the most vulnerable populations at risk of acquiring HIV infection are the sexual and needle sharing contacts and biological children of PLHIV. At the ICTC, the counsellor encourages the newly diagnosed PLHIV to share details of their sexual and needle sharing contacts as well as their biological children below 19 years of age, to motivate them for availing HIV counselling and testing services.

What are index testing services?

Index testing service (ITS), or partner notification service, is a voluntary case-finding approach wherein trained service providers with the consent of the HIV-positive client, focus on elicitation of sexual and needle sharing contacts and biological children less than 19 years of age of the client, and offer them HIV counselling and testing services.

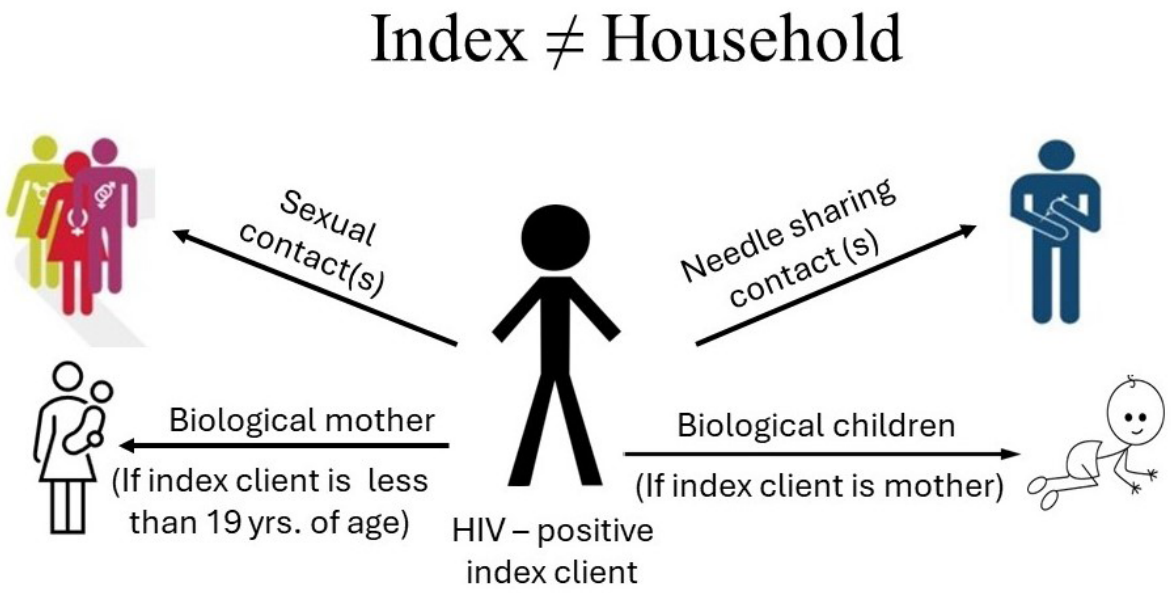
Index Client: All newly diagnosed PLHIV, as well as known PLHIV are the index clients under the Index Testing Services.

The priority groups for offering ITS are as below:

- Newly identified PLHIV
- All PLHIV yet to be offered ITS
- PLHIV with treatment interruption (MIS/LFU)
- PLHIV with unsuppressed viral load
- PLHIV with changed relationship status
- PLHIV who were offered ITS more than 6 months ago, with continued risk behaviour for HIV transmission
- PLHIV from key population group
- PLHIV with STI/RTI

The figure-7.1.1 illustrates the Index clients and contacts.

Figure 7.1.1: Index Client and Contacts



Contact: Sexual contacts should include ALL persons who have had sex with the Index client (even if it was just a single encounter and even if they have always used condoms). Needle sharing contacts including ALL persons who have shared needles, syringes or injection equipment with the Index client (even if it was just one time and even if they cleaned the needle, syringes or injection equipment before sharing). Contact elicitation should start with the most recent exposure and go backwards in time as far as possible, as per the recall capacity of the index client.

For Index clients who are children (<19 years), the contacts will include:

- Biological mother
- Biological father, if the child's mother is HIV-positive, deceased, or her status is unknown.
- Biological sibling/s
- Sexual and needle sharing contacts, if elicited during the history taking

Benefits of Index testing

Index Testing Service (ITS) is an effective case finding approach, as it focuses on assisting persons with known HIV exposures, to know their contact's status, in order to break the chain of HIV transmission, by offering HIV screening/testing to the contacts and biological children. Benefits of Index Testing are enlisted below in Table-7.1.1.

Table 7.1.1: Benefits of Index Testing

Index Client	Contacts and Biological Children less than 19 years of age	Programmatic
• Provides support to PLHIV. • Assists PLHIV in getting their contacts and biological children tested for HIV. • Takes the responsibility of notification and disclosure of HIV status to the contacts. • Help prioritize effective HIV prevention for discordant couple • Can lead to mutual support for adherence, if both partners are tested positive	• Maximizes the proportion of contacts and children who are aware of their HIV status. • Provides opportunity for early detection of HIV for the contacts and children. • Timely linkage of HIV-positive children and contacts to treatment. • Access to prevention services for the HIV negative contacts.	• Effective high yielding case finding strategy to increase uptake of HIV testing services. • Reduces further HIV transmission by aiding in early diagnosis and treatment for partners and children • Facilitates achievement of the HIV prevention targets and the 95-95-95 goals

Approaches to Index Testing Services (ITS)

Index testing can be delivered through many approaches, including client referral and provider assisted referral. Client-centred counselling should be used to assist the index client to determine the best approach for each of the contacts. Clients may choose different approaches for different contacts. Ensuring client consent, confidentiality and safety are critical for Index Testing.

Terminology and definitions:

Client referral: In client referral (also called passive referral) a trained provider encourages HIV-positive clients to voluntarily disclose their status to their sexual and needle sharing contacts and encourage them to get tested. HIV-positive clients may also inform their contacts through anonymous means, such as coupons/ chits, web-based messaging services (emails, web-based applications, etc.), if they do not want to disclose their identity. The service provider may support the Index client in developing a disclosure plan.

Provider assisted referral: In provider assisted referral (also called active referral or assisted partner notification), a trained health care provider counsels the HIV-positive client to disclose the details of their sexual and/or needle sharing contacts and biological children less than 19 years of age. Thereafter, with the consent of the Index client, the health care provider will inform the contacts about their potential exposure to HIV. The health care provider will then offer voluntary HIV testing services to these contacts.

Provider assisted referral has three sub-approaches which are discussed below:

- **Provider Referral:** Health care provider approaches the contacts of the Index client and offers them voluntary HIV counselling and testing services, while ensuring confidentiality. This is done anonymously, unless consent is obtained to disclose the index client's details.

- **Contract Referral:** Index client enters into an informal contract with the health care provider to notify the contacts within a specific time period (which can be decided mutually on case-to-case basis but not extending beyond three weeks). If the index client is unable to notify or motivate their contacts for testing within the mutually agreed time-line, the health care provider can approach the contacts after re-affirming from the index client and offer voluntary HIV counselling and testing.
- **Dual Referral:** A trained health care provider sits with the PLHIV while they disclose their status to the contact. Subsequently, HCTS services are offered to the exposed contact.

Guiding principles for index testing services

HIV testing must benefit the individuals tested and improve health outcomes at the population level. All forms of HCTS, including Index Testing services should adhere to the WHO's 5 Cs: Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, care and treatment services). These are discussed in detail in Chapter-5.

Implementing quality and ethical index testing services

The Index Testing Service delivery points and focal person in charge are summarized in the following table (Refer to Table-7.1.2 and Figure-7.1.2 below)

Table 7.1.2: Summary of Index Testing Services

Facility offering ITS	The clients who are offered ITS	The service provider who will offer ITS
ICTC (confirmatory sites)	All newly diagnosed HIV-positive individuals including children <19 years	NACP Counsellor
ART/ Link ART Centre	All ART clients (including children <19 years) who have not been offered index testing services at the ICTC. All ART clients with an ongoing risk behaviour All ART clients (including children <19 years) with an unsuppressed viral load. All ART clients reporting a change in relationship. All ART clients returning to care after treatment interruption (MIS/LFU) All ART clients with an incomplete 'family tree' status documentation At least bi-annually as part of HIV treatment services for discordant couple	NACP Counsellor, Staff Nurse, Care coordinator
Care and Support Centre (CSC)	The line list of PLHIV shared with CSC on regular basis can be actively followed up for the Index Testing Services. At least bi-annually as part of HIV treatment services for discordant couple	Peer Counsellor or Outreach Worker

Facility offering ITS	The clients who are offered ITS	The service provider who will offer ITS
Sampoorana Suraksha Kendra (SSK)	All at-risk negative clients who turned out positive on subsequent visit	NACP Counsellor or Outreach Worker as applicable
One Stop Centre (OSC)	All active HRG PLHIV registered in the OSC who have never undergone index testing The repeat index testing services be offered to the contacts of the Index client whenever there is history of client reporting a change in relationship/ sharing of needle or syringes	Master Counsellor or Peer Counsellor or Outreach Worker as applicable
Targeted Intervention (TI)	All active HRG PLHIV registered in the TI facility, who have never undergone index testing. Repeat index testing services to be offered to the contacts of Index client whenever there is history of client reporting a change in relationship/ sharing of needle or syringes	Counsellor, Outreach Worker, Peer Educator/ Peer Navigator
OST/satellite OST Centre	All HIV-positive PWIDs, not offered index testing services at any of the other facilities. Repeat index testing services be offered to the contacts of the Index client whenever there is history of client reporting a change in relationship/ sharing of needle or syringes	Counsellor, Nurse, Outreach Worker, Peer Educator/ Peer Navigator as applicable
Sub-centres during ANC /PNC screening clinics	All HIV-positive Pregnant Women should be offered Index testing services at ANC clinic	ANM or Counsellor
Mobile Outreach	All PLHIV from hard-to-reach areas or who could not reach any of the above facilities (not offered or not opted for index testing services at any facility).	NACP Counsellor, Outreach Worker or Peer Educator/ Peer Navigator

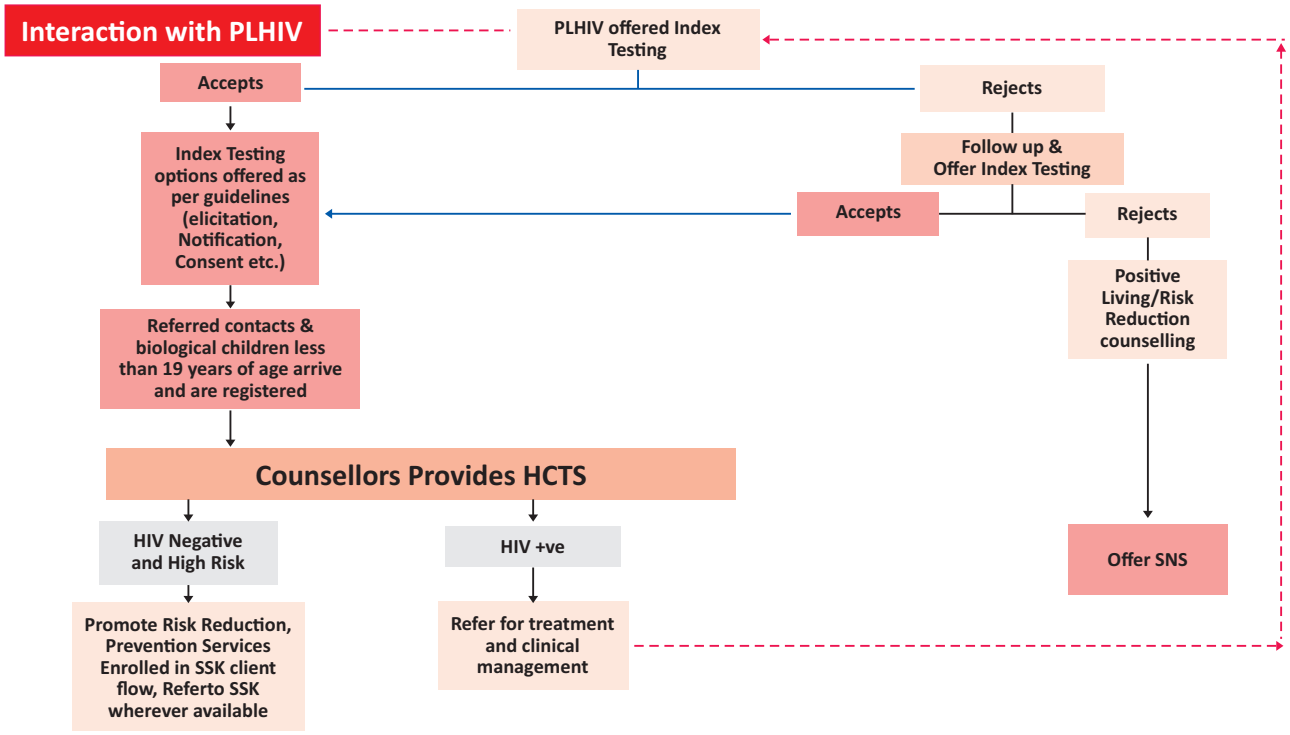
Kindly note:

(a) Children less than 19 years of age without an ongoing or new HIV exposure do not need re-testing, if status is known.

(b) To avoid duplication, all the HRG PLHIV registered with TI/OST/SSK/OSC program may be referred to the concerned facility for index testing services.

The Flow for Index Testing Services is depicted in Figure-7.1.2

Figure 7.1.2: Flow for Index Testing Services



How to improve access to Index Testing Services?

- Contacts and biological children of index clients should be offered the option of coming to the health facility for the HIV test or of a counsellor/health worker testing the contacts and children in the community (through mobile ICTC services or outreach services).
- Confidentiality of the procedures should be put in place before starting index testing to ensure the safety of the index client and index testing providers.

There are **10 steps** for providing Index Testing Services are described in detail below:

STEP 1: Introduce index testing services to the Index Client during first visit as PLHIV at the facility.

During first visit, the health care providers should:

- Explain the importance of ensuring all contacts and biological children to undergo HIV testing.
- Inform the client that index testing services are offered to assist the client to reach out to their contacts so that they can be aware of their contact's HIV status. This service is offered as disclosure of HIV status can be difficult and process becomes easier with the support of the health care provider.
- Inform the client that participation in index testing and partner elicitation is voluntary
- Inform the client that as part of index testing, they can share details of all persons they have had sex with (even if it was just a single encounter and even if they always used condoms with this partner) or that if they have shared needles, syringes or injection equipment with anyone (even if it was just one time and even if they cleaned the needle, syringes or injection equipment before sharing or using).

- Inform the client that they will be required to list out the names of all biological children <19 years of age with unknown HIV status.
- If the client is <19 years old, they will be asked to list the names of their biological mother/father and all the biological siblings.

STEP 2: Offer index testing as a voluntary service to all clients who test HIV-positive:

- Index testing should be provided purely as a voluntary service without coercion, where clients have the right to decline these services at any step or stage of index testing. The consent given by the client during pre-test counselling process for undertaking HIV screening/testing implicitly indicates for being ready to undergo HIV testing/screening process and ready to receive result following post-test counselling. The index testing service is an integral part of the post-test counselling, and hence will not require any explicit written consent.

STEP 3: Obtain consent from the client to proceed with index testing services:

- Obtain consent of the index client prior to eliciting names of their contacts.
- Inform the client that while index testing services is offered to all index clients, they have the right to decline these services at any time without any impact on their ability to receive other health services, including ART.

STEP 4: Obtain a list of sexual and needle sharing contacts and biological children <19 years with unknown HIV status:

- The client should be requested to share the contact details with empathy and sensitivity.
- Contact elicitation to start with the most recent exposure and go backwards in time as far as possible, as per the recall capacity of the index client.
- Client to be motivated and encouraged to share complete contact information including details of contacts with one time sexual encounter.
- Client to share the information regarding all contacts that they have shared needles, syringes and injecting equipment with.
- Record all details e.g. name, address, phone number, etc of all the contacts in SOCH.

STEP 5: Conduct an Intimate Partner Violence (IPV) risk assessment for each named contact.

- A client's safety is the most important factor in determining if they should participate in index testing services. Index clients should be asked about their experience or fear of violence or tangible/ intangible risk for each named partner. Recommended screening questions for IPV are compiled in table-7.1.3 below.

Table 7.1.3: Recommended Screening Questions for IPV

Recommended Screening Questions for IPV
• Has [partner's name] ever hit, kicked, slapped, or otherwise physically hurt you?
• Has [partner's name] ever threatened to hurt you in physical or non-physical way?
• Has [partner's name] ever forced you to do something sexually that made you feel uncomfortable?

- If the client answers "yes" to any of the screening questions, the health care provider must offer relevant referrals to support services, and then should work with the client to see which partner notification strategy may be most appropriate. All decisions about partner notification should ultimately be up to the client. However, health care providers should recommend to the client that they can consider not proceeding with partner notification if there is a risk of violence.
- As first line of response, the client could be informed about how they could protect themselves from potential violence. The repeat Index Testing Services may be offered to the Index Case after certain time period, which is mutually agreed upon and noted for follow up.

STEP 6: Determine the preferred method of partner notification or child testing for each named contact/child

- Review the four options for partner notification (Client referral, Provider referral, Dual referral and Contract referral, as explained above) with the client.
- The index client should be informed about all the available options and made aware that they may choose different notification models for different contacts. For example, HIV-positive individuals may want to use client referral (a passive approach) to contact some partners, whom they feel comfortable notifying on their own, while they may want the provider to assist them in contacting others.
- Depending on the context, some partner notification approaches may be more feasible or appealing to certain populations. For instance, young people may prefer using new technologies, text messaging and other internet-based communication systems, whereas older populations may prefer in-person meetings, telephone calls or e-mail. Depending on the setting, HRG who experiences stigma, discrimination and criminalization for their behaviour may prefer anonymous methods such as provider referral.
- Document the chosen notification method for each listed contact.

STEP 7: Approach all named contacts and biological children less than 19 years of age with unknown status using the agreed approach

- Based on the options for partner notification, all named contacts should be reached out to, using the agreed approach.

STEP 8: Record outcomes of partner notification and biological children:

- Record the type of Index Testing Service, date and method of contact attempts, and whether the contacts /biological child was successfully contacted or not.
- If partner/biological child was contacted, the outcome of the partner/child testing (e.g. whether or not the partner/child was tested for HIV or was a known case of HIV and his ART initiation Status) should be recorded.

STEP 9: Provide appropriate services for partner(s) and children based on HIV status:

- Facilitate linkage to prevention, treatment and care services based on the HIV diagnosis status.
- Newly diagnosed partners should, in turn, be offered Index Testing Services for all of their sexual and drug-injecting contacts and biological children <19 years of age.
- Newly diagnosed children should, in turn, be offered index testing for their mother/father and/or siblings with unknown status.

STEP 10: Follow-up with Index client for adverse event

- Follow up with Index client after two weeks to understand if there were any psychosocial issues including anxiety or depression and address them through referrals, if required. Reporting of the social harm and other adverse events following index testing and partner services are rare. However, concerns exist about the possible harm that could result from disclosure of HIV-positive status, particularly for women, key populations and other vulnerable groups. A site-level adverse event should be addressed through proper referral to services catering to the need of the client identified on a case-to case basis.
- Clients should be informed of their right to decline participation or report adverse event in index testing services throughout the process, and not just during the elicitation interview.

Operationalization

All NACP facilities with trained health care providers (refer to table-7.1.2) should operationalize ITS as per this guideline.

Monitoring and Evaluation

Monitoring to optimize index testing services Index testing should be reported in SOCH on daily basis.

7.2 Social Network Strategies (SNS)

Background

Social Network Strategy (SNS) is an evidence-based, effective approach to identify and motivate people at high-risk of HIV, who may not know their status and to accept HIV testing services. WHO recommends SNS as an important HIV testing approach, especially for populations at higher risk of HIV as part of the package of partner services (WHO 2019). SNS relies on the premise that people in the same social network will have similar behaviours which may put them at-risk for HIV and that people in the same social network trust each other for information. As per WHO, SNS addresses confidentiality concerns and broadens the reach of services to include both HIV-positive and HIV negative members of networks of populations at higher risk of HIV and may improve the acceptability of services.

NACO implemented the Social Network Strategy (SNS) among populations at high-risk of HIV across Assam, Manipur, Mizoram, Nagaland, Maharashtra, Telangana and Andhra Pradesh. The experiences in these states have shown that SNS is an important strategy for reaching and providing HIV testing services to populations with higher risk of HIV who live in underserved geographies.

Definition of Social Networks

A social network refers to a group of individuals linked by a common set of relationships or behaviours and includes sexual and drug-injecting partners as well as social contacts. Social networks form organically and membership of the network is voluntary and without external pressure. It can be differentiated and adapted according to the local context, setting and clients' preferences.

Type of networks include:

I. Sexual

II. Drug injecting/needle sharing networks

III. Social contacts (close friends, substance sharing buddies)

IV. HIV+ ve or At Risk HIV – ve

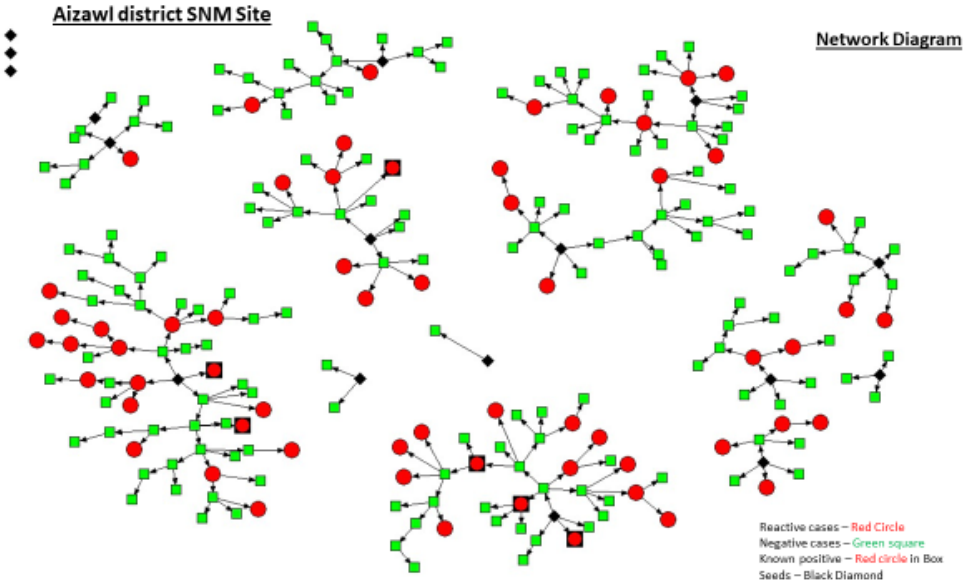
V. Populations at higher risk of HIV (Female Sex Workers, Men who have sex with Men, Hijra/ Transgender persons and people who inject drugs).

Definition of Social Network Strategy (SNS)

SNS is a chain referral engagement strategy for reaching and providing HIV counselling, testing and referral services to persons who are unaware of their HIV status by using social network connections to identify individuals at-risk for HIV and offer the testing services. The SNS is an adapted version of the snowballing and respondent driven sampling and is used primarily in public health programs.

Under SNS, a trained health care provider asks people living with HIV or those who are HIV negative and at ongoing risk of HIV (referred as 'seeds') to encourage and invite individuals in their sexual, drug injecting or social networks, referred to as "network associates' to participate in voluntary HIV counselling and testing services (HCTS). Each of the seeds are provided with coupons/reference note/referral card for distribution to their networks to encourage HCTS. After voluntary testing and confirmation of the HIV test result, each of the seeds who received testing services are now voluntarily encouraged to invite their contacts from their sexual, drug injecting or social networks for HCTS, thus expanding the network. These 'waves' of engagement and HCTS could continue until there is saturation of new individuals in a given geographic area and resources available for implementation of such strategy. Social network-based approaches are most effective when focused on networks of high-risk population. Longer duration or more waves generally allow deeper penetration into these social networks and thus, may identify more people with undiagnosed HIV. Figure-7.2.1 depicts the Network Diagram Sample of SNS Implementation

Figure 7.2.1: Network Diagram Sample of SNS Implementation



Implementation Steps

(a) Orientation of stakeholders and consultation with community members: Before initiation of SNS, it is important to orient all important stakeholders at the state and district level including SACS officials, District AIDS Control Officer, DISHA officials, TI NGOs, ICTC staff as well as

Community Champions on SNS, its importance and the implementation steps. To engage the community in the SNS process, consultations need to be organized in each district with the community members representing high-risk groups, the PLHIV networks and the Community Champions. They are oriented on SNS and asked to provide feedback and input for effective and efficient implementation of SNS activities for their local area. These consultations elucidate greater understanding of local community dynamics, the size and proportion of at-risk population who are currently not accessing any HIV service, and whether the coupon-based, chain referral strategy is acceptable to the community.

(b) Orientation of staff on SNS: The staff responsible for SNS implementation including Program Manager, Outreach Worker and Peer Educator in TI NGO settings; NACP Counsellors; Manager and Outreach Workers in Sampoorna Suraksha Kendra should be oriented on SNS including coupon/referral tracking and management, linkage referral to ICTC for confirmation of HIV diagnosis as well as referral to ART for those clients who test positive for HIV. During the training on SNS, staff members should also be oriented on their responsibilities and reporting mechanism. It is vital to reiterate to maintain client confidentiality and ensure that client participation is completely voluntary and non-coercive.

(c) Identification of networks of populations at higher risk for HIV: The success of social network testing depends on the identification of networks of populations at higher risk of HIV through systematic implementation of mapping of high-risk networks.

(d) Location/Setting where SNS can be implemented are detailed in Table-7.2.1.

Table 7.2.1 Summary of Social Network Strategy

Facility/ programme offering SNS	Clients who are to be offered SNS	The service provider who will offer ITS
Targeted Intervention projects	All active HRG, bridge population registered under TIs or LWS who know their HIV status	Counsellor, Outreach Worker, Peer Educator, Peer Navigator
Mobile Outreach including Community-based screening	People at-risk of HIV but underserved by conventional health services or who could not reach to any of HIV facilities to know their HIV status.	Outreach Worker or Peer Educator, Peer Navigator, Counsellor
OST/satellite OST Centre	All PWIDs who are aware of their HIV status	Counsellor, Nurse, Outreach Worker, Peer Educator, Peer Navigator as applicable
Sampoorna Suraksha Kendra (SSK)	All at-risk negative persons who are at-risk of HIV infection registered in the SSK	Counsellor, SSK Manager or Outreach Worker as applicable
One Stop Centre (OSC)	All active HRG registered in the OSC and know their HIV status	ANM cum Counsellor or Outreach Worker as applicable
ICTCs (confirmatory sites)	ICTC clients who are at-risk negative as well as HIV-positive including children <19 years and who have sexual, injecting or social networks	Counsellor

Facility/ programme offering SNS	Clients who are to be offered SNS	The service provider who will offer ITS
DSRC	DSRC clients who is at-risk negative	Counsellor
ART/ Link ART Centre	PLHIV on ART (including children <19 years) who have sexual, injecting or social networks, even if index testing services have been offered	Counsellor, Staff Nurse, Care Coordinator
Care and Support Centre (CSC)	The line list of PLHIV shared with CSC on regular basis can be actively followed up for SNS through the sexual, injecting or social networks, even if index testing services have been offered.	Peer Counsellor or Health Promoter

(e) Location of SNS: The venue as mentioned in the table above should have adequate space with adequate ventilation and easily accessible. Measures should be taken to ensure participant privacy within the venue by using separate rooms, wherever possible or by installing screens or partitions to counsel clients. Data confidentiality to be maintained as per the data management guidelines of NACP.

(f) Identification and mobilization of seeds: Any person at-risk of HIV or PLHIV with social networks comprising members with similar risk factors and behaviours for HIV and are willing to participate in the program, should be engaged as seeds at each SNS site. There is a need to strengthen efforts in mobilizing and motivating the seeds to participate in network testing.

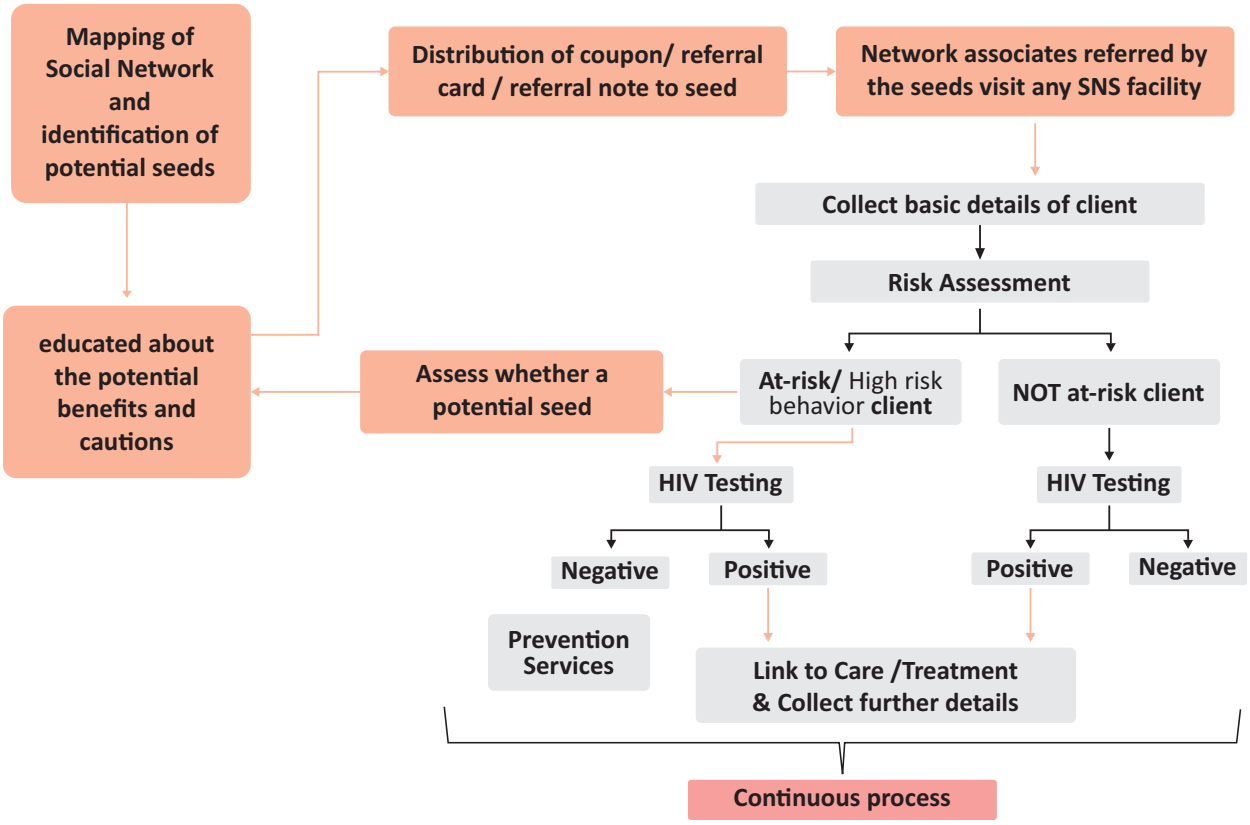
(g) Distribution of coupons/referral note or referral card to the seeds: Each of the engaged 'seed' should be provided minimum of four (4) coupons/ referral note/ referral card and encouraged to distribute among their sexual, injecting or social networks.

(h) Counselling and HIV testing of Network Associates: The network associates referred by the seeds can visit any SNS facility within the district with the coupon/ referral card / referral note provided. The basic demographic information will be collected and the individual will be engaged in HIV Counselling and Testing Services. After pre-test counselling, consent for HIV screening will be obtained from the individual and a rapid HIV screening test will be conducted. If the test is reactive, the individual will be referred for a confirmatory test. If the counselling and testing is conducted at the ICTC, then confirmatory results will be provided to the network associates. Individuals with confirmed HIV-positive status will be linked to ART for treatment. If the rapid screening test result is non-reactive, the individual will be linked to HIV prevention services. At the end of every month, the counsellor or the responsible person for SNS should monitor the coupons that have been distributed and the number of coupons returned.

(i) Further Distribution of coupons/referrals to the Network Associates as a new "seed": Subsequently, the network associates [regardless of their HIV status] will be provided four coupons/ referral note/ referral card for further engagement from their respective networks.

(j) Waves of engagement of clients: Through the above client referral mechanism, various waves of engagement can be initiated till there are no more people who are at high-risk of HIV are available in a specific geography.

Figure 7.2.2: describes the Service delivery frame work for SNS.



Monitoring indicators

- Number of seeds engaged in the month, disaggregated by age, sex, and typology
- Number of coupons/ referral note/ cards distributed in the month, disaggregated by age, sex, and typology
- Number of network associates with coupons/ referral note/ card returned for HIV counselling and testing in the month, disaggregated by age, sex, and typology
- Number of network associates who tested HIV-positive in the month, disaggregated by age, sex, and typology

7.3 Provider Initiated Testing and Counselling (PITC)

Background

One of the approaches in reaching the first 95 is the Provider Initiated Testing and Counselling (PITC) wherein health care provider recommends HIV counselling and testing for their clients. In 2007, the World Health Organization (WHO) issued guidelines recommending that countries and organizations adopt PITC to increase HIV testing rates. It is important to implement PITC in health care settings to ensure that there are no lost opportunities to identify PLHIV among patients attending the facilities.

Definition of Provider Initiated Testing and Counselling (PITC)

Provider Initiated HIV Testing & Counselling (PITC) refers to HIV testing and counselling which is routinely recommended by health care providers to persons attending health care facilities as a

standard component of medical care. With this approach, an HIV test is recommended for all patients whose clinical presentation might result from underlying HIV infection or as a standard part of medical care for all patients attending health facilities in areas of high HIV prevalence.

Where PITC should be offered.

(a) Symptomatic patients

Adults, adolescents or children who present to health facilities with signs, symptoms or medical conditions that could indicate HIV infection. These include, but are not limited to tuberculosis, hepatitis, sexually transmitted infections (STI) and other conditions specified in the WHO HIV clinical staging system. The WHO Clinical Staging of HIV in children and adults is available as Annexure-1.

Certain cutaneous disorders are indicators for HIV testing and include presence of any one of the following:

- Exanthem of seroconversion
- Oral Candidiasis
- Oral Hairy Leukoplakia
- Recurrent Herpes Zoster
- Chronic Herpetic Ulcer
- Seborrheic Dermatitis
- Pruritic Papular Eruptions (PPE)
- Multiple Molluscum Contagiosum
- Any Sexually Transmitted Infection

(b) HIV exposed children

Infants born to HIV-positive women as a routine component of the follow-up care for these children. Untested children of women living with HIV (WLHIV)

(c) Consideration may be given to the implementation of provider-initiated HIV testing and counselling in the following health facilities or services:

- STI services
- Health services for populations at high-risk for HIV
- Antenatal services
- Index testing, Social Network Strategy (SNS) for Testing
- Individuals who have faced sexual assault
- Before initiating Pre and post exposure prophylaxis and the follow up testing.
- High Index of clinical suspicion or clinical discretion of treating physician
- Sexual, needle sharing partner as well as social networks of at-risk HIV negative persons
- Presumptive TB and Notified TB cases

Process and Elements

a. Pre-test, informed consent and post-test

In many health facilities, health care providers do not have adequate time to perform a detailed risk assessment. As the objective of provider-initiated HIV testing and counselling in health facilities is timely detection of HIV and access to health care services, pre-test information can be simplified. Individual risk assessment and risk reduction plans could be covered during post-test sessions, rather than in the pre-test information session, tailored to the patient's HIV status. The pre-test information and counselling, informed consent to be obtained prior to the screening/testing for HIV as detailed in Chapter 5 of this guideline.

b. Referral for other services (medical and non-medical)

If Provider Initiated Screening is undertaken in the health care settings, the screened reactive clients are to be referred to the nearest/ linked ICTC for confirmation of the diagnosis. Depending on the HIV test result, HIV-positive and at-risk negative clients to be referred to medical and non-medical services detailed in the Chapter 10 for referral and linkage in the guidelines.

7.4 HIV Self Testing

HIV self-testing (HIVST) is a convenient and confidential option of HIV testing for those who are not willing to avail HIV testing services at health facility or through outreach. In 2016 WHO recommended HIVST as a safe, accurate and effective way to reach people who may not test otherwise, including people from key populations, men, and young people. HIV self-testing gives people the freedom to test anonymously, confidentially and privately. Since it is easy, quick and private, people may be encouraged to take a test earlier than they would if they had to visit a health facility, potentially bringing an earlier diagnosis.

"HIVST is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their result, when and where they want." An HIV self-test (or rapid self-test) is an antibody test that can be used at home or in a private location. With an HIV self-test, client can get his/her test results within 20 minutes.

HIV self-testing is a screening test only. It is not a confirmatory test of HIV status. It is mandatory and indicates the need to visit the nearby ICTC/ confirmatory testing facilities.

Currently HIV self-testing is not offered under the NACP. Blood-based and oral-based HIVST kits are available in the market. It is very important to read the instructions for use (IFU) of the specific kit for the usage.

There are three possible test results:

1) Reactive/positive: The test assay has reacted to a substance in the blood. This does not mean that the person has HIV. It is an indication that the person must confirm the status of HIV with confirmatory testing facilities. It is preferred to use the term "Reactive", however the manufacturers have described it as 'positive' in the IFUs.
2) Non-reactive/Negative: The HIVST did not find any evidence of HIV infection.
3) 'Indeterminate', 'equivocal' or 'invalid': The test result is unclear. Another test needs to be done.

CHAPTER-8

HCTS through Mobile and Outreach

HCTS through Mobile and Outreach

Context:

HIV counselling and testing services under the National AIDS and STD Control Program are provided through around 4657 Integrated Counselling and Testing Centres across the country. HIV counselling and testing services (HCTS) play a key role to achieve the first 95 of the fast-track target of 95-95-95. It's central role in reduction of new infections makes it an imperative component for prevention and control of HIV and STI in the country. Even with the impressive gains in coverage, reaching last mile population remains a persistent challenge. Newer strategies such as client prioritization, establishment of Sampoorna Suraksha Kendras by re-modelling the existing facilities and integration with other health programs have been launched under NACP-V.

Need for the Outreach through HCTS

There is still a significant proportion of population and groups who are at-risk of contracting the HIV and/or STI infection or already have contracted HIV and are living in hard-to-reach areas or are not willing to access NACP services by visiting the health facilities for various reasons. This calls for an innovative and newer approaches to bridge the gap of service uptake. In order to increase the access and availability of HIV related services to these at-risk population, it was emphasized to provide the HCTS through outreach strategies. The main purpose of introducing outreach strategies is to take the NACP services to the doorsteps of these hard-to-reach at-risk population. This will help in reaching out to individuals who are carrying the infection but are unaware of their HIV status. Offering NACP services through outreach strategy will motivate individuals and groups to avail primary services at their doorsteps and in a conducive environment, in turn motivating them to access referral services at the nearest mainstream health care facilities.

8.1 Intended Beneficiaries/ priority populations & Services offered through HCTS outreach services:

Table-8.1.1 describes in brief about the type of uncovered priority populations and the population living in hard-to-reach areas with limited or irregular public transportation facilities and the types of services that can be offered through HCTS outreach services.

Table 8.1.1: HCTS Outreach Services offered for various population

Population/Groups	HCTS Outreach Services offered
Uncovered population	• Comprehensive Prevention Services • Differentiated HIV Screening / testing • Provider initiated HIV & STI Treatment and services • Other Health Services (TB, NCD, Hepatitis B and C, Mental Health, etc.)

PLHIV	• HIV Treatment (for stable PLHIV) • Index Testing • Follow up for LFU/MIS cases • Treatment adherence counselling
Pregnant Women	• Differentiated HIV screening/testing • ANC care and treatment • Other Health Services (TB, NCD, Hepatitis B, Mental Health, etc.)
Patients with STI/RTI	• Provider initiated STI Syndromic management • HIV and Syphilis screening • Partner Notification and management • Treatment adherence counselling • Prevention services for those who screened/ tested negative
TB Patients	• HIV Screening • Other Health Services (NCD, Hepatitis B and C, Mental Health, Tobacco cessation etc.)
Inmates of Prison & Other Closed Settings	• HIV and STI screening • HIV treatment and care • STI Syndromic management • Other Health Services (TB, NCD, Hepatitis B and C, Mental Health, etc.)
Any displaced populations due to natural / human made disasters	• Comprehensive Prevention Services • HIV and STI Screening • HIV treatment and care • STI Syndromic management • Other Health Services (TB, NCD, Hepatitis B and C, Mental Health, etc.)

There are two basic modalities for providing HCTS services through outreach strategy to the above cited populations/groups

1. Mobile Van based outreach services

The main purpose of mobile based outreach services is to increase access to services under National AIDS and STD Control Program (NACP) and other related health services for the at-risk population in the unserved/ underserved areas in select districts to minimise the gap of 95-95-95 by 2025 and to END AIDS as a public health threat by 2030. The mobile ICTC services can be provided through

the SACS hired or owned vehicles (bus, van or even a two-wheeler) for hard-to reach population for outreach activities and to set up temporary clinic with flexible working hours.

The different approaches that may be opted for while providing HCTS through such mobile vans/ vehicles are explained below.

1. Static Camp Based Approach by mobile van: To address the challenge of reaching out to hard-to-reach/ at-risk populations or high-risk groups, HIV related services through outreach activity can be delivered in specific locations through mobile ICTCs. The services can be delivered by halting the vehicle at an identified specific location as per plan and organize outreach camps to provide the required services to those at-risk or HIV-positive individuals who face challenges in accessing the facility-based services including IEC activities.

The counsellors (ICTC, ART, OST, SSK), lab technicians and need based additional workforce including outreach workers or staff nurse of nearby ART, OST, SSK, CSCs, and TI NGO can provide various HIV and STI services according to the roster prepared and approved by the district nodal officer (DISHA official, DACO, Chief District Health Officer (CDHO) or Chief District Medical Officer CDMO) and competent SACS authority, as deemed fit.

Extended outreach component under other Health Campaigns:

Based on the learnings of the Integrated Health Campaigns conducted in the North Eastern states, this strategy will be adopted as a supplement to the static health camp at a particular site, such that the staff engaged in conducting the camp will coordinate and carry-out Extended Outreach (EOR) at the hotspots or sites where the HRGs are available and feel comfortable.

This will also include index testing with HIV and STI screening of spouses and contacts (sexual and needle sharing) and their biological children less than 19 years of age. Social Networking Strategy (SNS) will be implemented to reach at-risk or high-risk behaviour populations who are unreached for the HCT services. SNS utilizes peers and outreach workers to reach their network members and motivate them to undergo HCT. Through a chain-based snowballing approach, ORW or the peers designated as seeds will encourage their peers, who are at-risk or with high-risk behaviours and who are hard-to reach or hidden, to access HCTS. The peer educators and outreach workers under the TI-NGO will play an important part in the implementation of this strategy.

2. Mobile approach:

Integrated health Campaign approach:

Coordination with other Campaigns: Coordination with Integrated health Campaigns/ ISHTH campaign/ IEC Campaigns / Observance of any special day/ Health Programmes conducted by District Health Society/ Campaigns and outreach activities of the general health systems.

- *Collaboration with other stakeholders:* The route map should be aligned with general health systems Medical Mobile Units (MMU) so as to avoid overlapping of services. Collaboration with the NHM and other NGO/CBOs implementing TI/LWS/CSC for community mobilization and support for service provision as deemed appropriate. Coordination meeting should be held with the Block or District Medical/Health Officer to seek further support.

8.2 Suggested Models for Operationalization of Mobile Outreach Services:

1. Operation of Mobile Vans on outsourcing basis: Mobile vans and human resources are provided on outsource basis. Kits, ARV Drugs, STI Colour coded kits and other commodities are to be provided by SACS/DISHA.
2. State-owned Mobile Vans: Mobile Vans and human resources are deployed by SACS. Kits, ARV Drugs, STI Colour coded kits and other commodities are to be provided by SACS/DISHA.
3. Mobile Bikes with the driver: Procured/ hired by the SACS for undertaking the camps in remote and hilly terrains where reach by the mobile vans is not possible.
4. Vehicle owned or rented by the TI or LWS NGO/CBO

Human resources requirement:

The human resources requirements are classified as essential and desirable.

Essential:

1. Driver/Rider
2. Counsellor
3. Lab Technician (If facilities for confirmation will be available in camp)

Desirable:

1. Medical Doctor
2. Nurse
3. ORW
4. Peer Educator
5. Other staff as deemed appropriate by SACS/DISHA

These human resources are from within the existing program facilities or are mobilized from health system and are not new recruitments. In addition, in the districts where there are existing TIs or LWS, the staff of the TI/LWS will provide necessary support to the Mobile Intervention Team for mobilising key populations and making necessary arrangements, as required.

Operationalization of Mobile Outreach Services

Approvals and coordination:

- SACS in coordination with DISHA will be responsible for operationalization of Mobile Outreach Services and the supervision and monitoring of these units. The Mobile Outreach plan may be prepared by DISHA officials in close coordination with SACS (who will act as nodal officer), while keeping all the programme and division personnel in the loop (ART, ICTC, OST, TI, SSK, LWS etc.) and approved by SACS nodal persons.

- NGO/CBO implementing TI/LWS should develop a detailed monthly micro-plan, based on their own prioritization process, in consultation with the team and prominent community members of the area and nearby ICTC. Activity will be planned and overseen by the PM with the support of the team. The counsellor/ANM or Senior ORW will undertake HIV counselling and Screening for the clients during the camp whereas concerned PEs and ORWs will be involved in the community mobilization process.
- The frequency of the mobile intervention will be decided based on an initial mapping of villages/ blocks in the district, time-distance factor and the size of the at-risk populations to be covered. The schedule along with location of the mobile vans during camps may be shared with local health service providers (ASHA, ANM, FHW etc.) for better coordination.
- As such each district may require different numbers of mobile interventions per month. However, on an average, the frequency of mobile outreach interventions is to be about 15-20 camps per month.
- The mobile intervention may choose a service site in villages with a weekly market/Haat or where people from nearby village clusters (which are otherwise inaccessible) tend to congregate at. In urban areas, the site of mobile intervention should be located in the Mohallas or localities occupied by marginalised populations. Deciding the site of the camp should be led by the programmatic findings and local community intelligence.
- If possible, the services in rural areas could be conducted in any adequate building with one or two rooms with toilet facility, such as an Anganwadi Centre or Panchayat Bhavan or Primary School.
- Adequate arrangements for waiting area should be made in coordination with Gram Panchayat/ VHSND, etc.
- The additional services to be provided to the clients including pill pick-up services or follow up with LFUs or missed cases or CD4 or viral load or DBS sample collection required in the area where a camp is being organized, has to be pre-planned and a list to be collected from the CST division or the nearby ART centre.
- The necessary coordination with the general health system needs to be established, in case an integrated health camp is to be undertaken. Necessary approval of the DTO/DHO/CMHO is to be taken to ensure that the camps are convened smoothly.
- Infection prevention measures and biomedical waste disposal guidelines must be followed.

8.3 Community Engagement and Collaboration

NACP counsellors under leadership of DISHA will arrange initial meetings with local government authorities, local community leaders, community champions, HIV-positive networks, etc to engage communities and carry out community mobilization as needed. Community sensitization activities will be conducted for members of the general population as well as HRGs.

Conduct IEC activity:

- IEC or advocacy activities will be conducted prior to organizing the camps. This will help in spreading information and awareness about camps well in advance and will help in mobilizing people when the camps are organized. IEC activities can be in the form of street-plays, poster exhibitions, simple announcements through audio-visual systems, pamphlet or IEC material distribution, etc. The Mobile Unit can be painted and decorated with key messages on health including HIV, to ensure stigma free services.
- For the Bridge Populations, ORWs and PEs will conduct IPC sessions/mid-media event in the field to identify the high-risk Migrants and/or Truckers, 2-3 days/hours before the planned CBS camp in the area.

Equipment and Inventory Management

- The expected number of beneficiaries or clients in the camp should be identified and resources required to be quantified accordingly.
- Counsellors should prepare a list of the equipment based on diagnostics and treatment services provided. The equipment may be mobilized from the nearest health facility/ICTC.
- The list of drugs and consumables along with required quantity will be prepared and shared with DISHA. The supply shall be provided from the nearest NACP facility or from district stores. The drugs and consumables as well as other items required for integrated health camps should be prepared well in advance and shared with other health programmes and systems like NTEP, NVHCP and NCD at the State and District level for timely availability.
- Regular inventory should be maintained in a physical format shared from time to time and as per national guidelines.
- The staff appointed at the mobile camps will ensure all temperature sensitive commodities are mobilized while maintaining the cold chain as prescribed by the program.

Effective Referral mechanism:

It is envisioned that the mobile vans will act as the ICTC. All the necessary arrangements are to be made accordingly, while ensuring the necessary HR and commodity requirement. In case the mobile unit acts as a screening centre, then the screened reactive clients will be referred to the nearby ICTC, if confirmation services not available in the mobile unit. The confirmed HIV-positive cases will be linked with the nearby ART Centre for initiation of treatment. In order to keep identified at-risk negative clients negative, an effective referral system with appropriate services will play a very crucial role.

The staff to ensure effective referral and linkages for diagnosis and management of TB, Hepatitis B and C and Non communicable diseases during the camp. A line list should be maintained for effective referrals and linkages and follow up.

Reporting and documentation:

Reporting will be done in existing SOCH portal. Monthly and Quarterly reports will be prepared and shared with DISHA. The Mobile Camp shall adhere to all the provisions of Motor Vehicle Acts and other applicable acts in this regard.

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SECTION IV: Diagnosis of HIV Infection

Section-IV of the National HIV Counselling and Testing Guidelines has two chapters

Chapter 9: The chapter focuses on the Diagnosis of HIV, gives guidance on Serological diagnosis of HIV infection, the HIV testing strategies for Adults and Children (above the age of 18 months), Diagnosis of HIV-2, Early diagnosis of HIV in babies below the age of 18 months, Point of Care testing for HIV and Syphilis, Sample Collection and Sample Handling, Laboratory testing and reporting and Lab Safety and Biomedical Waste Management.

Chapter 10: The chapter Quality Management System (QMS) covers the guidance on QMS at HCTS, the Quality Assurance in mobile outreach program and the Quality Information Management System.

CHAPTER-9

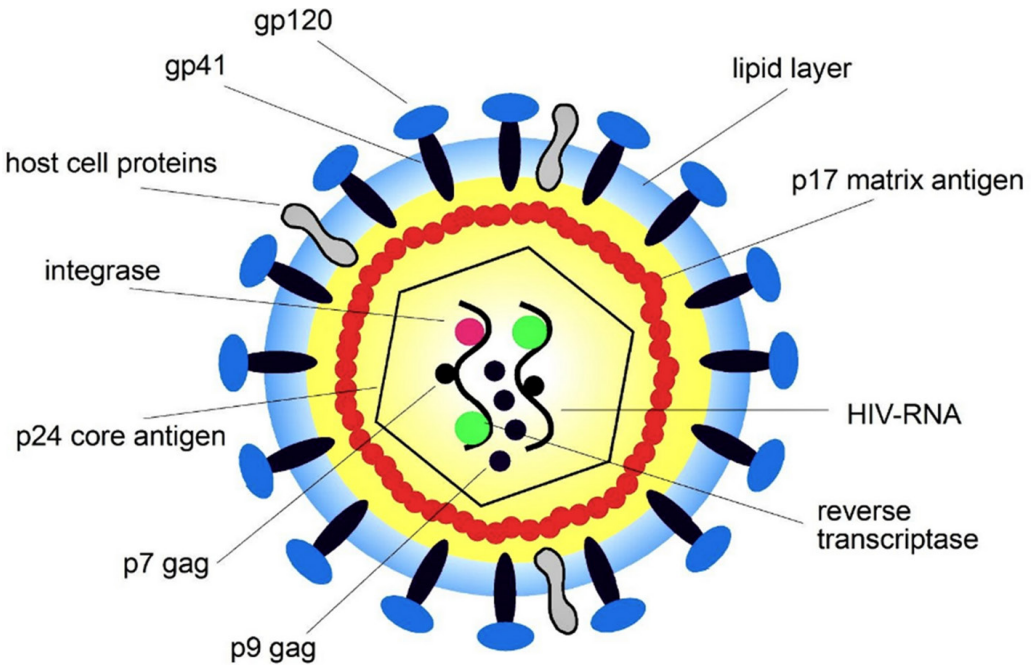
Diagnosis of HIV infection

Diagnosis of HIV infection

9.1 Structure of HIV

HIV is a lentivirus that infects and destroys cells in the immune system. Lentiviruses are in turn part of a larger group of viruses known as retroviruses. The name 'lentivirus' means 'slow virus.' They are thus named as they take a long time, often many years, to produce adverse effects in the body. Human Immunodeficiency Virus (HIV) is categorized into two main types: HIV-1 and HIV-2. Although HIV-1 and HIV-2 have the same routes of transmission and both can cause acquired immunodeficiency syndrome (AIDS), important differences exist between the viruses in terms of epidemiology, natural history, diagnosis and management. Compared to persons with HIV-1, persons with HIV-2 typically have attenuated clinical progression and lower rates of sexual and perinatal HIV transmission. Significant differences also exist in the antiretroviral management of HIV-1 and HIV-2, therefore it is essential to differentiate HIV-1 and HIV-2 infection. Figure-9.1.1 depicts the structure of HIV.

Figure 9.1.1: Structure of HIV



HIV is an enveloped virus. The virus envelope is composed of two phospholipid layers derived from the host cell membrane. The envelope also contains the trimers of an envelope coated protein, glycoprotein (gp) 160, wherein Gp160 is composed of two subunits, gp120 and gp41. While gp120 has external protein and contains sites that bind CD4 cells and co-receptors on the surface of human CD4 T cells, gp41 is membrane bound protein. Inside the viral envelope there is a layer called the matrix, which is made from the protein p17.

The viral core (or capsid) is usually bullet-shaped and is made up of protein p24. Inside the core are three enzymes required for HIV replication: Reverse Transcriptase (RT), integrase and protease. Also held within the core is HIV genetic material which consists of two positive strands of single stranded Ribonucleic Acid (RNA).

HIV infection in any individual above 18 months of age can be detected by laboratory test/s that demonstrate(s) either the virus or viral products, or antibodies to the virus in blood/serum/plasma. The HIV rapid diagnostic tests (RDTs) are the main diagnostic tools for HIV screening and diagnosis in resource-constrained settings. Given the potential for the severe medical, psychological, and social impacts of HIV misdiagnosis, it is imperative that HIV diagnosis is both sensitive and specific. In children below 18 months of age, due to persistence of maternal antibodies, diagnosis of HIV is made through molecular test that detect HIV nucleic acid- virus or viral products.

In 2019, in response to changing epidemiology, WHO recommended countries adopt a standard HIV testing strategy with three consecutive reactive tests for an HIV-positive diagnosis to ensure quality services as countries move toward and achieve the UNAIDS 95-95-95 targets. The guidance also highlighted the need to introduce dual HIV/syphilis rapid diagnostic tests (RDTs). Under the NACP, the most commonly employed rapid serological tests are based on the principle of enzyme dot immunoassay, immuno-chromatography (lateral flow), and immuno-concentration/dot-blot assays (vertical flow). All these different principles based rapid tests should have a sensitivity of 100% and specificity of ≥98%.

The window period represents the period of time from exposure to HIV infection to development of HIV antibodies to be detected by standard HIV antibody tests using serological assays (6-12 weeks). A blood test performed during the window period may yield a negative test result for HIV antibodies. These cases may require retesting after 12 weeks. Please refer to "National Guidelines for HIV Testing" for details on HIV testing, available at www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Testing_21Apr2016.pdf

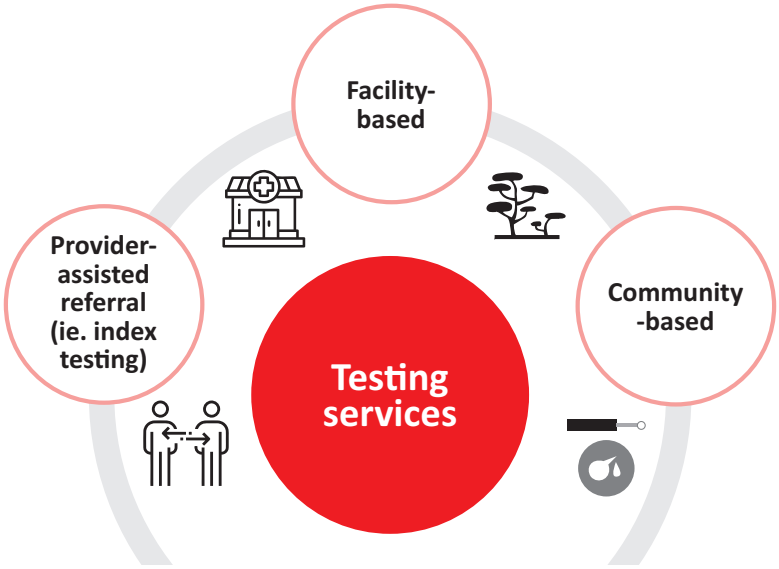
Differentiated HCTS under the National Programme

HIV testing may take place at any level of the health care system, and a diagnosis can be established for a majority of individuals on the same day. Many individuals access HIV testing in their community or in primary health care facilities. NACO has designed a differentiated service delivery (DSD) approach to provide high impact HIV testing services focusing on model designs that reach populations in need through facility and community-based testing and effectively link the person with screened reactive HIV/Syphilis results, for confirmation and treatment. In addition, linkages of HIV negative individuals to standard prevention package of services as follows:

- Screening for HIV and Syphilis is provisioned at facility-based screening sites and community-based screening sites using a single rapid diagnostic test kit. This approach offers optimization of HCTS and enhance linkage for confirmation at the ICTC and continuum of care.
- Confirmation of HIV is done at the ICTC using three rapid diagnostic kits as per the approved algorithm.
- Refer to figure-9.1.2 for different modalities of HIV counselling and testing services under the national program

For further information on referrals and linkages, please refer to chapter-11.5 Referrals and Linkages for Services under NACP around HCTS

Figure 9.1.2: Different modalities of HIV counselling and testing services under NACP



9.2 Serological diagnosis of HIV infection

Introduction

Laboratory diagnosis by HIV testing is the only method of determining the HIV status of an infected individual's infected blood, blood products, organs, and tissues. HIV diagnosis at ICTCs and other laboratories is based on the demonstration of antibodies. Antibody detection can be done using an ELISA test, rapid test, and western blot test. These tests are used as screening tests and/or confirmatory tests. All tests should be performed and interpreted as per test instruction manuals that are supplied with the kit. HIV testing should be based on testing strategy and algorithm.

NACO recommends the use of rapid test kits, which detect 100% of all HIV-infected individuals and have false-positive results in <2% of all those who are tested.

Commonly used HIV test kits are

1) Enzyme Linked Immunosorbent Assay (ELISA)
2) Rapid Diagnostics Tests (RDT)
   - Dot Immunoassay
   - Immunochromatography (Lateral Flow)
   - Immuno-concentration

In case of non-availability of RDTs, interim arrangement as mentioned in the guidance note issued by NACO may be followed (refer to Annexure-6)

Selection of test kits and testing algorithm

The selection of the rapid HIV tests and test algorithm to be used at HCTS sites is as per the recommendations of the National Technical Resource Group and approved technical specifications of NACP. The consortium of labs under the national programme conducts batch verification of the performance characteristics of the kit as claimed by the manufacturer, before distribution to the states.

9.3 HIV testing strategies for Adults and Children (above the age of 18 months)

The testing strategy apply equally to facility-based testing (for example, in laboratories, standalone HIV testing sites, clinical facilities and other testing services) and non-facility-based testing (for example, community-based testing conducted outside of conventional health facilities.

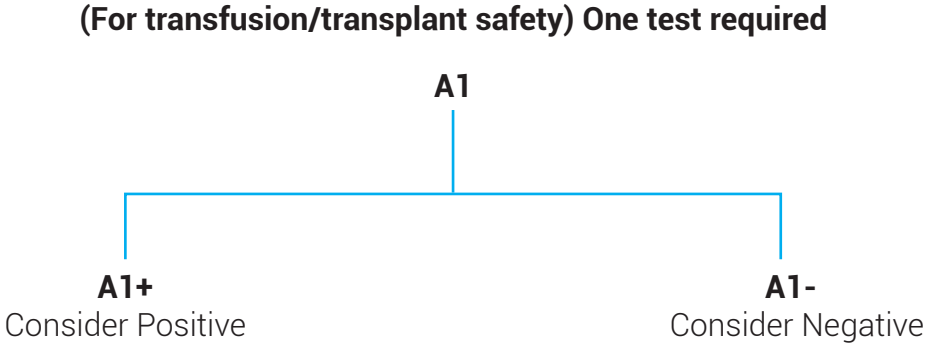
Choosing the most appropriate screening tests and the combination of tests for confirmation is essential to ensure an accurate diagnosis of HIV. The algorithm in Flow Chart 1 and 2 for clinical diagnosis is adapted from previously published WHO algorithms and is recommended by the National Technical Resource Group. It takes into account the increased specificity of current rapid tests, resulting in a higher positive predictive value.

The following strategies are to be used for HIV testing in adults and children above the age of 18 months: The type of strategy to be adopted would depend on the purpose of testing. The tests in the algorithm are used sequentially.

Strategy I (for blood transfusion/transplant safety)

The specimen is subjected to one test for HIV reactivity. The test used in strategy I must have high sensitivity. If non-reactive, the specimen is to be considered free of HIV (negative) and if reactive, the specimen is considered as HIV-positive. This strategy is used for ensuring donation safety (e.g., blood, blood products, organs, tissues, sperms etc.). The unit of blood that tests reactive (positive) is discarded. If the donor is to be notified of his result, based on his prior consent, it becomes a matter of diagnosis (in which case strategies II & III must be used after proper counselling) and the donor should be referred to an ICTC for the confirmation of the result. The figure-9.3.1 depicts algorithm for Strategy-I for HIV testing for blood transfusion/transplant safety.

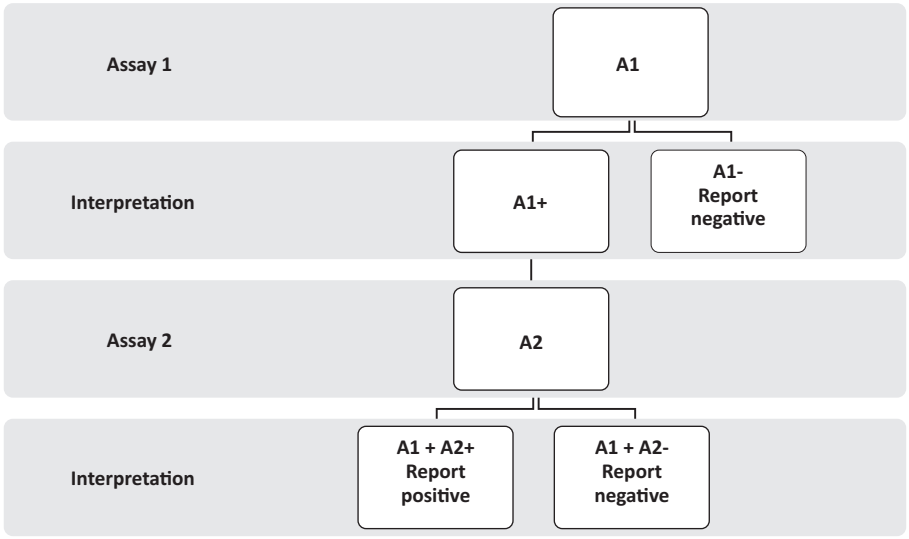
Figure 9.3.1: Algorithm for Strategy-I for HIV testing for blood transfusion/transplant safety



Strategy II (A)

Strategy II (A) is used in HIV sentinel surveillance wherein the same sample is tested twice using two kits with different antigens/principle in sequential. The first kit has higher sensitivity, and the second test is more specific. Venous blood is collected from pregnant mothers for ANC surveillance at the ICTC sites and DBS specimen is collected from Key population at TI sites. The samples are tested using the following algorithm at the designated HIV reference labs under the national programme. The samples are transported and tested at the designated national and state HIV reference labs. Figure-9.3.2 depicts the algorithm for Strategy IIA for HIV surveillance.

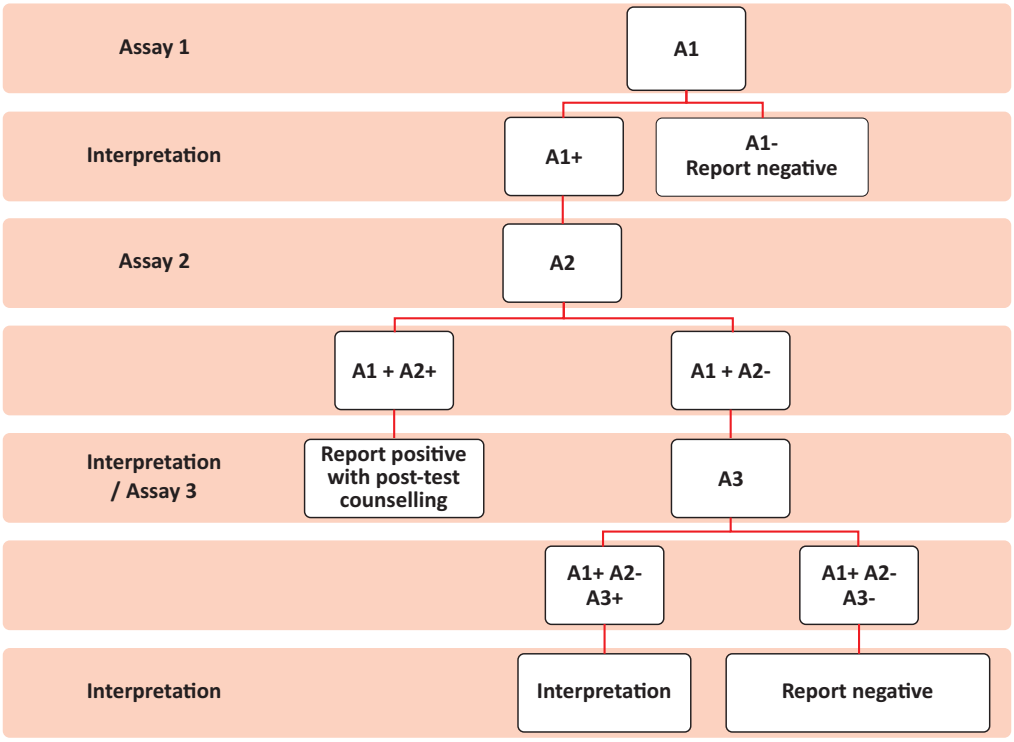
Figure 9.3.2: Algorithm for Strategy II(A) for HIV surveillance.



Strategy II(B) (For diagnosis of HIV in clinically symptomatic individual)

A patient who is clinically symptomatic and suspected to have an AIDS condition/disease is referred to the ICTC for confirmation of the diagnosis. In this case, the same blood sample is tested twice using kits with either different antigens or principles. The patient is declared HIV-negative if the first test is non-reactive and as HIV-positive when both tests show reactive results. When there is discordance between the first two tests (first reactive and the second non-reactive), a third test is done. When the third test is also non-reactive it is reported as negative. When the third test is reactive, it is reported as indeterminate, and the individual is retested after 14–28 days. Figure-9.3.3 depicts the algorithm for Strategy II(B) (For diagnosis of HIV in clinically symptomatic individual).

Figure 9.3.3: Algorithm for Strategy II(B) (For diagnosis of HIV in clinically symptomatic individual)



Source: National Guidelines for HIV Testing, 2015

Every individual at-risk of HIV infection and with HIV-non-reactive result should be counselled about window period, and that a non-reactive result does not always rule out the possibility of HIV infection if the individual has been recently infected and therefore, may follow up for HIV testing.

Strategy III for general population

Screening for HIV

- If the test is found non-reactive, the individual is considered HIV-negative and needs to be followed up for testing in future based on the risk behavior, as per the guidelines.
- If the test result is found reactive, the individual should be promptly linked to the ICTC for confirmation of the HIV diagnosis and further necessary action.

Confirmation

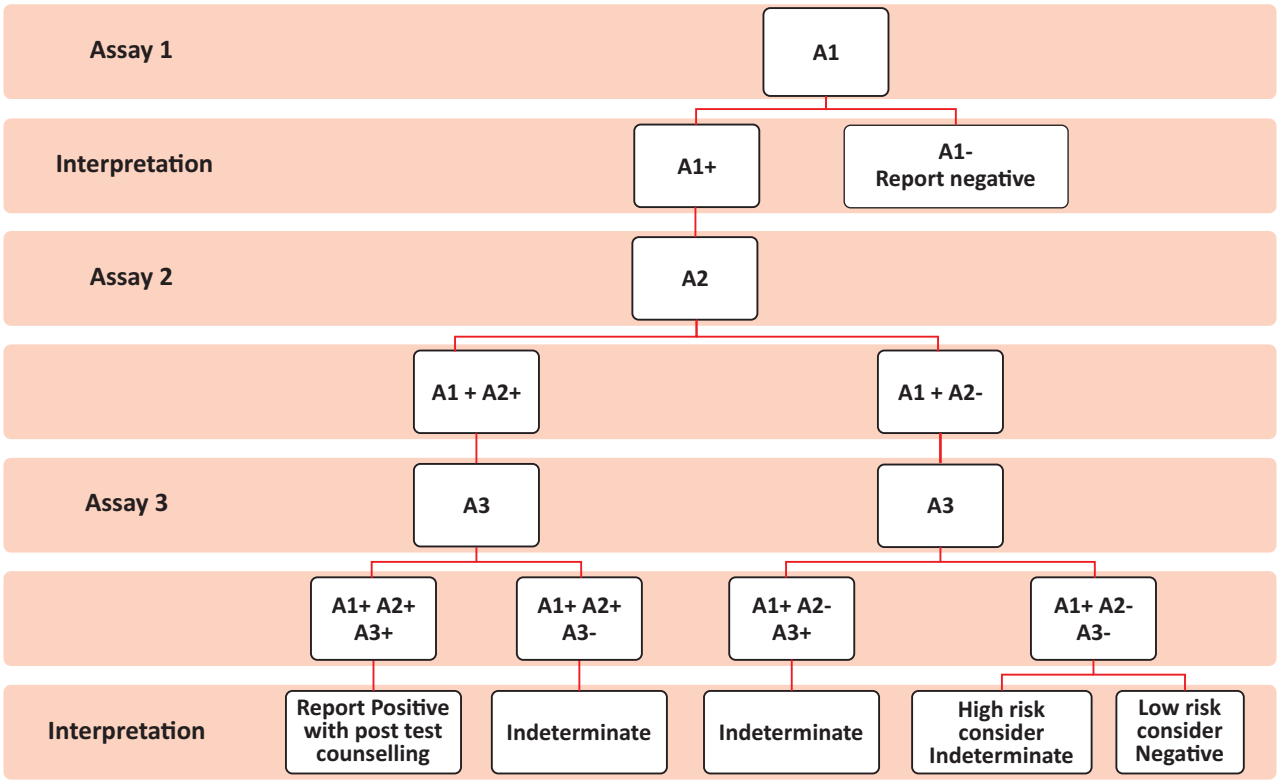
Confirmation of HIV diagnosis in asymptomatic individuals is done at ICTC using three rapid tests based on different antigens or principles. The three rapid tests are performed in a sequential manner as described in strategy III above. The individual is considered HIV negative if the first test is non-reactive and as HIV-positive when all three tests show reactive results. Figure-9.3.4 depicts the algorithm for Strategy III for HIV testing in general population.

This strategy is used for testing general population, in low prevalence settings, in areas with concentrated epidemic, and provider-initiated testing. The figure describes the sequence of assays and number of tests to be performed. Assay 1 (A1), Assay 2 (A2) and Assay 3 (A3) should be three different serological assays that do not share the same false reactivity.

In a low prevalence population, the positive predictive value based on two test results is too low to provide an HIV diagnosis. Therefore, for specimens that are reactive on the first and the second assays (A1+; A2+), a third separate and distinct assay (A3) should be used to confirm the results and issue an HIV-positive diagnosis.

- If the third test result is also reactive (A1+; A2+; A3+), the status is reported as HIV-positive.
- If the result of the third assay is non-reactive (A1+; A2+; A3–), then the test result is discrepant and inconclusive HIV status should be reported. The client should be asked to return in 14 days for additional HIV testing or should be referred to a higher-level facility, with a record of their test results, for additional testing and confirmation.

Figure 9.3.4: Algorithm for Strategy III for HIV testing in general population



Source: National Guidelines for HIV Testing, 2015

Assays A1, A2, A3 represent three different assays based on different principles or different antigenic compositions. Assay A1 should be of high sensitivity and A2 and A3 should be of high specificity. A2 and A3 should also be able to differentiate between HIV-1 and HIV-2 infections. Use strategies II B or III for diagnostic purposes.

Management of Indeterminate Results

If a result is inconclusive/indeterminate the person tested should be advised accordingly. Post-test counselling should focus on the possibility of the test having been performed during the window period, i.e. when antibodies have not yet formed after exposure to HIV, or the inconclusive result arising from a non-specific reaction.

All persons with inconclusive results should be encouraged to avoid the possibility of future risk behaviour and should be offered retesting at the same facility after 14-28 days, to allow the window period to have elapsed. If the same results are given by retesting after 14 to 28 days, then suitable specimen, should be sent to the State Reference Laboratory (SRL) for further HIV testing. SRL test the specimen and provide the conclusive HIV result to the ICTC. However, If the specimen status is still indeterminate at SRL, the specimen is referred to National Reference Laboratory (NRL) for confirmation by western blot.

If the confirmatory test at NRL fails to resolve the sero-diagnosis, follow up testing should be undertaken at four weeks, three months, six months, and 12 months. After 12 months, such indeterminate results should be considered negative. However, the molecular assays (HIV NAT) can be used to resolve specimens that are repeatedly (>2 times) giving indeterminate results.

Retesting of individuals who test HIV negative

Most individuals do not require retesting to verify an HIV negative status, particularly in the absence of any ongoing risk. However, it is important to accurately identify individuals who test HIV negative and may require retesting in certain circumstances.

HIV-negative individuals with ongoing risk

Certain individuals who test HIV negative warrant retesting. Schedule for repeat HIV testing is provided in table-5.6.1, in chapter-5.6.

9.4 Diagnosis of HIV-2

HIV-2 antibodies are confirmed by a reactive result to a HIV-1/2 Ab immunoassay and a positive result for HIV-2 Abs on an approved supplemental HIV-1/HIV-2 Ab differentiation immunoassay.

A HIV-2 positive result is given at the ICTC if there are two differentiating tests out of the three antibody that gives HIV 2 antibody positive result. For tests which are HIV 1+2 positive or indeterminate, then the results are confirmed at the HIV 2 referral lab. Refer National guidelines for HIV care and treatment 2021. The sample is collected at the ICTC and transported to the linked HIV-2 reference lab for confirmation. The final report is shared with the ICTC, ART centre, SACS and NACO (Basic Service Division, Care Support and Treatment and laboratory service division).

9.5 Early diagnosis of HIV in babies below the age of 18 months

An infant/baby may acquire HIV from the HIV infected mother-in-utero (during pregnancy), peripartum (during delivery) and postpartum (through breastfeeding). Early diagnosis is done to determine the HIV status among babies below 18 months of age. In infants who acquires HIV in-utero or peripartum, disease progression occurs rapidly in the first few months from birth, often leading to death.

Serological diagnosis of human immunodeficiency virus (HIV) infection in babies born to HIV infected mother is difficult because of presence of maternal anti-HIV antibody. Detection of HIV nucleic acid by polymerase chain reaction (PCR) at 6 weeks of life indicates perinatal infection. Qualitative PCR has sensitivity of >95% after one month of age, however, in some cases other tests like viral RNA detection by reverse transcription polymerase chain reaction (RT-PCR) and combination of tests may be required.

HIV-1 exposed infants less than 6 months of age

The baby's DBS sample is collected at the EID sample collection site for molecular test i.e. qualitative TNA PCR test for screening followed by the confirmatory HIV-1 qualitative TNA PCR test on a fresh DBS specimen tested at the EID lab.

HIV-1 exposed infants older than 6 months of age

HIV antibody tests using all three HIV rapid antibody detection in parallel are useful for detecting HIV infection in exposed infants/babies at 6 months or older in combination with molecular test done in the EID lab.

For details on clinical algorithm and sample collection requirements refer Laboratory technical guidelines on Early Infant Diagnosis for HIV exposed Infants, November 2023.

9.6 Point of Care screening for HIV and Syphilis

Under NACP phase V, the national programme is committed towards dual elimination of HIV and Syphilis by 2030. Dual HIV and Syphilis Rapid Diagnostic Test (RDT) can be used as the first test for screening of pregnant women during antenatal care and for vulnerable population at health facilities in peripheral locations and as a point of care, test in mobile outreach programme. Dual HIV and Syphilis Rapid Diagnostic Test detects antibodies to both Treponemal pallidum (the pathogen for Syphilis) and HIV. This is a screening test and uses whole blood/serum/plasma (as applicable) for testing and the most common method uses Whole Blood Finger Prick (WBFP). It is a rapid-diagnostic tests and the cartridge shows two bands for antibody detection along with in-built control to allow simultaneous screening for the two infections using single specimen and one test device. *Refer to Annexure-7: Whole blood finger prick sample collection for Adults and Children above the age of 18 months for HIV test.*

The Health Care Provider (HCP) should ensure the pre-requisites are met before conducting the rapid diagnostic test (RDT) (Refer Table-9.6.1). The test should be performed as per the manufacturer instructions and privacy and confidentiality of the client should be maintained at all times during the procedure.

Dual Test should be performed by trained staff. Testing personnel should ensure that kit storage temperature is maintained as specified by manufacturer. When test is being conducted in community, cold box should be used during transport to maintain the temperature.

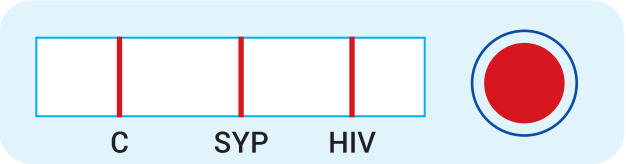
Table 9.6.1: Pre-requisites prior to conducting the RDT

- Availability of trained HCP
- Test kits stored at temperature conditions as per manufacturer's instructions
- Availability of valid test kits
- Availability of PPE
- Sample collection devices available
- Flat surface to keep the cartridges
- Sufficient light to read the results
- Colour coded bags/puncture proof containers to dispose solid bio waste material biomedical waste regulation

Figure 9.6.1: Interpretation of HIV Syphilis Dual Rapid Test Kit

Negative: Appearance of only the control band, corresponding to control region 'C'

HIV Reactive: In addition to the control band 'C,' appearance of reactive band at test region 'HIV' and no band in test region 'SYP'



Syphilis Reactive: In addition to the control band 'C,' appearance of reactive band at test region 'SYP' and no band in test region 'HIV'

HIV and Syphilis both Reactive: In addition to the control band 'C,' appearance of reactive band at both the test region i.e. 'HIV' and 'SYP'.

Invalid test result: The test should be considered invalid if the control band does not appear. In case of invalid test, repeat the test using a new device.

Follow up and Linkages:

- If screening test result is found reactive for HIV, refer the client to the linked ICTC for confirmation.
- If the screening test results is found reactive for Syphilis, the client should be referred to the nearest treatment facility (with availability of Injection Benzathine Penicillin e.g., DSRC). After the first dose of BPG, the RPR/VDRL should be performed at the ICTC/DSRC for confirmation.
- If screening test result is non-reactive for both HIV and Syphilis, repeat testing in third trimester and at labour, if the Pregnant women is at-risk for HIV or Syphilis.

The testing personnel should enter the report of HIV and Syphilis screening in HMIS/RCH portal-ANMOL/IIMS (Refer EVTHS guideline for more detail) and should ensure data confidentiality.

9.7 Rapid point-of-care testing for syphilis

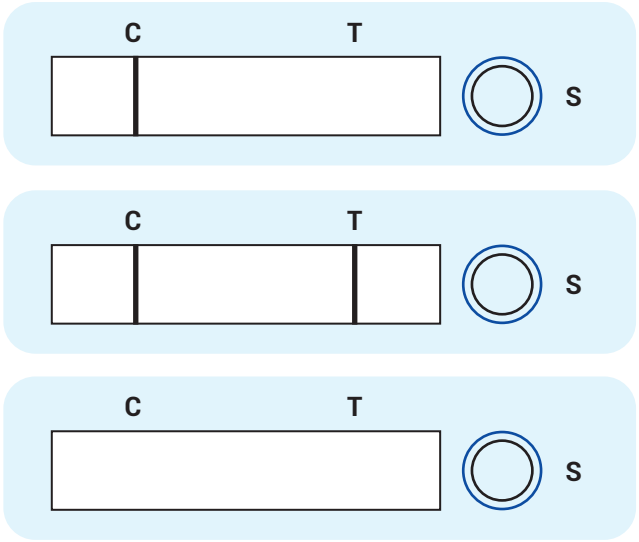
Rapid point-of-care (POC) syphilis testing is recommended where traditional laboratory tests for syphilis screening (VDRL or RPR) or Dual Test Kit for HIV and Syphilis are not available. Rapid POC testing helps ensure that there are no missed opportunities for screening and initiating treatment in case the test is reactive. Perform the test as specified in the kit insert.

Steps in Rapid POC testing for syphilis include:

- Removing the test strip from the wrapper and placing it on a flat surface
- Collecting the whole blood sample through a finger prick (as described earlier in the section on HIV rapid screening test)
- Adding a specified amount of blood in the well of the test strip (S)
- Adding a specified amount of diluents buffer to the well of the test strip (S)
- Waiting for time period, as recommended by the manufacturer of the kit

Interpreting the test result: is depicted in Figure-9.7.1: Interpretation of results from the strip test for syphilis screening

Figure 9.7.1: Interpretation of results from the strip test for syphilis screening



Negative: Online one line below C (control line)

Positive: Lines below C (control line) and T (test line)

Indeterminate: Nol lines below C or T

9.8 Sample Collection and Sample Handling

Venous blood sampling for Adults and Children above the age of 18 months for HIV test

The lab technician/health care provider at the HCTS should be trained in phlebotomy, to prevent unnecessary risk of exposure to blood. Clear information – either written or verbal – should be made available to each patient who undergoes phlebotomy.

Vacutainer blood collection tubes and needles with safety mechanism are preferred for the safety of the health care worker. For adults, vacuum evacuated tube and 21-gauge eclipse needle is commonly used. For children or adults with small, fragile veins (especially PWIDs), a butterfly needle (Sizes available: 23, 21, 19 gauge) and a 3-5 ml syringe is used. Selection is based on vein size and ICTC should ensure that equipment and supplies are available at all times. Ensure pre-test counselling is done and informed consent has been obtained. For list of required equipment and supplies for blood collection, refer to the National Guidelines for HIV Testing, available at: www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Testing_21Apr2016.pdf

Steps in blood sample collection are as follows:

- Assemble equipment and supplies.
- Introduce yourself and confirm the identity of client.
- Explain the procedure briefly to the person and inform that a sterile blood collection device is being used.
- Document unique Patient Identification Detail (PID) number of the individual in lab register.
- Label the tube for blood collection with at least two patient identifiers.
- Wash hands or disinfect with an alcohol-based hand sanitizer.
- Put on gloves to comply with standard precautions.
- Place the individuals in a supine or sitting position with arm supported under good light.
- For the avoidance of soiling, place absorbent material below the forearm before commencing venipuncture.
- Collect the blood sample as per defined procedure (Refer: National Guideline for HIV Testing)
- A bandage may be applied to the punctured site if required. Do not recap the needle.
- Discard the biomedical waste generated while collecting blood into appropriate colour coded bins.
- Enter the date and time of the sample collection into the Laboratory Test Report form

Dried Blood spot for sample collection for children below the age of 18 months for EID

Under the EID testing programme of NACP, Dried blood spot (DBS) is made from blood obtained from a heel or finger prick and used for the HIV-1 qualitative PCR test. The sample is collected at EID sample collection site and is transported to the linked EID testing lab through post/courier.

Refer to 'Laboratory technical guidelines on Early Infant Diagnosis for HIV exposed Infants' for details on sample collection, sample handling and sample transportation for children less than 18 months.

Single-prick/single-window blood sample collection for testing

An individual may attend a health care facility for multiple purposes; HIV testing may be one of them and they may require multiple blood tests at the same visit. The person in-charge of the health care facility should attempt that the blood sample of such an individual is collected in one department of the facility and transported to the relevant testing facilities along with properly filled requisition slips. HIV testing should be undertaken only after administering pre-test counselling and informed consent, duly documented in the counselling register.

Non-ambulatory in-patients

In some situations, within the public health-care facility, there may be a non-ambulatory in-patient who requires HIV testing and is not able to visit the HIV testing site. The blood sample of such a patient should be sent to the nearest HCTS facility with test requisition slip. The responsibility for the appropriate pre-test counselling and obtaining informed consent will be that of the referring health-care provider. Post-test counselling will be provided by the concerned HCTS functionary/designee in the ward where the patient is admitted.

9.9 Pre-dispatch evaluation of HIV kits:

HIV rapid test kits are supplied to the HCTS sites on a regular basis by the district HIV/AIDS nodal agency through SACS. Pre-dispatch evaluation of kits is done by the Consortium labs before it is made available in the field. These consortia of labs ensure quality of rapid HIV kits before distribution in the state and field.

The rapid kits should be stored under controlled temperature as defined by the manufacturer and should be used before the expiry date. HIV kits come with the temperature track indicator (TTI) and it should be monitored by the user for kit integrity. Kits that show a change in colour in the TTI should not be used and promptly reported to SACS.

"Consortium of laboratories for Kit Quality"– Any HIV test kit used at the HCTS facility for screening and testing under the NACP is evaluated by the NACO established consortium of laboratories for kit quality. ICMR-NITVAR, Pune is currently the secretariat of the consortium.

The test should be performed in compliance with procedure specified by the manufacturer. The test results should be read within the time limit specified and interpreted as per the manufacturer's instructions. The quality control procedure for rapid HIV test kits should be adhered as detailed in the National HIV testing guidelines.

A. Testing and reporting at HIV screening sites

HIV rapid test kits are supplied to the HIV screening sites- facility based and mobile outreach by the linked ICTC. The designated staff should ensure the adequate number of kits are available and stored under controlled environment and TTI is monitored 12 hourly.

Test results found non-reactive should be reported as 'HIV negative on the same day of HIV screening on the prescribed format signed by medical officer/In-charge. Those found 'Reactive' should be referred /accompanied referral to the linked ICTC for confirmation using linkage form.

B. Testing and reporting at ICTC

All HIV tests should be performed adhering to the national guidelines and testing strategies. Laboratory must ensure the quality of HIV testing. Positive result means that one has HIV infection. The patient is linked to the nearest ART Centre for treatment and HIV care. Negative result means either there is no HIV infection or the infection is recent and that the body has not had time to make enough antibodies to be detected and is in the window period.

Please refer to Annexure- 8 for the revised HIV test reporting format which should be used by Confirmatory facilities

C. For Indeterminate test results

The testing should be repeated after 14–28 days. In case the serological results continue to be indeterminate, then the sample should be referred to the linked State Reference Laboratory for further testing and confirmation. SRL test the specimen and provide the conclusive HIV result to the ICTC. However, If the specimen status is still indeterminate at SRL, the specimen is referred to National Reference Laboratory (NRL) for confirmation by western blot.

However, if the confirmatory test-Western blot fails to resolve, then the molecular assays-HIV-1 NAAT can be used to resolve specimens that are repeatedly (>2 times) giving indeterminate results.

(Please refer to the National HIV testing guideline, for sample storage and transport to the referral laboratory for confirmation)

D. Western Blot Test

HIV Western Blot test is solid-phase Enzyme immunoassay with immobilized viral antigens separated as per the molecular weight on nitrocellulose strips to detect antibodies to specific HIV proteins. Under the NACP, Western Blot is used as a confirmatory test for confirmation of discordant results between ICTC and SRL and confirmation of sample status with Indeterminate results.

9.10 Lab Safety and Biomedical Waste Management

Lab Safety

1. All specimens, kit reagents should be considered infectious and should be handled as per safety precautions (universal precautions).
2. Wear Personal Protective Equipment (PPE) (laboratory coats, shoes and gloves etc.) when collecting, processing and testing the specimens,
3. Never pipette by mouth. Use safe pipetting devices.
4. Never recap needles. Dispose of the needles and syringes in puncture-proof containers.
5. Hand washing: Always wash hands before and after removing gloves. Gloves are not a substitute for hand washing.
6. After working with specimens, remove gloves and discard them in red bags as per the BMWM regulation and wash hands with soap and water.

7. Do not eat, drink, smoke, apply cosmetics, or handle contact lenses while working in the laboratory.
8. All personnel handling infectious material should be vaccinated with Hepatitis B.
9. Ensure safety equipment like PPE, First-aid box, Spill Management kit, Fire Extinguisher, Emergency evacuation routes are available.
10. Decontaminate and dispose of all potentially infectious materials in accordance with biomedical waste management rules 2016 and its amendments.

As per the Bio-Medical Waste Rules, 2016 (along with subsequent amendments), segregation should be done at the source, using colour coded, leak-proof bags/ containers. Figure-9.10.1 depicts the segregation of hospital waste into colour coded bags or containers.

Figure 9.10.1: Segregation of Hospital waste into colour coded bags or containers



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

The bags should be tied tightly when three fourths full and disposed of as per the Bio-Medical Waste Rules, 2016 (along with subsequent amendments).

CHAPTER-10

Quality Management Systems

Quality Management Systems

Introduction

Quality assurance implemented through quality management system (QMS) is essential for any medical laboratory testing service, ranging from HIV testing conducted in laboratories and health facilities to community-based settings, including rapid diagnostic tests (RDTs). Misdiagnosis of HIV status – both false-positive and false-negative results can have adverse/detrimental effect on the patient, therefore it is the ethical responsibility of the staff conducting HIV and syphilis testing in the facilities offering HCTS to conduct testing in accordance with quality management system principles to ensure the highest level of quality and accuracy. Ensuring correct HIV test results is a priority and a crucial component of WHO's 5 Cs for HCTS. The National AIDS and STD Control Program is committed to implement robust quality management system that delivers high-quality and accurate reporting of HIV/Syphilis test results as part of the strategy towards dual elimination and attainment of UNAIDS treatment targets and end AIDS epidemic as a public health threat by 2030.

10.1 Quality Management System (QMS) at HCTS

Since 2009, several key initiatives have been undertaken to assure quality in laboratory diagnostic services through step wise quality improvement towards certification and ISO 15189 accreditation with successful outcomes.

HIV counselling and testing services within the tiered health system is provided by the ICTC using a validated national testing algorithm in accordance with the WHO recommended testing strategy. These ICTCs are linked to the state and national reference labs in a tiered laboratory network for quality assurance, proficiency testing, mentoring and supportive supervision. The ICTC is linked with Screening sites and provides confirmatory HIV test for those screened reactive using one rapid diagnostic test.

NACO is implementing a structured quality improvement program at HCTS sites that is based on Clinical and Laboratory Standards Institute (CLSI's)Quality System Essentials and International Organization for Standardization (ISO) 15189. It provides a step wise approach towards fulfillment of the standard checklist requirements through series of trainings, mentoring and periodic assessments. Adequate training and supportive supervision of the HIV testing provider is conducted by trained staff from the HIV Reference Labs, State and district program officers through a comprehensive training package, delivered in blended training programs and EQA workshops.

How to implement step wise continuous quality improvement towards certification

The ICTCs implements step wise continuous quality improvement plan through a structured QMS framework that incorporates the 12 elements summarized below. The degree of compliance to the 12 elements given below are assessed and reassessed during the supervisory visits using a standard checklist. The ICTCs with attainment of full compliance (score 90 % or more) are certified as centre of excellence by NACO

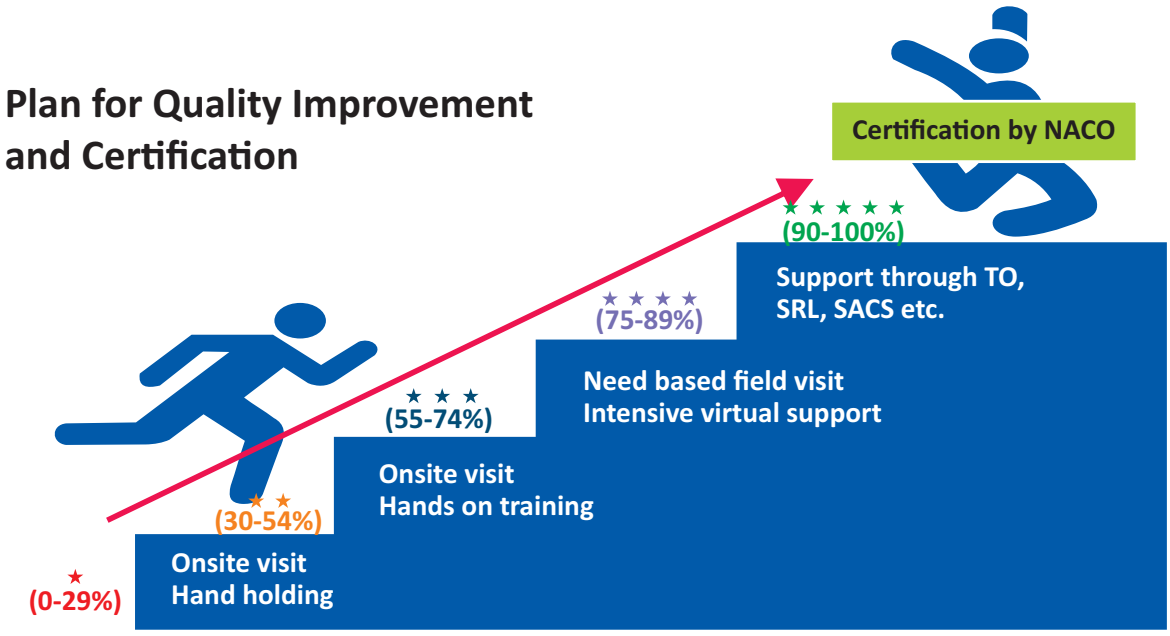
Refer to the Annexure- 9 for the Checklist to review Quality Management System at ICTC

The ICTC Checklist is designed to:

- Review laboratory functioning at ICTCs in a standardized manner
- Generate numerical indicators related to laboratory capacity and quality.
- Track progress of ICTCs over a period of time.
- Implement the Quality Improvement (CQI).

The checklist is divided into 4 Domains: – Operations, Technical, Monitoring & Evaluation and Logistics. This categorisation of parameters into domains makes it possible to clearly identify the strengths and short comings of the ICTC. The grade of the facility is calculated using the total percentage of scores obtained. The percentage score is also reflected as 1 to 5 stars rating. Figure-10.1.1 depicts the process for NACO Certificate of Excellence. This provides a one-point reflection of performance, helps facilities keep an end goal in mind and mark the improvement in their performance with each assessment. The star rating also serves to provide insights for the level of investment required for technical assistance and mentoring.

Figure 10.1.1 Process for NACO Certificate of Excellence



10.2 Essentials for QMS

The 12 essentials of quality are described in detail below:

1. Organization:

Irrespective of their location, both facility-based testing services (laboratories and clinical facilities) and community-based testing services should have a commitment to assure quality. All testing sites should have a quality policy that specifies the following aspects of the quality of HCTS:

- Ensuring that competent staff (including lay providers) are available.
- Ensuring purchase of quality-assured test kits, equipment, and consumables
- Ensuring QC of testing processes

- Ensuring a system for creating and managing documents
- Keeping records confidential
- Recording and following up on complaints
- Evaluating and following up on results of EQA /proficiency testing and on-site supervision

2. Personnel: All personnel, including those drawing specimens, performing laboratory testing, providing reports of HIV status, data managers and other auxiliary staff, must be trained adequately. All staff members should have appropriate qualifications/certifications with demonstrated proficiency in performing the tasks within their scope of work.

3. Equipment: Regardless of where testing takes place and whether it is performed using HIV RDTs in the community or laboratory-based diagnostics, it is critical to have appropriate equipment available and fully functional.

For testing services using primarily RDTs, it is essential to have temperature loggers attached to the refrigerators, to maintain temperature as per manufacturer's recommendation.

For HCTS facility that rely on laboratory-based techniques, calibration and maintenance of equipment is paramount for providing accurate testing results.

4. Procurement and inventory: Purchasing refers to activities that must be undertaken at the programmatic level to ensure that adequate supplies of test kits and other items required for the testing process are available on-site.

Stock-outs of HIV test kits or any other essential consumables, such as lancets, alcohol swabs or specimen transfer devices, are one of the biggest reasons for client dissatisfaction.

It is necessary to ensure that an adequate system is in place at the testing service site to track procurement of test kits, reagents and consumables (venous or capillary blood collection supplies), when they are ordered and when received. Each HIV testing service should then track consumption of all test kits and consumables so that they can inform the central medical stores (or other purchasing body) when they need to replenish stock. As stocks are received, it is critical to take note of expiry dates and when to order ahead, allowing adequate time for the next delivery.

5. Process control: refers to processes and activities to ensure that testing procedures are performed correctly, that environmental conditions are suitable and that the assay performs as expected. Quality Control (QC) intends to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance, before test results are reported. Hence, QC is a multi-step process with critical checkpoints throughout the testing process.

• Before testing (pre-examination):

Check that the temperature of the testing area is within the manufacturer's recommendations and record the same.

Check that stocks of test kits and required consumables are on hand.

• While testing (examination):

Ensure that any QC specimens have been run (for example, test kit controls and/or external QC specimens) and that the results are within acceptance criteria.

Built in controls refers to processes within the assay that check whether the test procedure is working; the appearance of a control line for HIV RDTs is an example.

Internal QC: sometimes the manufacturer supplies positive and negative controls, if not available retained known patient samples can be used for this purpose. Internal QC material should be run according to the manufacturer's instructions in the following conditions:

- once weekly, preferably at the beginning of the week
- for any new operator (including trained staff members who have not conducted testing for some time)
- for each new lot of test kits
- for each new shipment of test kits
- when any environmental conditions (for example, temperature and humidity) fall outside the range recommended by the manufacturer.

Ensure that a second technologist rereads (double-checks) all visually read assays.

• **After testing (post-examination):** Double-check the report of the test status before release to the client.

6. Information management: Information management consists of the paper-based and electronic systems for storing records and documents, including emails or text messages that provide testing results or reminders to clients. It is closely linked to documentation and record-keeping.

To assure the quality and integrity of the test status released to a client, HTS must minimize the risk of transcription errors. Assigning client identification numbers/ specimen identification numbers to each subsequent specimen received from the same individual will reduce the possibility of transcription errors. It will also protect the confidentiality of people undergoing HIV testing. Linking a series of HIV test results also is critical when retesting is used to verify a client's HIV-positive diagnosis or to resolve a client's HIV-inconclusive status. It is critical that all information be kept confidential, with access restricted to qualified staff.

7. Documents and records: Each HCTS facility shall ensure that Standard Operating Procedures (SOPs) exists for all the procedures including specimen collection and processing requirements, testing algorithm and all testing procedures with QC and final reporting.

The types of records required for a quality system include, but are not limited to:

- Specimen request forms
- Testing/laboratory logbook
- The logbook should record details of the identity of the person undergoing testing (client identifier, name [optional], date of birth [optional]), the assays used (with lot numbers and expiry dates), the test results (preferably, band intensity when using RDTs), both readers' results (when using RDTs), date of test run, name of operator and QC results.
- Overall status as given to the individual.
- Referral slips for retesting or other post-test services.

- Staff training records and other personnel records.
- Internal and external assessment reports
- Non-conformance and complaint records, with action taken.
- Equipment maintenance records and inventory charts

8. Occurrence management: An "occurrence" is an error or an event that should not have happened. The following sources of data may be used to check if there are problems or potential errors:

- Assessment reports
- Supervisory visit reports
- QC data, including higher than expected rates of invalid results (for example, when using RDTs, if no control line appears or a high background on the test strip obscures the reading window)
- Results of EQA (proficiency testing)
- Higher than expected rate of discrepant test results.

9. Assessment: testing sites should undertake both internal and external assessment to assure the quality of testing. Internal assessment is usually carried by either a site supervisor, HIV reference lab or a district health management team, that observes testing practices at least annually but preferably every three to six months using a standard checklist. Internal assessment may also be performed by another staff member who is independent of the system but has enough familiarity with the process to conduct an assessment using the standard checklist and measures the degree of compliance to the national/ international quality standards.

The HCTS sites which attain 90% or more compliance with the standard checklist requirements are encouraged and supported by the SACS and HIV reference laboratory for NACO Certificate of Excellence.

External Quality Assurance (EQA) assures that assays are performed accurately and the results obtained are accurate, reliable and reproducible. EQA usually takes the form of participation in EQA (also called proficiency or panel testing), which include testing of panel samples (blinded four-member panel sent to ICTCs from their linked SRL) follow-up up of any unacceptable EQA results with corrective actions.

Interlaboratory comparison by re-checking/ re-testing proportion of tested specimens (20 percent of HIV-positive and 5 percent of HIV negative sera (0.5 mL sample volume) tested in the 1st week of each quarter of the year (January, April, July, and October) with the designated SRL is an additional quality step to check the accuracy of the test results. An ICTC implementing QMS is assessed by the auditor periodically for fulfilment of the 12 quality elements and NACO's certificate of as per the framework described.

10. Process improvement: The DISHA needs to ensure client (customer) satisfaction with the testing services. This includes both internal clients, such as doctors; and external clients, such as individuals undergoing testing, through identifying areas requiring improvement and putting a corrective and preventive action in place.

11. Customer service: Programme needs to ensure that clients are satisfied with the testing service. This includes both internal clients, such as clinicians and other linked centre (e.g. linked NGOs, NACP screening sites and other screening sites), and external clients, including people undergoing testing.

12. Facilities and safety: It is important that testing facilities are well-designed and maintained. The testing site, including where counselling takes place, specimens are collected and tested, should be clean, clutter free with adequate space and lighting (for visually reading assays) and free of potential hazards.

10.3 Quality Assurance in mobile outreach program

Decentralization and continued expansion of HIV testing necessitates complementary quality assurance measures to ensure individuals received correct HIV status. Specifically, all HTCS in mobile outreach program including HTCS at screening sites should have the following:

- Instructions for RDT procedure and interpretation should be clear and concise, preferably in the local language.
- Health care workers using the tests should be trained to follow the national validated algorithm and assessed, and systematically monitored on test procedure and interpretation.
- The entire quality chain must be underpinned by appropriate handling/transport and storage practices.
- Periodic quality control of test kits; refer the HIV testing guidelines.
- External on-site quality assessment and supervision at all testing sites. Responsibility for overseeing quality assurance processes should be clearly defined and coordinated at state/ district level.

Refer to Annexure-10 for Checklist for Assessment of Screening Sites

The checklist includes six domains to assess compliance with the basic requirement of quality in CBS testing using RDT for HIV and HIV/Syphilis dual test. Refer annexure-11 for Testing Kits principles, specifications and advisories.

Personnel and Training:

Staffs designated for conducting screening test must be trained and proficient to conduct HIV and HIV/Syphilis dual test using RDT as per guidance given in chapter-7, in the National HIV counselling and testing services (HCTS) guidelines 2016

1. Physical Facility and Safety

Ensure that adequate space and light in a clean area is available to perform the test. Appropriate temperature-controlled equipment is available for storage of kits. Personnel protective equipment must be available and staff must be vaccinated for Hepatitis-B.

2. Process control:

Process control cuts across all steps of laboratory workflow i.e. before testing, during testing and after testing. The goal of Process Control is to minimize errors and correct them before test results are reported throughout the cycle through checkpoints as summarized in the table-10.3.1

Table 10.3.1: Checkpoints for Process control

Before Testing	During Testing	After Testing
Verify kit storage temperature and TTI of Kits and see it is within the manufacturer's instructions	Label the test cartridge with the client ID mentioned in the test request form	Test result is interpreted as per the manufacturer's instructions
Check stock availability and test kit expiry	The inbuilt control line should be valid before interpreting the test result	Ensure referral and linkages of screened positive for test confirmation at the nearest HCTS facility
Verify the identity of the client with the test requisition form		

3. Quality Assurance:

In order to assure quality of CBS test and delivery of accurate test results, periodic monitoring of testing sites is important. In this regard, a comprehensive checklist has been developed by NACO for mentoring and monitoring. Refer to Annexure-9 for Checklist for Assessment of Screening Sites. The assessment should be conducted at least once in a year and or need based (when new staff / facility designated or major issues reported). The observations in the assessment should be discussed with the staff to find root cause of issue and provide technical assistance/need-based training for corrective and preventive actions.

4. Inventory management:

The ICTC will supply kits to NACP screening sites under the guidance of SACS. It should be ensured that adequate number of kits are available and stored under controlled environment and temperature is monitored 12 hourly at screening sites. The demand for NACP screening sites should be submitted to linked ICTC in advance. The record of issue and return of test kits should be recorded by issuing facility while ensuring the temperature integrity at all times.

5. Documents and Records:

Screening facility should have access to documented procedures for pre-examination, examination and post examination processes, preferably in local language that is easily understandable by the paramedical staff and health care providers providing screening sites.

The format for recording the client information, results and referral details as well as stock register should be available at screening site.

10.4 Quality Information management system

NACO has developed a digital solution for management of data for Proficiency testing pertaining to HIV serology, CD4, HIV1 viral load and for interlaboratory comparison for HIV serology (rechecking/ re-testing). In addition, the e tool offers data capture on the progress of the HCTS sites on the implementation of QMS model and certification. The tool is named as “NACO Prayogshala” with website as-www.nacopryogshala.in.

References for Section-IV

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SECTION V: Convergence and Linkages

Section V has two chapters.

Chapter 11: The chapter on Comprehensive and Integrated Service Delivery including HCTS, covers the concept of breaking silos and building synergies and further describes the various innovative strategies implemented under NACP phase V strategy, such as Sampoorna Suraksha Strategy, Differentiated-care models, Link ART centre and Care support centres. The chapter ends with guidance on the Referrals and Linkages for Services under NACP around HCTS.

Chapter 12: The chapter focuses on Optimization of HCTS under NACP for integration with health systems, covers the NACP-V strategies for integrating HIV services, including HIV testing services, with a range of other relevant clinical services, under the general health system. Topics covered are the strategies for integration of HIV with health services such as sexually transmitted infections, maternal and child health services, TB program, viral hepatitis control program and key population programmes such as harm-reduction programmes for people who inject drugs

CHAPTER-11

Comprehensive and Integrated Service Delivery including HCTS

Comprehensive and Integrated Service Delivery including HCTS

11.1 Operationalizing the Principle

NACP phase V recognizes opportunities available within the programme as well as in other national health programmes to catalyse progress on stated goals. The guiding principle of "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 national health programmes and related sectors, for an efficient service delivery mechanism. 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 communities concerned, including adolescents, young people, women in reproductive ages with HIV prevention needs, women living with HIV, ensuring full ownership and participation of beneficiaries in the national AIDS response. Structural interventions like community system strengthening and community-led monitoring will navigate beneficiary and community centric approaches under NACP phase V.

11.2 Sampoorna Suraksha Strategy

The Sampoorna Suraksha Strategy is a strategy to reach HIV negative and at-risk population to reduce new infections and promote early detection of HIV. Sampoorna Suraksha strategy aims to reach out to those not self-identifying as HRGs but are at-risk of acquiring HIV and STI, and then providing them with a cyclical, need-based and comprehensive package of supportive services that help them stay uninfected and healthy.

Objectives of Sampoorna Suraksha Strategy are:

- Identify individuals who are at-risk of acquiring HIV and STI
- To ensure delivery of evidence-based human centric comprehensive prevention service package to maintain their HIV and STI negative status.
- Sustain focus on all at-risk HIV negative clients.
- Drive the development and roll-out of new generation communication strategies tailored to the current context.

Target Population

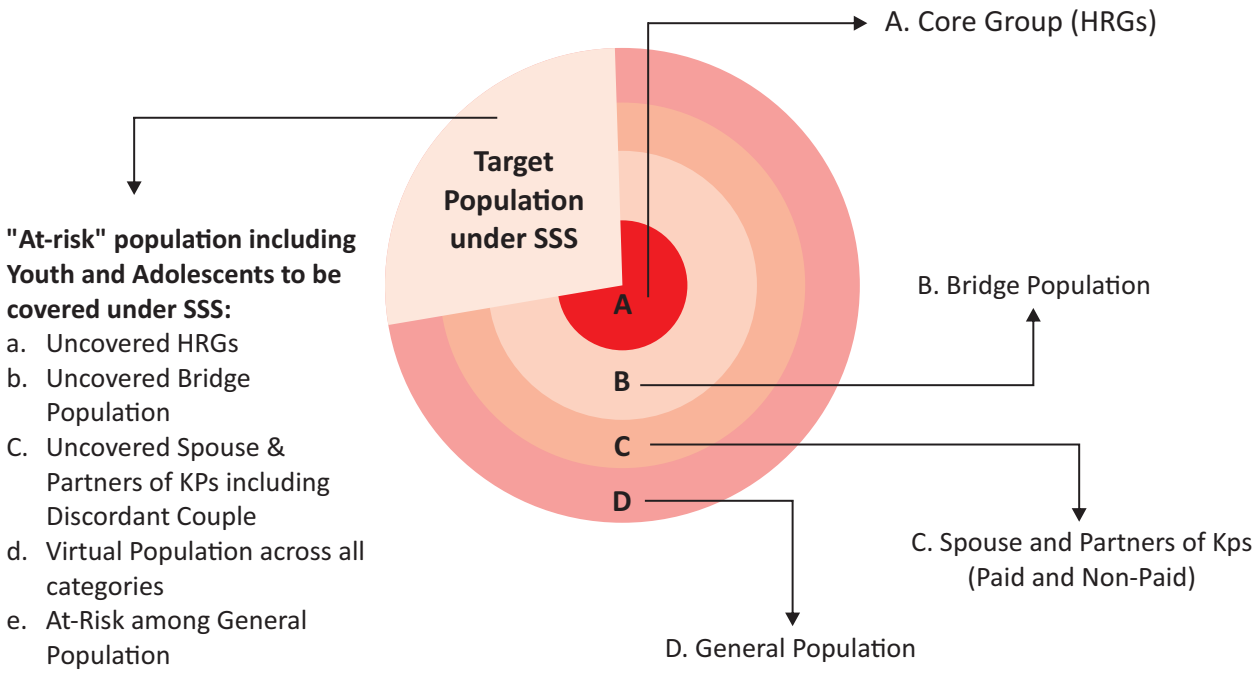
The population at-risk for HIV and STIs is defined as 'any individual who is at-risk of acquiring HIV or STI due to high-risk behaviours of self or partners'.

The population to be covered through SSS are the individuals at-risk of contracting HIV and STIs which are as below but not limited to:

- Self-initiated clients at ICTC with risk behaviour
- Social and sexual networks of self-initiated clients / individuals

- Youth and adolescents at-risk
- Individuals having casual sexual relation with regular/non-regular partner/s
- STI/RTI clients visiting DSRC/STI Clinics with STI complaints
- HIV negative but at-risk clients identified through virtual outreach, NACO Helpline 1097 etc.
- Regular and Non-Regular Partner/s/Spouse of HRG (FSW, MSM, H/TG) who are not associated / covered with TIs, LWS & OSC
- Needle/Syringes sharing Partners (PWID/FIDU) and their sexual Partners (who are not associated with TIs/ LWS/OSC)
- HIV negative partners of among discordant couples

Figure 11.2.1: At-risk Population Chart



Implementation of Sampoorna Suraksha Strategy

SSS is being implemented as an "Immersion Learning Model" implemented through existing identified NACP facilities i.e., ICTCs or DSRCs functional at the districts by re-modelling it as Sampoorna Suraksha Kendras (SSKs) in selected 150 districts in 20 states under the Global Fund Grant 2021-24, which shall further be up scaled to additional 339 SSKs in Global Fund Grant 2024-27 along with continuation of 150 SSKs, hence there will be 489 SSKs by the end of March 2027.

The at-risk clients registered for the SSK services will be followed up for 2 years with follow up plan prepared by Counsellor basis risk assessment. The comprehensive services will be provided to the client as per their need.

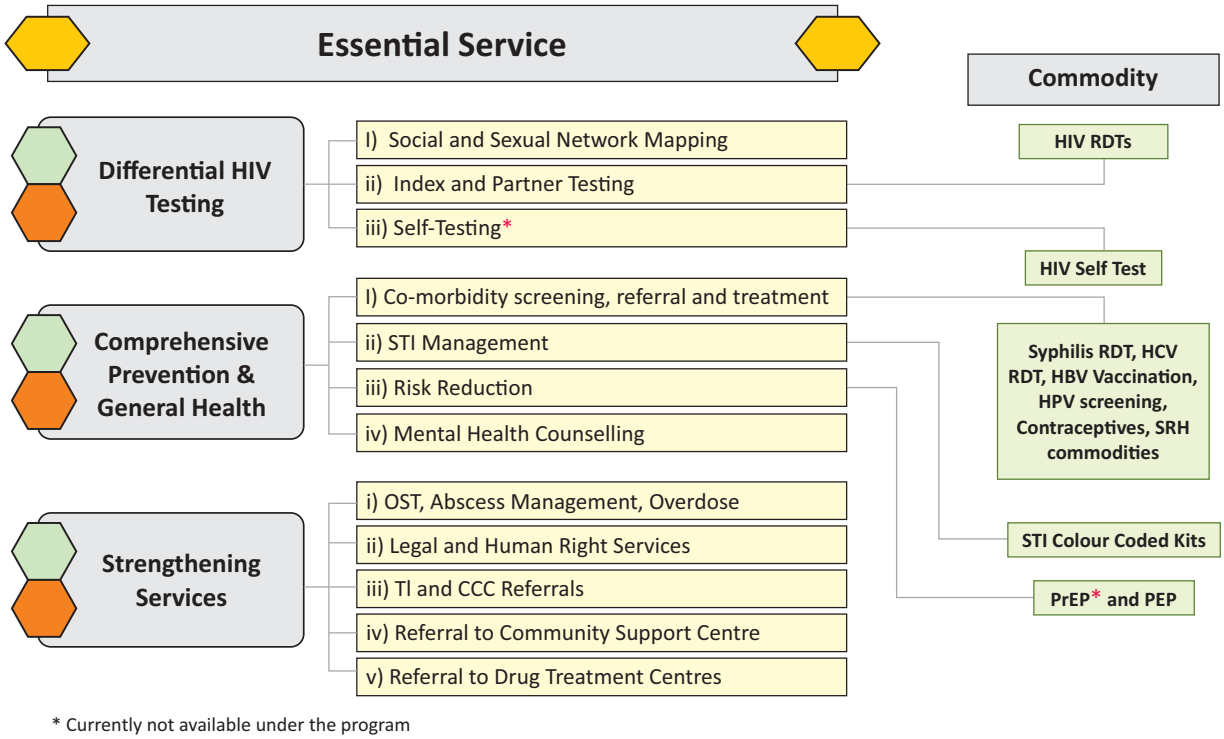
Since it is in immersion learning approach, final operational guidelines are yet to be developed. Content that we mention in this chapter has to be sanitized to meet general principles and have a shelf life irrespective of changing operational flow.

Comprehensive Service Package under SSS

The details of the services offered to at-risk HIV negative population through the SSK is as below:

A. Essential Services: These are essential services that are to be provided across all SSKs and their linked centres uniformly. Figure-11.2.2 describes the essential services available at SSK

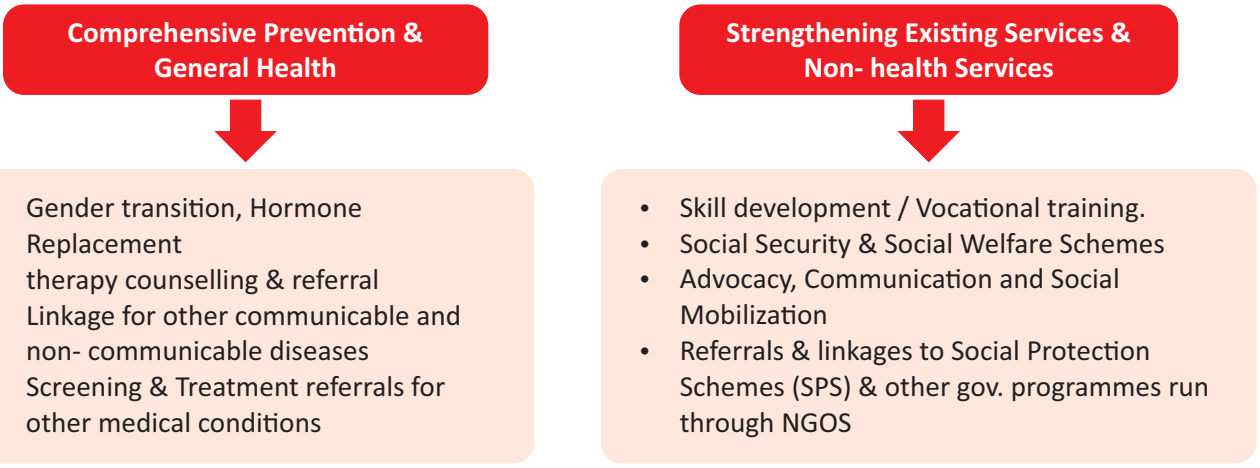
Figure 11.2.2: Essential Services at SSK



* Currently not available under the program

B. Desirable Services (Non-Exhaustive): These are heterogeneous services tailored to the client-based needs at each SSK. The list of such services has been provided in the SACS implementation plan for respective states. Figure-11.2.3 describes the desirable services available at SSK

Figure 11.2.3: Desirable Services at SSK



For the Client Flow at ICTC remodelled as SSK and the Client Flow at DSRC remodelled as SSK, refer to Annexure-12 and Annexure-13 respectively.

Sampoorna Suraksha Ready Facilities

It is being increasingly felt that the sporadic distribution of at-risk individuals and groups, who do not identify themselves with any of the HRGs or BPs and are not willing to be associated with any of the traditional prevention programmes, are required to be covered with preventive counselling and testing services through differential strategy, and also are not currently covered by existing SSKs. Hence, the districts that do not have a Sampoorna Suraksha Kendra during the existing and next plan or are with too vast or challenging geographies to be covered through a single Sampoorna Suraksha Kendra, will be considered for the process of assessment of the facilities which can be re-modelled as Sampoorna Suraksha Kendra. Shortlisted ICTCs and DSRCs in these districts will be assessed for their readiness to initiate such Sampoorna Suraksha centre. The existing Counsellor and Lab Technician of the facilities will manage these centres and implement the Sampoorna Suraksha Strategy as well as provide the services to such at-risk individuals who are tested HIV negative.

11.3 Link ART Centres (LAC)

Link ART Centres (LAC) in the public health facilities are set up to make ART accessible near the client's residence. The goal of the LAC 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, need for long travel distance and cost to the patients. These centres are linked to a nodal ART centre and function as its outreach units. The main functions of LACs include monitoring PLHIV on ART, drug refill to clients on ART, treatment of minor OIs, identification and management of adverse effects and reinforce adherence on every visit. Table-11.4.1 describes the functions of the Link ART Centre.

Table-11.4.1: Functions of Link ART Centre

1. ARV drug refill
2. Monitoring of PLHIV on ART
3. Counselling on adherence, nutrition & positive prevention
4. Treatment of OI based on capacity
5. Identification of adverse effects of ARVs
6. Tracing of MIS/LFU cases
7. Screening for TB symptoms on every visit and documentation
8. Psychosocial support to PLHIV
9. Back referral to nodal ART centre as per specified criteria at every 6 months, or earlier if required

Most of the LACs are ICTCs and thus are part of HIV confirmatory facilities. However, there are a few LACs situated at sites, other than ICTC, such as TI-NGO, OST, Prisons and OCS. These LACs may be optimized for providing HIV screening services for high-risk /at-risk clients visiting the facility as well as for index testing.

For further details on LAC, please refer National Operational Guidelines for ART Services, 2021

11.4 Care and Support Centres (CSC)

A Care and Support Centre is a community-based service delivery point which serves as an extension of treatment services for providing care and support to enhance retention by providing counselling, psychosocial support, outreach activities, linkages to welfare schemes and enabling environment for PLHIV.

Care and support centres (CSC) may be optimized as HIV screening sites. At these delivery points, HIV screening particularly index testing may be provided.

The line list of PLHIV should be shared with CSC on regular basis for:

- Active follow- up for the Index Testing for discordant couple, at least bi-annually as part of HIV treatment services
- Active follow- up for SNS through the sexual, injecting or social networks, even if index testing services have been offered.
- The process of HIV testing and reporting at LAC and CSC will remain same as discussed earlier in chapter 2.

11.5 Referrals and Linkages for Services under NACP around HCTS

Context

Individuals entering the HCTS ecosystem of NACP, are offered a wide spectrum of services for HIV prevention, testing, linkage to treatment and care. These services are met by effective linkages to various service providers. The service delivery should be implemented, ensuring the human rights of people infected and affected by HIV in line with the provisions of the HIV and AIDS (Prevention and Control) Act, 2017.

In addition, HCTS also gives cognizance to the special needs of individuals who are at-risk or high-risk for HIV and STI. These needs are met through integrated service delivery packages via robust referrals and linkages, in coordination with related national health programmes.

Furthermore, NACP phase V aims to expand the scope of various HIV related services in a cost-neutral manner through collaboration with the public and private sectors. In this context, the already established convergence with other national health programmes and existing government schemes would be strengthened. Similarly, convergence with other related line ministries will be enhanced through mainstreaming and partnership for provision of HIV services and referral for additional health/ social services available under these ministries.

Referral in context with HIV prevention, counselling and testing, is the process by which immediate and long-term needs of the client for care and supportive services are assessed, and prioritized. Referral should also include follow-up efforts to facilitate contact with care and support service providers.

Linkages are the connections facilitated by the counsellor or any other health care worker between a service provider and a client as per the assessed need is defined as a linkage.

Navigation support is needed by clients for ongoing engagement in the referral and linkage services. The navigation support under the program is provided through the Outreach Worker, Peer Educator, and if needed by the counsellor, etc.

Key referral and linkages for ICTC:

Referrals and linkages, could be in-referrals, for clients being referred to the ICTCs or out referrals, for clients being referred from the ICTC to other health facilities. While referral provides the client with information about referral services, linkages ensure that the client is able to successfully access the referred services.

In Referrals to ICTC

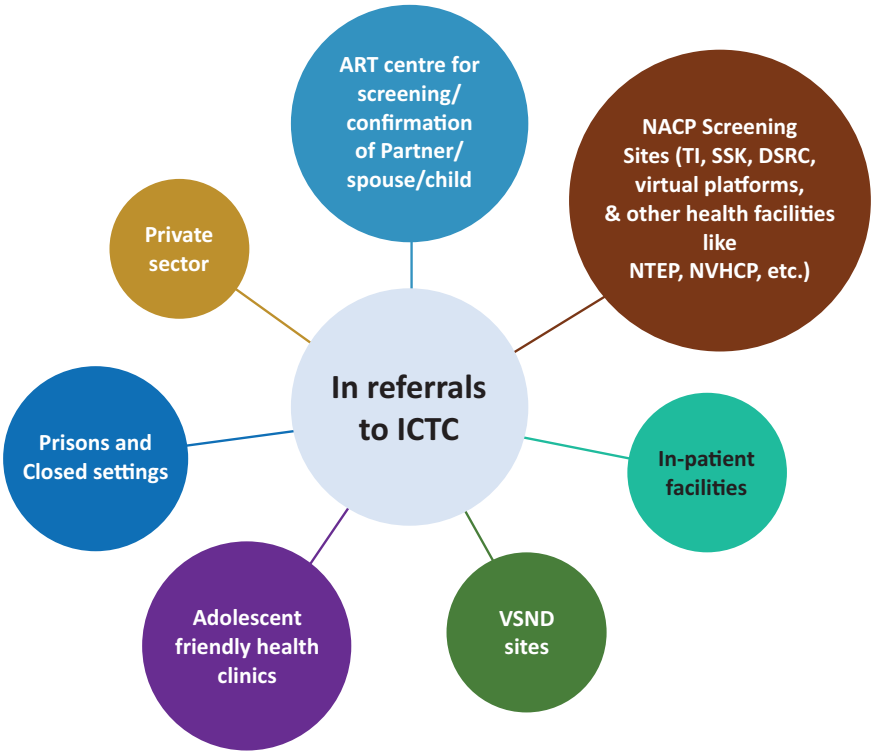
ICTC receive numerous clients referred for screening or confirmation of HIV infection, besides the walk-in clients. The client reaches the ICTC with a referral slip given by the screening site. Refer to Annexure-14: Referral/Linkage slip for the HIV Counselling & Testing Services.

The following facilities refer clients to confirmatory sites for HIV confirmation:

1. **VHSND Sites:** refer pregnant women who test screened HIV reactive.
2. **NACP Screening sites:** refer clients who test screened HIV reactive at TI NGOs, SSK, DSRC, virtual platforms and other health facilities like NTEP, NVHCP, etc.
3. **Prisons and Closed settings:** all prisoners and people living in closed and incarcerated stings are regularly screened for HIV/ STI/ Hepatitis B and C and TB. Clients who test screened HIV reactive are referred for confirmation.
4. **ART centre:** refers Partners, Spouses and Biological Children of PLHIV registered at their centre. If the ART centre is providing Index testing at their centre, then the HIV reactive clients are referred for confirmation of infection.
5. **In-patient facilities:** refer admitted clients for screening and confirmation of HIV.
6. **Adolescent friendly health clinics:** refer adolescents with history of risk behaviour.
7. **Private sector:** private hospitals and private practitioners, refer persons with clinical suspicion of HIV or persons with a HIV confirmed report. A HIV report from an ICTC is essential to register in the program and avail the HIV care and treatment services.

All clients referred to ICTC undergo the counselling and testing process explained in the previous chapters of the guidelines. Figure-11.5.1 depicts the various types of in-referrals received by ICTC.

Figure 11.5.1: In-Referrals to ICTC



Out Referrals from ICTC

Referrals from the confirmatory sites is based on the HIV result of the person and the risk categorization by the counsellor. A HIV-positive person will be referred and linked to an ART centre or a LAC Plus centre at the earliest. HIV negative persons will be assessed for risk of HIV, STI, Hepatitis B and C and TB infections and accordingly counselled and referred.

Following are the common out referrals and linkages initiated from the ICTC:

1. **ART Centre/ LAC Plus centre**: All persons, including pregnant women, detected HIV-positive at ICTC should be immediately referred to the nearest ART centre/LAC plus and information should be updated in IIMS/ SOCH. Referral is initiated through a Triplicate referral format. For co-located ART Centres, a mechanism for accompanied referral to ART centre (e.g. counsellor, ORW, volunteer etc) should be established. For non-co-located ICTC, where possible, and if acceptable to the PLHIV, peer navigation should be encouraged to support PLHIV in linkage and early case management. For HIV-positive pregnant women, services of outreach worker, and for key population, peer navigators should be utilized to ensure linkage with ART centre. After the HIV-positive person is registered at the ART centre, the ART centre counsellor should provide the feedback in IIMS/SOCH.

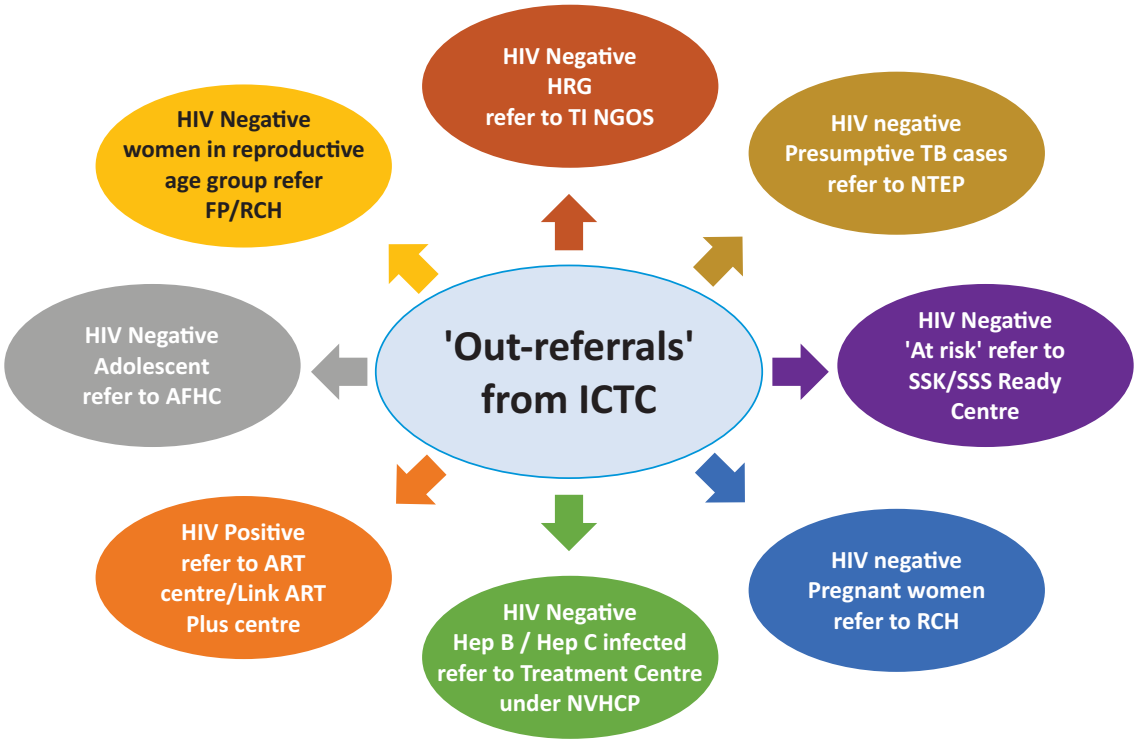
   NACP counsellor posted at ICTC should thereafter make a list of PLHIV who are not registered at the ART centre and follow them up by phone/ home visits. This follow up should be coordinated by DISHA /JD (BSD) at SACS. It should be ensured that all PLHIV, including HIV-positive pregnant women get registered and initiated on ART.

2. **HIV-negative PWID are referred to TI NGOs** for linking for the harm reduction services.
3. **HIV-negative Presumptive TB** cases referred to NTEP centres for further TB evaluation.

4. **HIV-negative at-risk clients** are referred to SSK/SSS Ready Centre for registration and follow-up.
5. **HIV-negative HRGs are referred to TI NGOs** for registration and follow-up.
6. **HIV-negative Pregnant women** are referred to RCH services for ante-natal care.
7. **HIV-negative and Hepatitis B and C infected persons** are referred to Treatment Centre under NVHCP.
8. **HIV-negative Adolescent are referred** to Adolescent Friendly Health Clinics.
9. HIV-negative Women in reproductive age group are referred to Family Planning or RCH services based on their needs.

Other referrals include linking to Drug Deaddiction or Rehabilitation Centres, Religious Groups/Faith Based Organization and Youth Organisations, (NGOs/CBOs). Figure-11.5.2 depicts the various types of out-referrals initiated by Confirmatory sites.

Figure 11.5.2: Common Out-Referrals from ICTC



Process of Linkage

The process of linkage flows through a series of steps starting from assessing the need and priority of the individual, to facilitation, linkage and documentation of the referral. The counsellor or other staff at HCTS or other facilities should make a list of the services required based on findings from counselling of the clients and PLHIV. Further, the service providers are identified, listing is prepared of the Point of Contact persons at facility. Follow up with the client on completion of linkage and feedback for the quality of the service/s. For any drop-out case or clients not availing the service/s, the clients should be reached out to identify the specific barrier or challenge for the same and provide additional assistance and information whenever needed.

Social Protection and Social Welfare Services in the context of HIV

- Social protection is viewed with great importance for reducing vulnerabilities and to mitigate the impact of HIV. PLHIV face various vulnerabilities such as: job insecurity, loss of livelihood, poor access to health care facilities, low access to nutritional support, loss of education for children, issues of identity and lack of support for orphan and semi-orphan children, losing a house and/or family, if WLHIV.
- Self and social stigma and discrimination diminishes the social support system for the PLHIV. The burden by increased illness, loss of job and income, rising medical expenses, depletion of savings and other resources, food insecurity, psychological stress and social exclusion further worsen the socioeconomic condition of PLHIV.

The Health Care Provider under the program should be aware of the inclusive as well as exclusive Central Government or State Government Social Protection and Welfare schemes, for people infected and affected by HIV and AIDS. Necessary referrals to these schemes should be provided for them.

CHAPTER-12

Optimization of HCTS under NACP for integration with health systems

Optimization of HCTS under NACP for integration with health systems

Background

NACP phase V has a vision of integrating HIV services, including HIV testing services, with a range of other relevant clinical services, such as those for TB, viral hepatitis, sexually transmitted infections, maternal and child health, sexual and reproductive health, primary health care and harm-reduction programmes for people who inject drugs, etc. The primary purpose of such integration is to make HIV testing services more convenient for people accessing health facilities for other reasons and to increase the uptake of HIV testing. Integration needs to be appropriate in all epidemic settings and is especially of importance, in regions where the HIV prevalence is high and should be designed according to the focus populations and context.

12.1 HIV and STI/RTI services

Sexually transmitted infections (STI) are infections that spread primarily through sexual contact. These infections can also be transmitted from an infected mother to her infant (vertical transmission) during pregnancy, at-labour and through blood products and tissue transfer. More than 50% of cases of all STIs may be asymptomatic (without any symptom). Therefore, absence of signs/symptoms does not guarantee that a person is free from STI. An asymptomatic infection can be transmitted to the sexual partners and lead to complications and associated with sequelae. A person may also be infected with more than one STI at a time. The term 'STI' is usually used in place of 'STD' (refers to sexually transmitted diseases) to indicate that infections do not always result in a disease.

The term reproductive tract infections (RTI) refer to any infection of the reproductive tract. In women, it includes infections of vagina, cervix, uterus, fallopian tubes and/or ovaries and may also involve external genitalia. In men, it may involve testes, epididymis and/or prostate but may also involve external genitalia. Some RTI are caused in the same way as STI. But RTI can also be caused by overgrowth of normal organisms in the reproductive system (e.g., bacterial vaginosis) or they could be infections caused by improper medical procedures such as catheterization, termination of pregnancy or IUD insertion. However, practices like douching, multiple sexual partners and inconsistent condom use are also associated with increased risk of RTI.

Not all reproductive tract infections are sexually transmitted, and not all sexually transmitted infections are located in the reproductive tract.

The names of common STI/RTI are mentioned in table-12.1.1.

Table 12.1.1: Common STI/RTI and their causative agent

Causative Agents	Name of STI/RTI
Viral	• HIV • Genital Herpes (HSV) • Genital Warts (HPV) • Hepatitis A • Hepatitis B • Hepatitis C
Bacterial	• Syphilis • Gonorrhea • Chlamydia • Bacterial Vaginosis • Chancroid • Granuloma Inguinale • Mycoplasma genitalium infection
Protozoal	• Trichomoniasis
Fungal	• Vulvovaginal Candidiasis
Infestations	• Pubic Lice • Scabies

Relationship between STI/RTI and HIV

- HIV can also be transmitted through sexual route and is an STI.
- Presence of STI/RTI facilitates the risk of HIV acquisition and transmission as a result of breach of protective mucosal barriers and increased recruitment and activation of susceptible immune cells at the site of infection.
- Immune dysregulation among PLHIV results in reduced protective response against STI/RTI.
- Presence of STI/RTI may result in increase in HIV viral load in blood, plasma and genital fluids and decrease in CD4 cells.
- STI and HIV appear to exist in a bi-directional pathogenic relationship where presence of one infection can accelerate disease progression of the other infection.
- Local inflammation of genital-reproductive tract due to STI/RTI increases HIV infectiousness as a result of increased viral shedding.
- The manifestations of STI/RTI among people living with HIV may be unusual, atypical, or severe. STI/RTI co-infections in PLHIV are associated with significant risk of complications and increased sexual-reproductive morbidity and sequalae for the person and their sexual partners.
- Sign, Symptoms and Syndromes of STI/RTI

- A symptom is what a client/patient complains about or reports to a doctor or a counsellor.
- A sign is the observation of a doctor on examination of a client/ patient.
- A syndrome refers to a set of medical signs and symptoms that are correlated with each other and often associated with a particular disease or disorder.

The common symptoms of STI/RTI are mentioned in Table-12.1.2.

Table 12.1.2: Common Symptoms of STI/RTI in Males, Females and Transgender Persons

Anatomical Part	Symptom
Oral (With history of oral sex)	• Blisters or ulcers in mouth, tongue, and lips • Sore throat, • Voice changes, difficulty in speaking or shortness of breath
Male Genitalia	• Urethral Discharge • Burning/ pain during urination • Increased frequency of urination • Genital Itching • Swelling in groin area/ scrotal swelling • Blisters or ulcers on the penis, foreskin, urethral meatus, and urethra • Genital Warts
Female Genitalia	• Unusual Discharge from Vagina • Abnormal or heavy vaginal bleeding • Genital Itching • Pain while having sex (dyspareunia) • Lower abdominal pain (below belly button/ pelvic pain) • Blisters or ulcers on internal/external genitals • Genital Warts
Anal/peri-anal area	• Anal discharge (with history of receptive anal sex) • Blisters or ulcers on anus or surrounding area • Pain while passing stools • Anal or peri-anal Itching • Anal/peri-anal warts
Generalized Symptoms/ presentation	• Fever, body ache, muscle pain, dark-coloured urine, infertility
Note: • The signs, symptoms, and syndromes of STI/RTI among transgender persons correspond to their current anatomy and physiology as well as their engagement in risky behaviour. • Adequate history taking is important to understand the symptoms of transgender persons. The history should involve the sexual behaviour as well as the details of the gender affirmation procedures.	

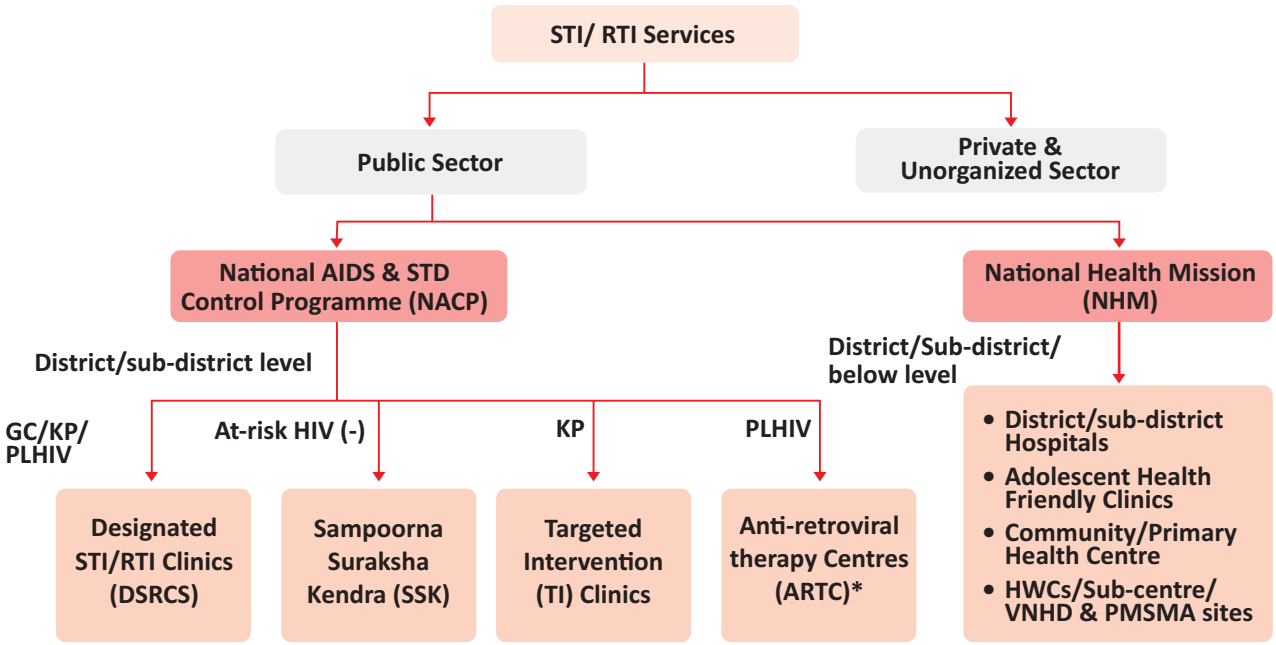
STI/RTI Services Delivery Framework

The STI/RTI services are delivered across the entire spectrum of health systems. The services are delivered through following:

1. Public Sector (through NACP, NHM Facilities and Tertiary Care Hospitals)
2. Private Sector (including unorganized sector)

While the services under NACP phase V are largely delivered up to district and sub-district level, the services under NHM are delivered across the spectrum of facilities ranging from sub-centre/ health and wellness centre to district hospitals. The services are also delivered through specialized tertiary care hospitals including medical colleges. Figure-12.1.1 describes the service delivery framework for STI/RTI services.

Figure 12.1.1: Service Delivery Framework for STI/RTI Services



GC: General Clients; KP: Key Population; PLHIV: People living with HIV

**Screening & Referrals of PLHIV for STI/RTI services*

For further details on the service delivery framework for STI/RTI service, refer to following:

- Sampoorna Suraksha Strategy- Operational Guidelines under NACP phase V
- Standard Operating Procedures, Preventive and Clinical Services for High-Risk Groups and Bridge Population under National AIDS and STD Control Program

For further details on case management and syndromic management of STI/RTI please refer National Technical Guidelines on Sexually-transmitted infections and Reproductive tract infections, 2024.

12.2 HIV and RCH services

The National AIDS and STD Control Programme phase V aims towards achievement of elimination of vertical transmission of HIV and syphilis. The National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) recommends universal screening of all pregnant women for HIV and Syphilis. Moreover, the universal screening of pregnant women for Hepatitis B (HbsAg) is recommended under National Viral Hepatitis Control Program (NVHCP).

A) Screening of HIV and Syphilis

- All pregnant women should be screened for HIV and Syphilis in the first trimester (preferably at the first ANC visit). The testing and treatment algorithms for syphilis are to be followed as prescribed in the EVTHS Guidelines.
- The screening can be conducted using HIV and Syphilis Dual Rapid Diagnostic Testing (Dual RDT) kits. If Dual RDT is unavailable, separate point-of care (PoC) test kits for HIV and syphilis, or laboratory based Rapid Plasma Reagin (RPR) or Venereal Disease Research Laboratory (VDRL) tests for Syphilis may be used for screening.
- The screening of pregnant women is undertaken in facilities providing antenatal care (ANC) services, such as in Village Health Sanitation and Nutrition Day (VHSND) or Health and Wellness Centres (HWC) etc, as well as labour rooms (for direct-in-labour cases). These facilities should be adequately supported by the nearest HCTS facilities.
- If pregnant women are at-risk or high-risk of HIV and Syphilis infection, the screening should be repeated in third trimester and at-labour.
- The additional criteria for repeat testing for syphilis in pregnancy are:
- Pregnant women who live in areas with high prevalence of Syphilis among pregnant women (>1% sero-positivity).
- Testing at the time of delivery in cases where the partner was not tested/managed?.
- Pregnant women with a history of repeated abortions, stillbirths or past history of delivery of premature babies or neonatal deaths.
- All pregnant women with unknown HIV and Syphilis status must be screened in the labor room, and appropriate linkages must be established for subsequent confirmation, care and treatment.
- The availability of HIV and Syphilis screening kits should be ensured at facilities providing ANC services such as VHSND/ HWC/ PHC/ CHC/ FRU and labour room. There should be adequate provision for maintaining the cold chain throughout supply chain.
- The reporting of HIV and Syphilis screening in HMIS/RCH portal-ANMOL/SOCH should be ensured by nurses and data entry operators (as per the job responsibility).

B) Linkages of HIV reactive cases. (By ANM/Nurses)

- If any pregnant woman is screened reactive for HIV, then the ANM should write on the MCP card "Referred to ICTC" and refer the pregnant woman to ICTC. This will ensure proper management of the pregnant women and reducing the risk of vertical transmission. This would facilitate timely initiation of antiretroviral therapy (ART) for the woman to improve her own health and reduce the risk of transmission to her infant.

- If confirmed positive for HIV, then ensure linkage to nearest ART Centre. This may be ensured by ANM following up with the pregnant women or by the counsellor of the confirmatory facility.
- The institutional delivery of the infected pregnant woman and initiation of ARV prophylaxis for the new borne to be ensured within first 72 hours of birth.
- The ANM will continue providing stigma free ANC to pregnant women with HIV, as per Extended Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) guidelines.

C) Linkages of Syphilis reactive cases (By ANM/Nurses)

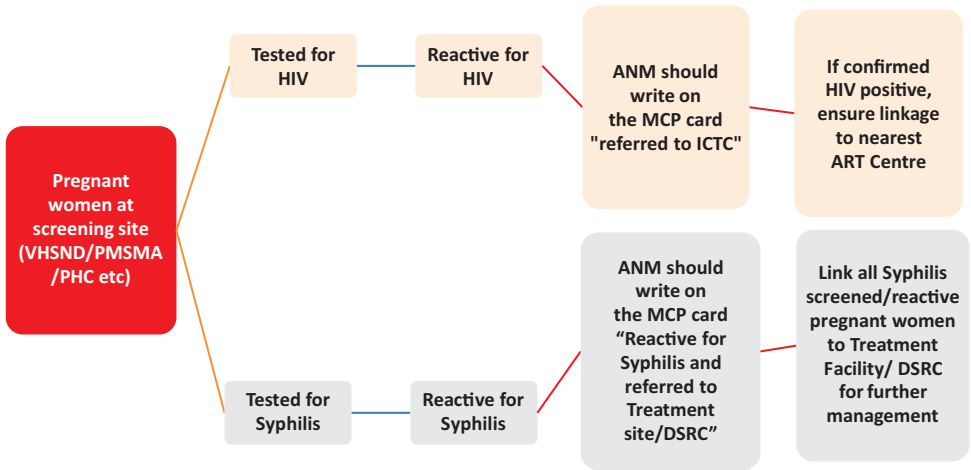
- If any pregnant woman is found reactive for Syphilis, then the ANM should write "Reactive for Syphilis" on the MCP card and refer the pregnant woman to the nearest facility with availability of injection Benzathine Penicillin.
- Ensure administration of at-least one dose of injection benzathine penicillin G to all the pregnant women screened reactive for Syphilis at the nearest treatment facility (any facility including DSRC with availability of injection benzathine penicillin).
- Link all Syphilis reactive pregnant women to confirmatory sites for confirmation. All women screened reactive/ confirmed for syphilis should receive complete treatment with Injection Benzathine Penicillin G at the nearest treatment facility (including DSRC) as per National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis (EVTHS).
- Ensure institutional delivery of the pregnant women with Syphilis and assessment of the exposed infant at birth by a paediatrician.

D) Follow up on all Reactive cases (HIV and Syphilis)

- All pregnant women referred to other HIV services including ART Centre, should be tracked to ensure that they are appropriately linked to the treatment services, and have been registered at the respective centre.
- All the pregnant women screened reactive for Syphilis should be followed for complete treatment. The treatment response should be monitored after 3 months/ in 3rd trimester/at-labour (whichever is earlier) of completion of treatment at DSRC/treatment facility.

Figure-12.2.1 describes the Care Cascade for Pregnant Women at screening sites.

Figure 12.2.1: Care Cascade for Pregnant Women at screening sites



E) Screening and Management of Viral Hepatitis B in pregnancy

- Screen all pregnant women for HbsAg during first contact with health care system, preferably during the first trimester.
- The screening can be conducted 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).
    - All HBsAg positive pregnant women must be categorised as 'High-risk Pregnancy'.
    - The 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.
    - Ensure counselling and referral of the pregnant women to the nearest designated Treatment site under NVHCP for further management.
    - The infected pregnant women should 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.

For further reading for management of Hepatitis B infection in pregnancy, refer to MOHFW. Technical Guidelines for management of Hepatitis B. New Delhi ;2019 Available from: https://nvhcp.gov.in

12.3 HIV and RMNCAH+N

Health Education and Counselling for Sexual and Reproductive Health are provided for school children and adolescents, through the following programs

- **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. Designated "Health and Wellness Ambassadors" shall educate school children on health promotion and disease prevention information on eleven thematic areas including HIV and STI.
- **Adolescent Education Program and Red Ribbon Clubs:** Engagement with youth through Adolescent Education Programs and Red Ribbon Clubs, which promote awareness, education and prevention of HIV and STI.
- **Adolescent Friendly Health Services** are delivered through trained service providers at Adolescent Friendly Health Clinics (AFHC), located at PHCs /CHCs/District Hospitals and Medical Colleges.

    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

12.4 HIV and TB

Tuberculosis (TB) is the leading cause of death among PLHIV. The early diagnosis of TB is critical for reducing the mortality/morbidity among PLHIV. The Ministry of Health and Family Welfare, Government of India, through the NACP and the NTEP (National Tuberculosis Elimination Programme) is systematically implementing HIV/TB collaborative activities across the country. The National Framework for HIV/TB Collaborative Activities aims to significantly reduce the morbidity and mortality due to HIV and TB co-infection through prevention, early detection and prompt management of both HIV and TB.

A) NACP-NTEP Coordination Mechanisms and Activities at HIV Counselling and Testing Services:

Systematic TB screening should be integrated and offered at all HIV testing facilities and to all populations receiving HIV testing, irrespective of their test results. Intensified TB case finding in clinical and outreach settings will facilitate early detection of HIV associated TB and linkage to treatment. Table-12.4.1 enumerates the definitions of Presumptive TB cases

Table 12.4.1: Definitions of Presumptive TB cases

1. **Presumptive Pulmonary TB** refers to a person with any of the symptoms and signs suggestive of TB, including cough for 2 weeks or more, fever for 2 weeks or more, significant weight loss, hemoptysis, any abnormality in chest radiograph.
    - Note: In addition, contacts of bacteriologically confirmed TB Patients, PLHIV, diabetics, malnourished, cancer patients, patients on immune-suppressants or steroid should be regularly screened for sign and symptoms of TB
    - The following are also to be investigated as presumptive PTB
    - Contacts of Bacteriologically confirmed TB patients having cough of any duration
        - Presumptive /confirmed extra-pulmonary TB having cough of any duration
        - HIV-positive patient having cough of any duration
2. **Presumptive Extra Pulmonary TB** refers to the presence of organ-specific symptoms and signs like swelling of lymph node, pain and swelling in joints, neck stiffness, disorientation, etc., and/ or constitutional symptoms like significant weight loss, persistent fever for 2 weeks or more, and night sweats.
3. **Presumptive Paediatric TB** refers to children with persistent fever and/ or cough for 2 weeks or more, loss of weight*/ no weight gain and/ or history of contact with infectious TB cases**.

    * History of unexplained weight loss or no weight gain in past 3 months; loss of weight is defined as loss of more than 5% body weight as compared to highest weight recorded in last 3 months.

    ** In a symptomatic child, contact with a person with any form of active TB within last years may be significant

4. **Presumptive Drug Resistance TB (DRTB)** refers to the patient who is eligible for Rifampicin resistant screening at the time of diagnosis or/and during the course of treatment for DSTB or H mono/poly. This includes following patients:
    - All Notified TB patients (Public and private) - Follow-up positive on microscopy including treatment failures on standard first line treatment and all oral H mono/poly regimen
    - Any clinical non-responder including paediatric (if specimen available)

B) NACP-NTEP Coordination Mechanisms and Activities at TB diagnostic facilities:

Similarly, routine HIV screening should be offered to all adult, adolescents and paediatric patients with presumptive and diagnosed TB.

Linkage of Presumptive TB

Linkage of presumptive TB cases from HCTS facilities to TB diagnostic facilities and TB diagnostic facilities to HCTS facilities should be recorded in SOCH or the information management system of the program, and track the individuals through the process of TB or HIV diagnosis and initiation of treatment. The staff of HCTS facilities and TB diagnostic facilities should participate in monthly HIV/TB coordination meetings at the district level to validate line-lists and monthly HIV/TB reports and to promptly resolve operational issues, if any.

For further details for TB management in PLHIV, refer to National Guidelines on HIV care and Treatment 2021.

12.5 HIV and Viral Hepatitis

Viral hepatitis is an inflammatory disease of the liver due to viral infection and can be caused by five known hepatitis viruses namely Hepatitis A, B, C, D and E (HAV, HBV, HCV, HDV and HEV). HAV and HEV are transmitted through faecal-oral route, present as jaundice and are prone to outbreaks. HBV is mostly transmitted from mother to child and HCV is mostly transmitted through unsafe injection practices. Chronic HBV and HCV are silent diseases, but if left untreated, may lead to cirrhosis and liver cancer. Therefore, prevention, early diagnosis and treatment are essential to combat viral hepatitis. The natural history of both HIV and HBV or HCV is affected when a person is co-infected. This may lead to rapid progression and complications, affect the management of hepatitis and may require modification in the regimen of anti-retro viral drugs.

Testing of hepatitis B and C

Screening serological tests and molecular tests are required to establish a diagnosis of Hepatitis C (HCV) and Hepatitis B (HBV) for evaluation for further management.

(i) Screening test: Rapid diagnostic test

- HCV: Anti HCV antibody test (anti-HCV)
- HBV: HBV surface antigen test (HBsAg)

(ii) Molecular test: Viral load testing

- HBV DNA: For decision on treatment
- HCV RNA: For confirmatory test

NACP and NVHCP Coordination mechanism

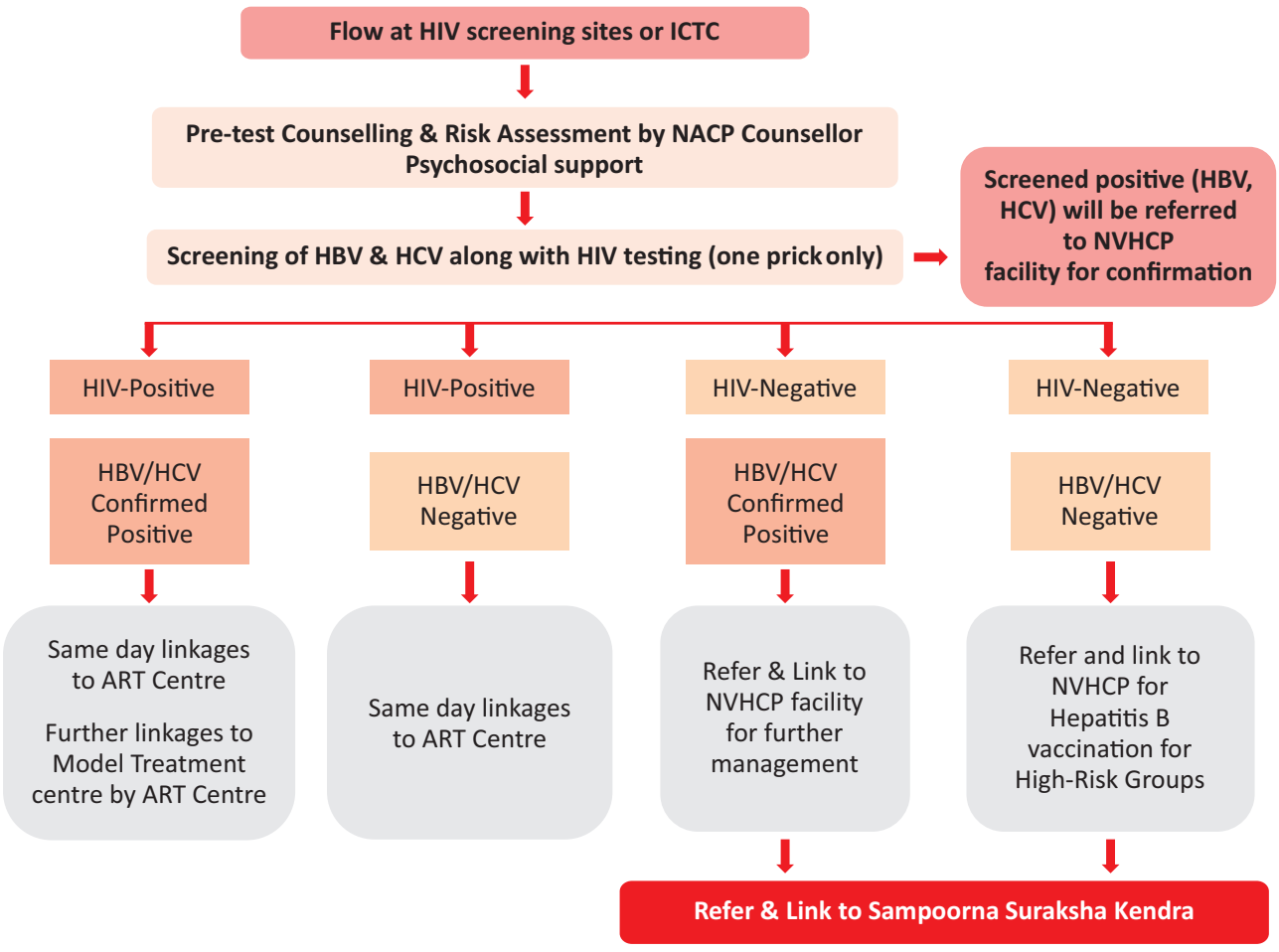
The NACP and NVHCP framework has been developed for the different stakeholders like programme managers at National, State & District level, health care workers from all cadres at the tertiary, secondary and primary level institutions like policy makers, bilateral partners and stakeholders including public and private sector to strengthen the NACP and NVHCP collaborative activities for expanding the services to all in need including the HRGs and PLHIV.

Screening of HIV, Hepatitis B and C at ICTC

- After informed consent, risk factor assessment and pre-test counselling, conduct testing for HIV, Hepatitis B and C at the ICTC or through the testing facility in the general system through single prick method. Screening for HIV, HBV and HCV should be done in a single prick using RDTs by a trained LT.

Figure-12.5.1 Describes the screening flowchart for Hepatitis B & C at NACP facilities

Figure 12.5.1: Screening flowchart for Hepatitis B & C at NACP facilities



Referral to the Designated health facilities for Hepatitis B and C. (treatment centres/model treatment centres)

- Explain the meaning of the antibody positive HCV test or antigen positive HBV (HbsAg) test and counsel on the need for quantitative HBV DNA and HCV RNA testing.
- Explain HCV is a curable disease with treatment of 12 weeks (84 days), extendable to 168 days in severely complicated cases.
- Explain HBV is manageable with lifelong treatment and all clients who are positive may not require treatment.
- Discuss the importance of minimizing risk behaviours to avoid transmitting HBV and HCV infection to others, and encourage notification and screening of needle sharing and other risk factors.
- Index testing for needle sharing partners for Hepatitis C and biological children for Hepatitis B.
- Clients must be provided with the NVHCP referral slip available at the ICTCs and ART centres.
- In case a client has co-infection of HIV and HBV and/or HCV, they should be referred to the ART centre. Further, it will be the responsibility of the ART centre to link the client to a model treatment centre under the NVHCP.
- Explain to the client about how co-infection of HIV with HBV or HCV may deteriorate their health despite taking ART regularly and lead to rapid deterioration in liver function. Also, inform the client that their ARV regimen may need modification in case of co-infection.
- HBV or HCV positive clients should be referred to the treatment centres/model treatment centres under the NVHCP, depending on their condition. The treatment centres are located at designated district hospitals and sub-district hospitals, CHCs, and PHCs, while the model treatment centres are in designated medical colleges/tertiary care hospitals. All co-infected cases of HIV-HBV, HIV-HCV and HIV-HBV and HCV should be referred to the model treatment centres as it is important for a hepatologist to evaluate the condition and function of the liver before treatment. (list available at www.nvhcp.mohfw.gov.in)
- Once a client reaches the relevant centre, they should meet with the physician/medical officer and they will be managed as per the NVHCP guidelines.

Reporting and Recording:

- ICTC will be responsible for data entry pertaining to HIV into SOCH and for hepatitis B and C into SOCH portal referral module and coordinate with district nodal officer NVHCP for uploading data on NVHCP MIS Portal
- For clients being referred to the designated mapped model treatment site, these sites will be responsible for data entry pertaining to Hepatitis B and C into the NVHCP MIS portal.

For further details on Management of Viral Hepatitis refer to NVHCP guidelines, available at https://nvhcp.gov.in

For further reading on Management of Viral Hepatitis in PLHIV, refer to 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

12.6 HIV and Drug Use

The National AIDS and STD Control Programme (NACP) under Ministry of Health & Family Welfare, Government of India has continuously evolved to respond to the changing dynamics of the HIV epidemic and the need of the times. Under NACP phase V, National AIDS Control Organisation (NACO) is committed to identify innovative strategies and institutional linkages to address the population at-risk to end the AIDS epidemic by 2030.

Drug use tends to produce effects that are long lasting and diverse, resulting not only in adverse physical and mental health consequences, but also in poor quality of life, strained family and social relations and negative impact on the community at large. People who use drugs/inject drugs (PWUD/PWID) are at higher risk of acquiring various diseases like Tuberculosis, HIV, Hepatitis and STIs compared to the general population due to various factors like lowered immunity, increased risk of exposure to infections due to unsafe injection practices, high-risk sexual behaviours under influence of drugs, poor hygiene practices due to pre-occupation with substance use, etc.

Comprehensive Harm Reduction Package for People Who Inject Drugs (PWIDs)

1. Needle and syringe program (NSEP)
2. Opioid substitution therapy (OST)
3 HIV counselling & Testing (HCTS)
4. Antiretroviral therapy (ART)
5. Prevention and treatment of sexually transmitted infections (STIs)
6. Condom promotion for PWIDs and their sexual partners
7. IEC for PWIDs and their sexual partners
8. Vaccination, diagnosis and treatment of viral hepatitis
9. Prevention, diagnosis and treatment of tuberculosis (TB).

A Technical Working Group with representation from NACO, MOSJE, NISD, NTEP, DDAP, IRCA, NMHP and NVHCP was constituted to guide the development of a strategy document on Integrated package of services for PWUDs. The objective of the integrated package of services is "to provide person-centred prevention, diagnostic, treatment and rehabilitation services for people who use drugs". The guidance document on Integrated Package of Services for People Who Use Drugs (PWUDs) has been developed as a joint effort between NACO, MOHFW and MOSJE to serve as a guidance document to the different stakeholders within and outside MOHFW with respect to convergence, linkage and standardization of the minimum service packages for the PWUD including PWID population.

National Programs providing services for PWIDs

1. National AIDS and STD control Program (NACP)
2. National Action Plan for Drug Demand Reduction (NAPDDR)
3. National Program for Tobacco Control and Drug Addiction Treatment (NPTCDAT)
4. National Viral Hepatitis Control Program (NVHCP)

5. National Mental health Program (NMHP)
6. National Tuberculosis Elimination Program (NTEP)

Service Facilities under the National program

1. OST/ICTC/ART/DSRC under NACP.
2. Integrated Rehabilitation Centre for Addicts (IRCA)/ Outreach Drop-In Centre (ODIC)/ Community Peer Led Intervention (CPLI)/ Addiction Treatment Facility (ATF) under NAPDDR.
3. Drug treatment clinics (DTC) and Tobacco Cessation Centre (TCC) under NPTCDAT.
4. CHC/District Hospitals/Medical Colleges under NVHCP.
5. District Hospitals/PHC under NMHP
6. TB Treatment centres under NTEP.
7. Private facilities like NGO/CBOs/private rehabilitation & de-addiction centres, etc

References for Section-V

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SECTION VI: Cross Cutting themes

Section VI of the National HIV Counselling and Testing guidelines has three chapters

Chapter 13: The chapter Supply Chain Management of commodities under NACP, explains the guidance about Commodities under HCTS and managing the commodities.

Chapter 14: The chapter on Legal and Ethical Issues, is focused on the provisions of the HIV and AIDS (Prevention and Control) ACT 2017. The chapter covers the important definitions under section-2 and key provisions under the remaining sections of the HIV and AIDS (Prevention and Control) ACT 2017.

Chapter 15: The chapter on Monitoring and Evaluation Framework of HCTS services describes the various aspects of data generation and data protection in context with the HIV and AIDS (Prevention and Control) ACT. It also gives an overview of the three programme monitoring systems of Health Management Information System (HMIS), Reproductive and Child Health (RCH)/ANM Online (ANMOL) portal of the National Health Mission (NHM) and the SOCH portal of the NACP. It further describes in detail the key monitoring indicators of HCTS services, important mechanisms for ensuring data quality and use of data generated.

CHAPTER-13

Supply Chain Management of commodities under NACP

Supply Chain Management of commodities under NACP

Background

Supply chain management of essential health commodities, involves a series of activities to guarantee the continuous flow of products from the manufacture to end users. Effective supply management and inventory control avoids stock out, over stocking (warehousing space issue, expiry of the commodities, damage due to non-monitoring, increase the number of stock transfer, theft, etc.) and ensures that adequate availability of the desired commodities is maintained. Supply chain ensures that the right commodities such as HIV Test Kits and consumable, Syrup Nevirapine and Zidovudine, DBS Cards and collection kits, are selected based on client needs; so that appropriate quantities of commodities are forecasted and procured. Supply Chain Management also ensures rational distribution of the commodities nationally, post procurement

13.1 Commodities under HCTS

Key Commodities required for effective HIV Counselling and Testing Services:

1. RDT kits for HIV at screening facilities
    - Dual (HIV and Syphilis) RDT for screening of pregnant women, key population, Prison and OCS, DSRC attendees
    - WBFPT for HIV screening for TB clients
2. Kits for ICTC (with different principles)
    - HIV kit 1
    - HIV Kit 2 and
    - HIV kit 3
3. Kits for HIV confirmatory test in children less than 18 months
    - EID diagnostic kits
    - Dried Blood Sample (DBS) Cards
4. Accessories
    - Consumables to collect samples such as gloves, needle/syringe, cotton, spirit etc
    - Other consumables for packaging and transportation of sample of DBS cards or sample for quality control

13.2 Managing the HCTS Commodities

1. Diagnostic HIV kits

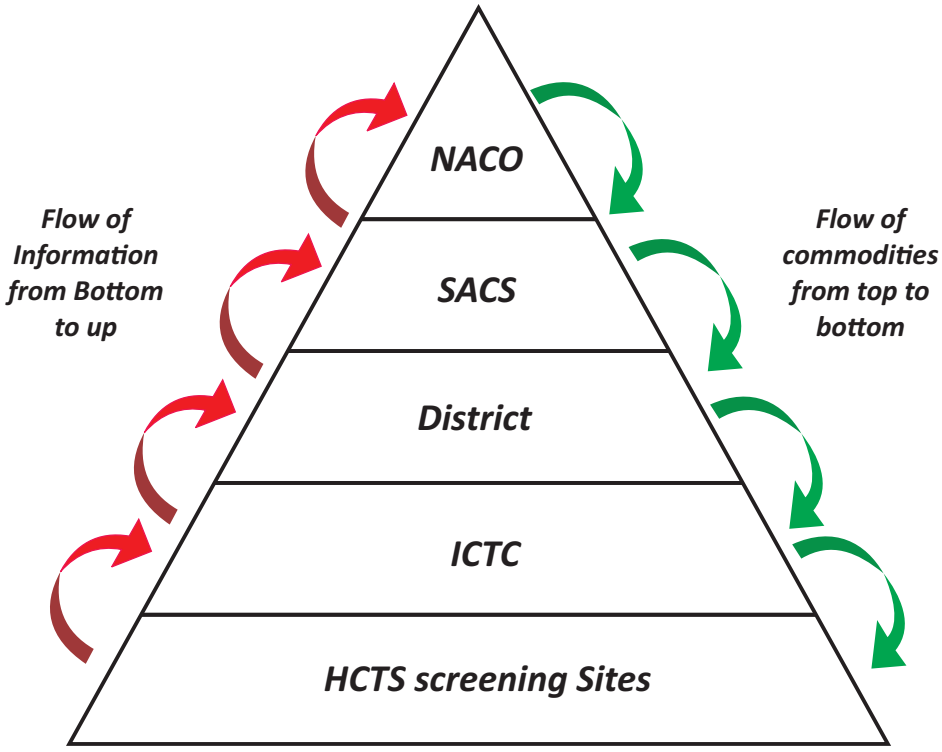
Diagnostic HIV kits will be supplied by NACO except dual (HIV and Syphilis) RDT kits for pregnant women testing. The Dual (HIV and Syphilis) RDT kits for pregnant women screening will be supplied by state NHM. Quality assurance of HIV kits should be done as per the guidelines mentioned in chapter 10.

For HIV testing Kits, the supply will be delivered to the walk in coolers directly from the suppliers. Further, distribution from the walk-in coolers to the screening/confirmatory facilities or in field will be arranged by SACS. The diagnostic kits should be supplied ensuring cold chain as per manufacturer's recommendation.

Consumables for blood collections or sample packaging should be arranged by the health facilities wherever possible. The consumables which are not available at health facilities should be provided by SACS.

Figure-13.2.1 describes the Supply Chain Management at each of the levels in HCTS supply chain hierarchy

Figure 13.2.1: HCTS Supply Chain Management (SCM) at different levels



Store Management

Always remember and practice

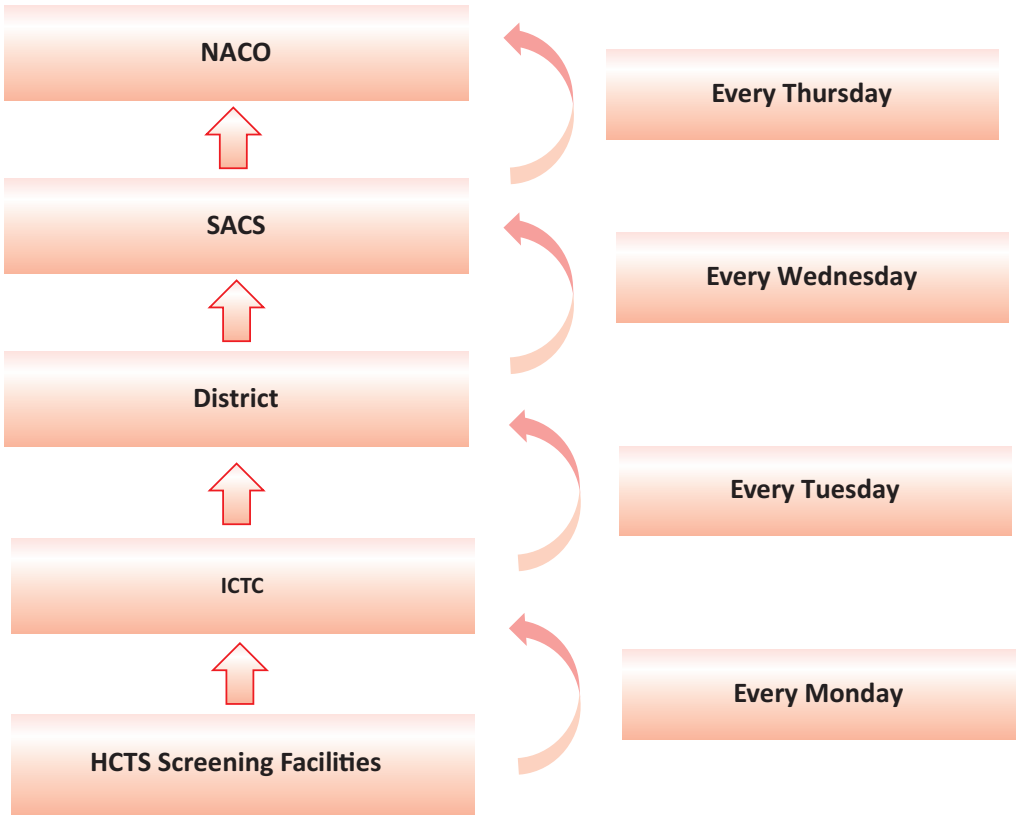
- Clean and disinfect storeroom regularly
- Store supplies in a dry, well-lit and well-ventilated storeroom, out of direct sunlight
- Secure the storeroom from water penetration

- Ensure that fire safety equipment is available and accessible, and that personnel are trained to use it
- Stored commodities should be kept away from electric motors and fluorescent lights
- Maintain adequate temperature in the storage area as specified in the technical specification of the cold chain commodities. For example, the HIV test kits should be stored at temperature between 2 to 8 °C at all level.
- Keep high value products/commodities in a locked place
- Store flammable products separately using appropriate safety precautions
- Store HIV Testing Kits and other commodities supplied separately, away from insecticides, old files, chemicals, office supplies and other materials
- Arrange cartons so that arrows point up, and ensure that identification labels, expiry dates, and manufacturing dates are visible to ensure FEFO (First expiry first out) principle is followed without any fail.

Reporting, review and prompt follow up action on status of commodities

The reporting structure for all HCTS facilities is reflected in the figure-13.2.2.

Figure 13.2.2: Reporting structure for HCTS facilities for stock status



For example: By Monday (say 28th March 2022), HCTS Screening Facilities will submit stock status for the previous week to ICTC. By Tuesday (29th March 2022), ICTC will submit a consolidated stock status of previous week to District HIV centre. District HIV centre will consolidate details of all ICTC and

share details of district level stock to SACS by Wednesday (30th March, 2022). SACS will in turn share the consolidated state level details with NACO by Thursday (31st March, 2022) of every week.

All HCTS facilities should also update daily stock status details in IIMS/SOCH without any fail. This will lead to real time data fetching and assist in early decision making.

It is necessary to ensure that an appropriate feedback mechanism is established for efficient functioning of all HCTS facilities.

1. NACO must share its feedback with SACS on all the important parameters
2. SACS can further provide feedback to Districts as well as HCTS screening and confirmatory facilities
3. District can also disseminate their feedback to all screening sites and ICTC
4. HCTS confirmatory facilities (ICTC) can provide feedback to HCTS screening facilities

For further reading refer to SOP for Supply Chain Management under NACO, MOH & FW, 2021; available at: https://naco.gov.in/sites/default/files/Standard%20Operating%20Procedures%20for%20SCM%20under%20NACP.pdf

CHAPTER-14

Legal and Ethical issues

Legal and Ethical issues

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 health care 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 acts.

14.1 Important definitions under section 2 of the HIV and AIDS (Prevention and 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 health care setting perspective.

Section 2 (a):

"AIDS" means Acquired Immune Deficiency Syndrome, a condition characterised 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.

14.2 Key Provision in Section 3, 4, 5, 6, 7, 8, 9, 11, 19, 20, 21, 23 and 24

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 the Context of HIV was notified by the Government of India on 4th July 2022.

Guidelines on Informed Consent in the context of HIV:

Manner of obtaining informed consent:

(1) Informed consent should always be preceded by provisioning of adequate information or counselling in which the risks and benefits are informed to the client in detail and, therefore the permission is based on an adequate understanding of the advantages, risks, potential consequences and implications of availing the HIV services.

(2) Informed consent given by the person or protected person is documented as his signature or thumb impression in the appropriate records.

(3) The permission is entirely on discretion of the client which can never be implied or presumed, and the permission can also be withdrawn at the client's discretion.

(4) No protected person should be subjected to medical testing, medical treatment, medical

interventions or research, except with the informed consent of such person or his representative.

Consent for individuals below the age of 18 years:

(1) In case of individuals below eighteen years of age, informed consent should be obtained from their parents or guardians or care-taking institutions or non-governmental organisation (NGO) and if there is no parent or guardian, then the local legal authority may grant permission for availing HIV services.

(2) In case the permission is sought from parents or guardians or care-taking institutions or non-governmental organization (NGO), such permission shall be termed as consent.

(3) For the purposes of these guidelines, a person below the age of eighteen years, but not below twelve years, who has sufficient maturity of understanding and who is managing the affairs of his family affected by HIV and AIDS, shall be competent to act as guardian of other sibling below the age of eighteen years for–

(a) admission to educational establishments; (b) care and protection; (c) treatment; (d) operating bank accounts; (e) managing property; or (f) any other purpose that may be required to discharge his duties as a guardian.

- Consent for non-ambulatory individuals.– In case of non-ambulatory sick individuals on treatment in a health care facility who requires HIV related services but is not in a position to visit the service delivery point or personally sign the register, the health care provider can sign the on behalf of the person after obtaining his or her or their verbal consent.
- Consent for patients in coma.–

  (1) In case of individuals in coma, informed consent should be obtained from their family or parents or guardians or care-taking institution, or non-governmental organisation (NGO).

  (2) If there is no parent/guardian, then the local legal authorities may grant permission for availing HIV services.

  (3) The relevant person or organisation providing consent shall also be responsible for signing the counselling register.

  (4) In case the permission is sought from parents or guardians or care-taking institution or non-governmental organisation (NGO), such permission will be termed as consent.

Manner of conducting Pre-test counselling:

(1) Pre-test counselling is provided to the individual before HIV testing using posters, flip charts, brochures and short video clips or any other communication means available so as to prepare her or him or them for the HIV test and to address myths and misconceptions regarding HIV or AIDS.

(2) Pre-test counselling may be done in two ways – (a) one-on-one counselling and (b) group counselling and one-on-one counselling should be done for all individuals accessing services.

(3) Group counselling can be done when the counsellor is addressing a group, such as, pregnant women at Ante Natal Clinic.

(4) The contents of pre-test counselling should include providing information on HIV or AIDS, window period, route of transmission, prevention message, care, support and treatment services.

(5) Pre-test counselling should include:

(a) discussion on HIV, risk factors and prevention methods;

(b) explaining the meaning of positive and negative test results and their implications;

(c) assessing the patient's personal and social supports;

(d) determining the patient's readiness to cope with test results;

(e) discussing disclosure of test results to others; and

(f) advising the patient, if reporting positive test results to health authorities is required.

(6) The benefits of HIV testing, right of individual to opt out of HIV testing without affecting access to any other health services should be explained to individuals.

(7) During pre-test counselling along with risk assessment, information should be provided on importance and benefits of spouse or partner testing.

(8) An opportunity shall be given to the individual to ask and clarify their doubts.

Manner of conducting Post-test counselling:

(1) Post-test counselling should prepare the individual to understand and cope with the HIV test result.

(2) Individual post- test counselling should be conducted irrespective of whether the result is HIV non-reactive, HIV-negative, HIV-Indeterminate or HIV-positive.

(3) Post-test counselling should include:

a. informing the patient of the results and meaning of the test results;

b. providing education about avoiding risks of sexual and injection drug exposures; and, for patients who test positive;

c. assessing the impact of test results for the patient and family;

d. explaining treatment options;

e. discussing partner counselling and disclosure of test results to others;

f. an explanation of test results and initiating a support and treatment plan;

g. risk reduction counselling, information about window period and retesting; and

h. risk assessment and importance and benefits of spouse or partner testing.

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:

i. 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 healthcare 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 healthcare 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, healthcare 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 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 healthcare 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

For further reading refer to 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

CHAPTER-15

Monitoring and Evaluation Framework of HCTS services

Monitoring and Evaluation Framework of HCTS services

15.1 Background and context with the HIV and AIDS (Prevention and Control) Act, 2017

The National AIDS and STD Control Programme (NACP) generates considerable amount of data on HIV and AIDS from service facilities across the country through the Information Management Systems, Research Projects, HIV Sentinel Surveillance, etc. NACO encourages the use of this data for evidence-based programme planning, research etc., at all levels under the programme.

The HIV and AIDS (Prevention and Control) Act, 2017 has come into force and according to the Act, every facility keeping records of HIV infected and affected population is mandated to adopt adequate data protection measures. Section 11 of the Act is clearly describes maintaining confidentiality of HIV related information the onus lies at all levels to ensure that no data or information is shared without the proper procedure and necessary approvals and consent.

15.2 Data Generation

Data generation activities under strategic information (SI) systems of NACP, are Program Monitoring, Surveillance & Epidemiology, and Research & Evaluation. These activities complement each other and have in-built mechanisms for data protection and sharing, quality assurance, analysis-interpretation-dissemination, while complying with the provisions of the HIV and AIDS (Prevention and Control) Act, 2017. Figure-15.2.1 depicts the Data generation activities under the Strategic Information systems of NACP-V.

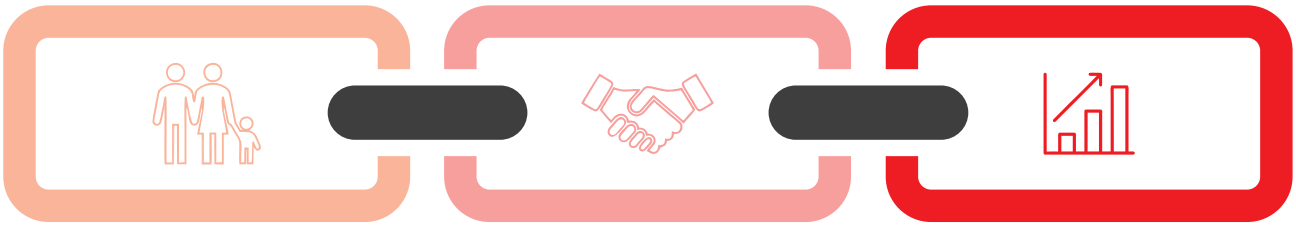
Figure 15.2.1: Data generation activities under strategic information systems of NACP-V



15.3 Overview of M & E framework for HCTS

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 HCTS, 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-15.3.1).

Figure 15.3.1: HCTS-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.

Each of the systems has been briefly summarized below:

A. HMIS

The Ministry of Health and Family Welfare, Government of India, uses a web-based HMIS portal to monitor all of its health programs. The portal captures 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.

HMIS Portal facilitates the flow of physical performance from the facility level to the Sub-District, District, State and National level using a web-based Health Management Information System (HMIS) interface. The data includes HIV and Syphilis testing among individuals who availed NACP service in these facilities.

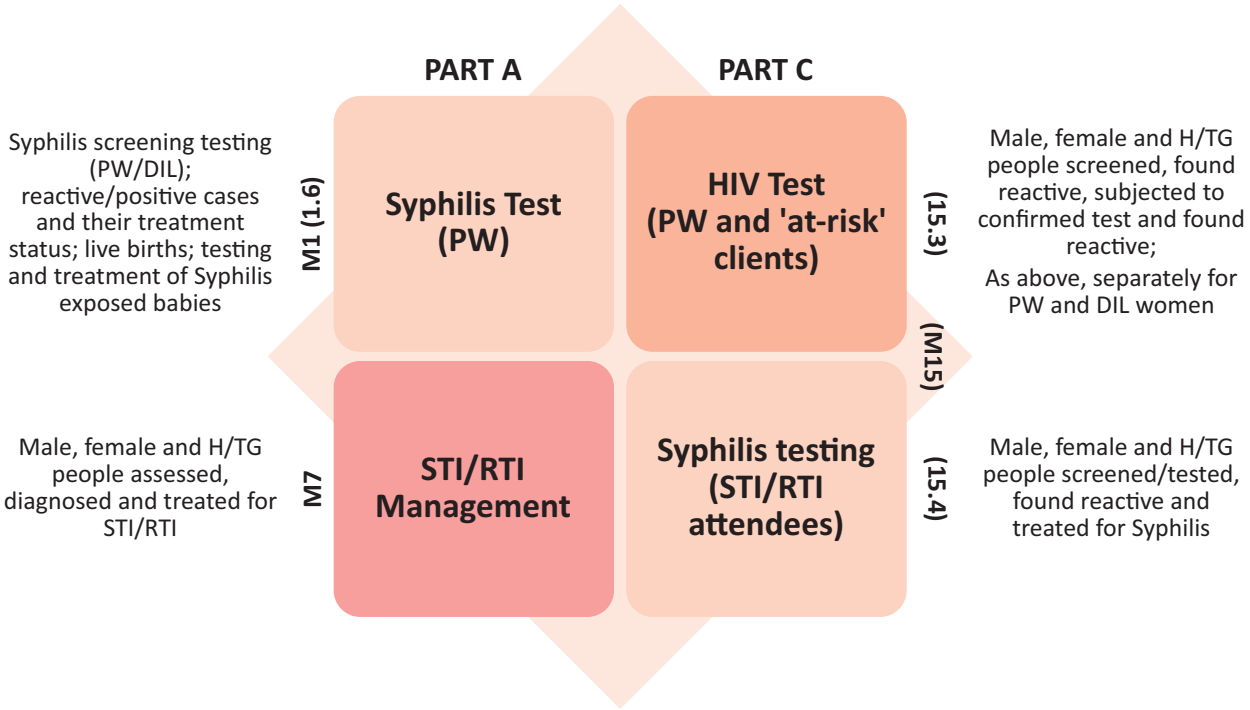
The HMIS format collects the information on the NACP indicators such as HIV and Syphilis testing/ screening of Male, Pregnant and Non-Pregnant Female and H/TG persons. HMIS format included 45 NACP indicators to be reported in the above said sections. Office order has been issued to All States/ UTs from NACO to use the HMIS format for reporting HIV Screening information from the HCTS site. (Annexure-15: Office Memorandum number- Z-17 01810412.01 5INACO (Monitoring & Evaluation), Government of India, Ministry of Health and Family Welfare, National AIDS Control Organisation, dated 28th July 2023).

The order clearly mentions the following actions:

1. Complete transition of the reporting for NACP-related indicators from the facility screening sites through HMIS. No reporting from the screening sites shall be now done through the SOCH Mobile App.
2. Inclusion of the monthly performance of the NACO'S supported. ICTC and Designated STI/RTI Clinics (DSRCS) in the HMIS report of the health facility. ICTC and Designated STURTI Clinics (DSRCS) under NACO would continue to do the reporting in SOCH.
3. Engage with a suitable officer of NHM in your State/UT for the creation of the login credential for the SACS SI officer in the HMIS portal.
4. Close monitoring of the NACP related data reported in the HMIS portal by the SI team and related program divisions at SACS. If any data quality issues (non-reporting or otherwise) are observed, the same may be shared with the concerned State HMIS team, with a copy to the NACO's SI-M&E Team.

NACP-related indicators captured in HMIS are depicted in Figure-5.3.2

Figure 15.3.2: NACP-related indicators captured in HMIS



For further details, refer to HMIS portal: https://hmis.mohfw.gov.in/#!/

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 it's 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 the data entered. ANMOL is currently operational in most of the States except a few.

Integration process of ANMOL with SOCH is ongoing, for data entry of reactive cases, following screening of pregnant women for HIV and Syphilis in pregnant women.

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 outcomes. The system will integrate into the overall IT/ MIS landscape of MoH&FW by having API-based linkages that intersect with the HIV continuum.

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 HCTS, SOCH is operational at the Integrated Counselling and Testing Centres (ICTC), Designated STI/RTI Clinics (DSRC), Anti-Retroviral Therapy (ART) Centres, Early Infant Diagnosis (EID) laboratories and Viral Load (VL) laboratories.

Integration of the Data information systems for HCTS services

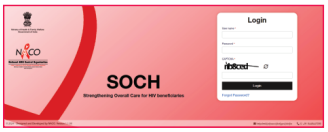
While aggregated data reported through HMIS will be the primary data source for measuring the progress on indicators of ANC visits and HIV and Syphilis screening/testing, the EVTHS indicator framework strongly encourages engagement with the persons-based digital health information system of the RCH portal/ANMOL App augmenting the quality of data with better handling of issues like double counting. Further details may please be seen at https://rch.nhm.gov.in/RCH/

Data flow for HCTS in HMIS, RCH and SOCH

HMIS capture health services related data from all public and private facilities registered under HMIS. It also captures around 50 indicators related to HCTS. The RCH portal is primary community-based data reporting system designed to capture RCH related services. The SOCH portal under NACP captures comprehensive data related to HIV and Syphilis.

RCH and SOCH captures line list details of each beneficiary while HMIS is a month wise cumulative data from each facility. The summary of the data flow related to HCTS is described in figure-5.3.3.

Figure 15.3.3: Summary of Data flow related to HCTS services

Data Portal			
Type of data	Line List	Consolidated	Line List
NACP related Data variables captured	HIV and Syphilis Testing, treatment, Prevention services, Comorbidities, Referral	HIV and Syphilis Testing, linkages to treatment	HIV and Syphilis Screening during pregnancy
Facilities reporting	NACP facilities (ICTC, DSRC, ARTC, TI, OSTC)	All Public and Private facilities registered in HMIS including ICTCs	Community level data entry of RCH
Data entry personnel	Module wise: NACP facility staff	Facility Staff assigned by State/District Authority	ANM
Integration	Integration of SOCH with ABHA ID and various related portal of MoHFW (such as HMIS, RCH, Nikshay) are under process		

15.4 Components of the HCTS monitoring indicator framework

The following are the components of the HCTS monitoring indicator framework:

1. HCTS Indicators
2. EVTHS indicators
3. DSRC Indicators
4. HRG and Bridge Population Indicators
5. Index testing Indicators
6. Outreach services Indicators
7. Prison and other closed setting indicators
8. TB screening and testing

Key programme monitoring Indicators for HCTS services are enlisted in Table-15.4.1. For the comprehensive list of indicators for HCTS services, please refer annexure 16.

Table 15.4.1: Key programme monitoring Indicators for HCTS services

Testing Details of clients other than pregnant women					
1	**ICTC Testing Indicators for clients other than pregnant women**				
No	**Indicator**	**Numerator**	**Denominator**	**Source**	**Reporting Frequency**
1.1	Percentage of at-risk clients identified at the ICTC	Number of at-risk clients identified based on risk assessment	Total number of clients underwent risk assessment	SOCH	Monthly
1.2	Percentage of clients who have been tested for HIV	Number of clients tested for HIV during the reporting period	Annual target during the reporting period[1]	N: SOCH D: Annual Target provided by NACO	Monthly
1.3	Percentage of clients confirmed HIV-positive	Number of clients confirmed HIV-positive during the reporting period	Number of clients screened for HIV during the reporting period	SOCH	Monthly
1.4	Percentage of clients tested for Syphilis	Number of clients screened for Syphilis during the reporting period	Total number of HCTS attendees (excluding pregnant women) during the reporting period	SOCH	Monthly
1.5	Percentage of clients found syphilis reactive	Number of clients found syphilis reactive during the reporting period	Number of at-risk clients (excluding pregnant women) screened/tested for Syphilis during the reporting period	SOCH	Monthly
2	**Indicators for HIV and Syphilis Screening[2] at all sites (other than pregnant women)**				
2.1	Percentage clients screened for HIV at screening and confirmatory Sites	Number of clients Screened/tested for HIV at all Sites (ICTC, all screening sites) during the reporting period	Annual target during the reporting period[3]	N: HMIS D: Annual Target	Monthly

1. Refer to state and population wise targets provided
2. Refer to figure number 2.2.2
3. Refer to state and population wise targets provided

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
2.2	Percentage of clients screened HIV reactive	Number of clients found reactive at screening sites during the reporting period	Number of clients Screened for HIV at screening sites during the reporting period	HMIS	Monthly
2.3	Percentage of clients screened for syphilis	Number of clients screened for syphilis during the reporting period	Annual target during the reporting period[4]	HMIS	Monthly
2.4	Percentage of clients found syphilis reactive	Number of clients found syphilis reactive during the reporting period	Number of clients screened for syphilis during the reporting period	HMIS	Monthly
3	**DSRC Clients (HIV and Syphilis Screening for DSRC clients screened at ICTC)**				
3.1	Percentage of DSRC attendees screened for HIV	Number of DSRC attendees screened for HIV during the reporting period	Total DSRC attendees during the reporting period	SOCH	Monthly
3.2	Percentage of DSRC attendees screened for Syphilis	Number of DSRC attendees screened for Syphilis during the reporting period	Total DSRC attendees during the reporting period	SOCH	Monthly
HIV & Syphilis screening of Pregnant Women and HIV/Syphilis positive pregnant women					
4	**Syphilis screening of Pregnant Women at all screening sites including ICTC**				
4.1	Percentage of Pregnant Women screened for Syphilis	Number of Pregnant Women screened for Syphilis during the reporting period	Estimated Pregnant Women during reporting period	HMIS	Monthly
5	**HIV Screening of Pregnant Women from Screening Sites**				
	Percentage of Pregnant Women Screened for HIV	Number of Pregnant Women Screened for HIV during the reporting period	Annual target during the reporting period[5]	N: HMIS D: Annual targets	Monthly
6	**HIV testing of Pregnant Women at ICTC**				

4. Refer to state and population wise targets provided
5. Refer to state and population wise targets provided

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
6.1	Percentage of Pregnant Women tested for HIV at health facility where ICTC is situated	Number of Pregnant Women tested for HIV at health facility where ICTC is situated during the reporting period	Estimated Pregnant Women during the reporting period	N: SOCH D: Annual Targets	Monthly
6.2	Percentage of pregnant women confirmed HIV Positive	Number of Pregnant Women confirmed HIV-Positive during the reporting period	Number of Pregnant Women Tested at any facility	N: SOCH D: HMIS	Monthly
6.6	Pregnant WLHIV: Time of diagnosis of HIV infection				
6.7	No of Pregnant WLHIV Tested for Viral Load Testing at 32-36 weeks				
6.7.1	Percentage of Pregnant WLHIV tested for Viral Load at 32-36 weeks	Total number of Pregnant WLHIV tested for Viral Load at 32-36 weeks of pregnancy during the reporting period	Total number of Pregnant WLHIV Eligible for Viral Load Testing at 32-36 weeks of pregnancy during the reporting period	SOCH	Monthly
7	**HIV/Syphilis Exposed Babies**				
7.1	HIV Exposed Babies: Coverage of ARV Prophylaxis				
7.1.1	Percentage of HIV exposed babies received ARV Prophylaxis (NVP/ZDV)	Total number of HIV exposed babies received either single or dual ARV prophylaxis during the reporting period	Total number of live births to the Pregnant WLHIV during the reporting period	SOCH	Monthly
8	**HIV Exposed Babies: EID testing**				
8.1.	EID Testing at 42-Days (6 weeks)				
8.1.1.	Percentage of babies screened for HIV at 6 weeks	Number of babies screened for HIV between 6-8 weeks during the reporting period	Number of HIV exposed babies eligible for 6 weeks EID during the reporting period	SOCH	Monthly
8.1.2.	Percentage of babies confirmed HIV-positive using two DBS tests	Number of babies confirmed HIV positive through two DBS tests during the reporting period	Number of babies who underwent HIV testing at 6 weeks during the reporting period	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
8.1.3.	Percentage of babies confirmed HIV-positive at 6 weeks initiated on-ART	Number of confirmed positive babies at 6 weeks initiated on-ART during the reporting period	Number of babies confirmed HIV positive using two DBS test during the reporting period	SOCH	Monthly
DSRC Reporting Format					
9	**Number of patients availed STI services at DSRC**				
9.1	Percentage of at-risk clients identified at the DSRC	Number of at-risk clients identified based on risk assessment	Total number of clients who underwent risk assessment	SOCH	Monthly
9.4.	STI/RTI Syndrome diagnosed at DSRC				
9.4.1	Percentage of DSRC attendees reported with STI/RTI syndromes	Number of DSRC attendees reported with STI/RTI syndromes during the reporting period	Total number of DSRC attendees during the reporting period	SOCH	Monthly
9.4.2	Percentage of syphilis reactive provided with treatment (excluding pregnant women)	Number of eligible syphilis -reactive cases provided with treatment (excluding pregnant women) during the reporting period	Total number of syphilis reactive cases (excluding pregnant women) eligible for treatment reported during the reporting period	SOCH	Monthly
9.4.3	Percentage of people living with HIV(PLHIV) diagnosed with STI/RTI at DSRC	Number of people living with HIV(PLHIV) diagnosed with STI/RTI during the reporting period	Number of PLHIV referred to DSRC during the reporting period	SOCH	Monthly
10	**Testing Details of HRG (FSW, MSM, H/TG, PWID) and Bridge (Migrant, Transport worker) population**				
10.1	Percentage of HRG (except Prison inmates) screened for HIV	Total number of HRGs (except Prison inmates) screened for HIV either in ICTC or TI during the reporting period	Total number of HRG (except Prison inmates) active[6] during the reporting period	Program data/ SOCH	Monthly

6. Provided at least one service in six months

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
10.2	Percentage of Bridge population screened for HIV	Total number of bridge population screened for HIV either in ICTC or TI during the reporting period	Total number of bridge population contacted during the reporting period	Program data/ SOCH	Monthly
10.3	Percentage of HRG (except Prison inmates) screened for syphilis	Number of HRG (except Prison inmates) screened for syphilis during the reporting period	Total number of HRG (except Prison inmates) active during the reporting period	Program data/ SOCH	Monthly
11	**Index testing of PLHIV**				
11.1	Percentage of PLHIV offered Index Testing	Number of PLHIV offered Index testing during the reporting period	Number of PLHIV eligible for index testing during the reporting period	SOCH	Monthly
11.2	Percentage of contacts elicited from index cases	Number of contacts elicited	Number of PLHIV accepted for Index Testing during the reporting period	SOCH	Monthly
11.3	Percentage of contacts tested for HIV	Number of contacts tested for HIV during the reporting period	Number of contacts found eligible for testing during the reporting period	SOCH	Monthly
11.4	Percentage of confirmed HIV positive among contacts	Number of contacts identified as confirmed HIV positive during the reporting period	Number of contacts tested during the reporting period	SOCH	Monthly
12	**Outreach services**				
12.1	Percentage of unregistered HRGs (except Prison inmates) screened for HIV through Community Based Screening	Total number of unregistered HRGs (except Prison inmates) reached during camps under revamp strategy and are screened for HIV during the reporting period	Total number of unregistered HRG(except Prison inmates) reached through camps	N: SOCH D: Annual target	Monthly
12.2	Percentage of Clients Tested for HIV at mobile ICTC	Total clients Tested for HIV at mobile ICTC during the reporting period	Annual target assigned during the reporting period	N: SOCH D: Annual target	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
13	**Prison and Other Closed Setting**				
13.1	Percentage of inmates tested for HIV against estimation	Total inmates tested for HIV during the reporting period	Estimated inmates during the reporting period	SOCH	Monthly
13.2	Percentage of Inmate screened for Syphilis	Total inmates who have been screened for syphilis during the reporting period	Estimated inmates during the reporting period	SOCH	Monthly
14	**TB screening and testing**				
14.1	Percentage of clients screened for TB	Number of clients screened for TB(4S)	Total no. of ICTC attendees	SOCH	Monthly
14.2	Percentage of clients identified as Presumptive TB cases among those screened for TB	Number of clients identified as Presumptive TB cases among those screened for TB during the reporting period	Number of clients screened for TB(4S) during the reporting period	SOCH	Monthly
14.3	Percentage of clients identified as Presumptive TB case tested for TB	Number of clients identified as Presumptive TB case tested for TB during the reporting period	Number of clients identified as Presumptive TB referred for TB testing during the reporting period	SOCH	Monthly
14.4	Percentage of clients diagnosed as TB among tested for TB	Number of clients diagnosed as TB among tested for TB during the reporting period	Number of clients identified as Presumptive TB case tested for TB during the reporting period	SOCH	Monthly
14.5	Percentage of clients diagnosed as TB, put on TB treatment	Number of clients put on TB treatment during the reporting period	Number of clients diagnosed with TB during the reporting period	SOCH	Monthly
14.6	Percentage of clients completed TB treatment	Number of clients completed TB treatment during the reporting period	Number of clients put on TB treatment during the reporting period	SOCH	Quarterly

7. Mainly includes high-risk and other vulnerable population

15.5 Ensuring Data Quality & Use

The ensuring the quality of data collected poses a major challenge to M&E system which need to be addressed carefully. The data flow for collecting data involves multiple points where data quality can be verified and improved by DISHA and SACS officials. The process begins by using standardized formats and extends to conducting site visits to reporting units to verify the quality of data reported.

Clear definitions and instructions for data collection and compilation

Consistency and accuracy in data reporting requires clear written definitions and instructions that are accessible to those who are reporting in SOCH/HMIS/RCH Portal-ANMOL at facility level along with SACS and DISHA who are involved in supervising the facility data reporting. A Standardized Monthly Progress Report (MPR) is downloadable in SOCH for routine monitoring of data at various levels for SACS nodal point persons.

15.6 Training and supportive supervision for staff

The M&E focal person at DISHA should ensure that the reporting unit level person/staff responsible for data reporting, should receive proper training (hands-on training) on the data reporting tool and its functionality to maintain the quality of data. The State M&E officer should ensure every field level staff responsible for data reporting are trained. Regular joint training should be provided to the facility level staff through a structured schedule of induction and refresher training.

The regular field visits by DISHA and SACS officer to provide hand holding and supportive supervision to be planned on a regular basis. The responsible person in the facility along with the M&E focal point person at DISHA and SACS should ensure the data pertaining to NACP should be reported through SOCH as well as HMIS and to be compared across reporting sites, geographic units or over time.

15.7 Timely and regular reporting

Currently, the SOCH, HMIS and RCH Portal produces a standard report that describes the reporting performance of different reporting units and geographic areas in a defined time period. This report helps to identify reporting units that require more attention with respect to improving regularity of reporting. Units which have poor reporting records should be frequently monitored, contacted consistently and provided feedback until reporting patterns improve. The follow up on reporting timeliness is a key activity for which district level M&E officers can support SACS M&E officers.

Data Discrepancy

In addition to regular supervisory review, occasional site visits by District or State M&E officers should include a record review with data monitoring tool to ensure electronic reports have consistent data entry. The M&E officers should check a sample of reports every month and provide feedback to the responsible facility staff for immediate rectification.

Some important mechanisms for ensuring data quality would be:

- A bimonthly feedback from National SIMU to states on data quality would be communicated
- A quarterly review meeting of State SIMU at National level where the data received from states would be analysed and presented. The trends discussed and data gaps identified and communicated

- Project Directors of SACS would include a session on M&E in their review meeting with other program officers and district units to discuss the reports, analysis and trends and issues in data collection.
- A data quality validation checklist developed and used for verification of data at facility level and all SIMU staff would use it during their field visits.
- Constitution and regular meetings of an interdepartmental M&E Technical Working Group to support the M&E activities at national and state level.

Use of information from Data generated

- Data use at facility level:
  - Patient management and clinical decision making
  - Inventory management
  - Identifying gaps in treatment cascades and sub-cascades (HRG, pregnant women, children, HIV-TB coinfected etc)
  - Planning activities to address gaps in cascade and patient specific issues based on data
  - Making patient management systems more efficient to enhance retention.
- Data use at SACS Level:
  - measure the progress towards identified targets and goals and should be used for planning and mid-course corrections
  - provide feedback to the facility for improvement through positive reinforcement
  - plan for supportive supervision, guidance and mentoring of based on performance for key indicators
  - address remedial actions for indicators on which state is not performing well.
  - dissemination of information to state-level stakeholders
  - prepare annual action plans (AAP) based on data and evidence

Data use at National Levels

Data generated at national level can be analysed to determine the gaps and cascade leaks in a holistic manner. This will assist the program in program management, taking policy decisions on newer approaches or specific HIV detection campaigns and HIV prevention strategies, etc.

15.8 Data Management Guidelines

In compliance to the provisions of the HIV and AIDS (Prevention and Control) Act 2017, the facilities offering the HCTS and related services will have following contours in context of the data protection and data sharing. The data management guidelines have been formulated by NACO and shared with all the State AIDS Control Societies for implementation at facility, district, state and national level. The Data Management guidelines focus on the Data Management Committee at all levels, data protection measures, data sharing through the shared confidentiality and the exemption through Shared

Confidentiality, monitoring of protected and shared data at facility level and the Do's and Don'ts for the NACP data management at various level.

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

References for Section-VI

1. Supply Chain Management under NACO, MOH & FW, 2021; available at: https://naco.gov.in/sites/default/files/Standard%20Operating%20Procedures%20for%20SCM%20under%20NACP.pdf
2. HIV AIDS Policy for Establishments, 2022; available at: https://naco.gov.in/sites/default/files/HIV_and_AIDS_Policy_for_Establishments_2022_0.pdf
3. Standard Operating Procedure for NACP Data Management at NACO, SACS and NACP establishment; available at: http://naco.gov.in/sites/default/files/SOP_for_data_management.pdf
4. 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

Annexure 1:
WHO Clinical Staging in Adults, Adolescents and Children

Adults and adolescents	Children
Clinical Stage 1	
• Asymptomatic • Persistent generalized lymphadenopathy	• Asymptomatic • Persistent generalized lymphadenopathy (PGL)
Clinical Stage 2	
• Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory tract infections (Sinusitis, Tonsillitis, Otitis Media, Pharyngitis) • Herpes Zoster • Angular Cheilitis • Recurrent oral ulceration • Papular Pruritic Eruption (PPE) • Fungal nail infections • Seborrhoeic Dermatitis	• Unexplained persistent hepatosplenomegaly • Recurrent or chronic upper respiratory tract infections (Otitis Media, Otorrhoea, Sinusitis, Tonsillitis) • Herpes Zoster • Lineal gingival erythema • Recurrent oral ulceration • Papular Pruritic Eruption (PPE) • Fungal nail infections • Extensive wart virus infection • Extensive Molluscum Contagiosum • Unexplained persistent parotid enlargement
Clinical Stage 3	
• Unexplained severe weight loss (>10% of the presumed or measured body weight) • Unexplained chronic diarrhoea for more than 1 month • Unexplained persistent fever (intermittent or constant for longer than 1 month) • Persistent Oral Candidiasis • Oral Hairy Leucoplakia (OHL) • Pulmonary Tuberculosis • Severe bacterial infections (such as Pneumonia, • Empyema, Pyomyositis, bone or joint infection, Meningitis, bacteraemia) • Acute necrotizing ulcerative stomatitis, Gingivitis or Periodontitis • Unexplained anaemia (<8 g/dl), neutropenia (<0.5 x 10°/l) and/or chronic thrombocytopaenia (<50 x 10º/1)	• Unexplained moderate malnutrition not adequately responding to standard therapy • Unexplained persistent diarrhoea (14 days or more) • Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one 1 month) • Persistent Oral Candidiasis (after the first 6 weeks of life) • Oral Hairy Leucoplakia (OHL) • Lymph node Tuberculosis • Pulmonary tuberculosis • Severe recurrent bacterial Pneumonia • Acute necrotizing ulcerative gingivitis or Periodontitis • Unexplained anaemia (<8 g/dl), neutropenia (<0.5 x 109/1) or chronic thrombocytopaenia (<50 x 10°/1) • Symptomatic Lymphoid Interstitial Pneumonitis • Chronic HIV-associated lung disease, including • Bronchiectasis

Clinical Stage 4	
• HIV wasting syndrome • Pneumocystis (jiroveci) Pneumonia • Recurrent severe bacterial Pneumonia • Chronic Herpes Simplex infection (orolabial, genital or anorectal of more than 1 month duration or visceral at any site) • Oesophageal Candidiasis (or Candidiasis of trachea, bronchi or lungs) • Extra pulmonary Tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous system Toxoplasmosis • HIV encephalopathy • Extra pulmonary Cryptococcosis, including Meningitis • Disseminated non-tuberculous mycobacterial infection (NTM) • Progressive Multifocal Leukoencephalopathy (PML) • Chronic Cryptosporidiosis • Chronic Isosporiasis • Disseminated mycosis (extra pulmonary Histoplasmosis, Coccidioidomycosis) • Lymphoma (cerebral or B-cell non-Hodgkin) • Symptomatic HIV-associated nephropathy or cardiomyopathy • Recurrent septicaemia (including non-typhoidal Salmonella) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis	• Unexplained severe wasting, stunting or severe • malnutrition not responding to standard therapy • Pneumocystis (jiroveci) Pneumonia • Recurrent severe bacterial infections (such as • Empyema, Pyomyositis, bone or joint infection, • Meningitis, but excluding Pneumonia) • Chronic Herpes Simplex infection (orolabial or cutaneous of more than 1 month duration or visceral at any site) • Oesophageal Candidiasis (or Candidiasis of trachea, bronchi, or lungs) • Extra pulmonary Tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month) • Central nervous system Toxoplasmosis (after the neonatal period) • HIV encephalopathy • Extra pulmonary Cryptococcosis, including Meningitis • Disseminated nontuberculous mycobacterial infection (NTM) • Progressive Multifocal Leukoencephalopathy (PML) • Chronic Cryptosporidiosis (with diarrhoea) • Chronic Isosporiasis • Disseminated endemic mycosis (extra pulmonary Histoplasmosis, Coccidioidomycosis, Penicilliosis) • Cerebral or B-cell non-Hodgkin Lymphoma • HIV-associated nephropathy or cardiomyopathy
a) In the development of this table, adolescents were defined as 15 years or older. For those aged less than 15 years, the clinical staging for children should be used. b) For children younger than 5 years, moderate malnutrition is defined as weight-for-height <-2 z-score or mid- upper arm circumference ≥115 mm to <125 mm. c) Some additional specific conditions can be included in regional classifications, such as penicilliosis in Asia, HIV- associated rectovaginal fistula in southern Africa and reactivation of trypanosomiasis in Latin America. d) For children younger than 5 years of age, severe wasting is defined as weight-for-height <-3 z-score; stunting is defined as length-for-age/height-for-age <-2 z-score; and severe acute malnutrition is either weight for height <-3 z-score or mid-upper arm circumference <115 mm or the presence of oedema.	

Source: National guidelines on HIV Care and Treatment 2021

Annexure 2: e gazette HIV AIDS Act

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(राष्ट्रीय एड्स नियंत्रण संगठन)

अधिसूचना

नई दिल्ली, 17 सितम्बर, 2018

सा. का. नि. 888(अ).—केन्द्रीय सरकार मानव रोगक्षम अल्पता विषाणु और अर्जित रोगक्षम अल्पता संलक्षण (निवारण और नियंत्रण) अधिनियम, 2017 (2017 का 16) की धारा 47 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, निम्नलिखित नियम बनाती है, अर्थात्:-

अध्याय- I

प्रारंभिक

1. **संक्षिप्त नाम और प्रारंभ.**—(1) इन नियमों का संक्षिप्त नाम मानव रोगक्षम अल्पता विषाणु और अर्जित रोगक्षम अल्पता संलक्षण (निवारण और नियंत्रण) नियम, 2018 है।

(2) ये राजपत्र से प्रकाशन की तारीख से प्रवृत्त होंगे।

2. परिभाषाएं—

(1) इन नियमों में जब तक संदर्भ के अनुसार अन्यथा अपेक्षित न हो,

(क) "अधिनियम" से मानव रोगक्षम अल्पता विषाणु और अर्जित रोगक्षम अल्पता संलक्षण (निवारण और नियंत्रण) नियम, 2017 (2017 का 16) अभिप्रेत है;

(ख) "समुचित प्राधिकारी" से अभिप्रेत है;

(i) केंद्रीय सरकार के मामले में राष्ट्रीय एड्स नियंत्रण संगठन; और

(ii) राज्य सरकार के मामले में राज्य एड्स नियंत्रण सोसाइटी;

(ग) "उच्च भार जिले" से अभिप्रेत उस जिले से है जहां –

(i) प्रहरी निगरानी में प्रसवपूर्व परिचर्या में एक प्रतिशत से अधिक का प्रचलन हो; या

(ii) प्रहरी निगरानी में उच्च-जोखिम जनसंख्या में पांच प्रतिशत से अधिक का प्रचलन हो; या

(iii) एकीकृत काउंसिलिंग और समय-समय पर केंद्रीय सरकार के अधीन समुचित प्राधिकारी द्वारा अधिसूचित किए गए परीक्षण केंद्र में आम मरीजों में एचआईवी पाजिटिव राष्ट्रीय औसत से अधिक हो।

(2) इसमें उपयोग किए गए शब्दों और अभिव्यक्तियों जिन्हें इन नियमों में परिभाषित नहीं किया गया है परंतु अधिनियम में परिभाषित किया गया है, का अर्थ वही होगा जो अधिनियम में निर्दिष्ट किया गया है।

अध्याय – II

स्थापनों के लिए एचआईवी और एड्स नीति को अधिसूचित किए जाने की विधि

3. केंद्रीय सरकार के अधीन समुचित प्राधिकारी स्थापनाओं के लिए मॉडल एचआईवी और एड्स नीति को अधिसूचित करने से पूर्व इस नीति के संबंध में-

(क) एचआईवी पाजिटिव व्यक्तियों के प्रतिनिधियों सहित सभी पणधारकों;

(ख) एचवाईवी प्रभावित व्यक्तियों और संरक्षित किए गए व्यक्तियों;

(ग) स्वास्थ्य देखरेख प्रदाता;

(घ) शिक्षा, स्वास्थ्य परिचर्या सेवाएं उपलब्ध कर रही स्थापनाओं, विशेषज्ञों और एचआईवी तथा एड्स के क्षेत्र में कार्य रहे संगठनों, नियोजकों, ट्रेड यूनियनों एवं अन्य सुसंगत पणधारकों के साथ परामर्श करेगा।

4. केंद्रीय सरकार के अधीन समुचित प्राधिकारी राजपत्र में स्थापनाओं के लिए मॉडल एचआईवी और एड्स नीति अधिसूचित करेगा।

5. केंद्रीय सरकार के अधीन समुचित प्राधिकारी नियम 3 और 4 के अनुसार स्थापनाओं के लिए समय-समय पर मॉडल एचआईवी और एड्स नीति की पुनर्विलोकन करेगा तथा उसे अद्यतन करेगा।

6. (1) स्वास्थ्य देखरेख सेवाओं के उपबंधों का अनुपालन कर रही स्थापनों तथा एचआईवी के व्यावसायिक खुलासे की अत्यधिक जोखिम वाली दूसरी प्रत्येक स्थापनों में मॉडल एचआईवी और एड्स नीति लागू करने से कार्य करने में तथा अधिनियम के उपबंधों के अनुरूप परीक्षण, उपचार और अनुसंधान के लिए संसूचित सहमति के लिए सुरक्षित वातावरण उपलब्ध होगा।

(2) किसी स्थापना पर लागू मॉडल एचआईवी और एड्स नीति, जिसमें 100 अथवा उससे अधिक व्यक्ति सम्मिलित हों, चाहे कोई कर्मचारी अथवा अधिकारी या निदेशक अथवा न्यासी या प्रबंधक है, जैसा भी मामला हो, द्वारा अधिनियम के उपबंधों और इन नियमों के अनुरूप एक शिकायत समाधान तंत्र की व्यवस्था की जाएगी।

परन्तु स्वास्थ्य देखरेख स्थापनों के मामले में स्थान पर और इस उप-नियम के उपबंध इस प्रकार लागू होंगे जैसे कि "सौ अथवा अधिक" शब्दों के स्थान पर "बीस अथवा अधिक" शब्दों को रख दिया गया हो; और

7. (1) केन्द्रीय सरकार के अधीन समुचित प्राधिकारी द्वारा समय-समय पर लागू संशोधित और अद्यतन मॉडल एचआईवी और एड्स नीति को इसकी अधिसूचना होने पर प्रत्येक स्थापना द्वारा अंगीकार किया जाएगा।

(2) स्थापन में कार्यरत सभी व्यक्तियों को एचआईवी और एड्स नीति के विषय की जानकारी स्थापना के प्रभारी व्यक्ति अथवा उत्तरदायी व्यक्ति द्वारा दी जाएगी।

(3) प्रभारी व्यक्ति अथवा स्थापन हेतु उत्तरदायी व्यक्ति एचआईवी और एड्स नीति के पाठ को अंग्रेजी में अथवा कार्यरत अधिकांश व्यक्तियों द्वारा समझी जाने वाली भाषा में अथवा प्रवेश द्वार पर अथवा उसके समीप, जहां से कार्यरत अधिकांश व्यक्ति आते-जाते हैं, पर इस उद्देश्य हेतु लगाए गए विशेष बोर्डों पर प्रमुखता के साथ प्रदर्शित करेगा।

(4) स्थापन एचआईवी और एड्स नीति को समझने और इसके क्रियान्वयन के लिए कार्य करने वाले व्यक्तियों के लिए वार्षिक प्रशिक्षण सत्रों का आयोजन करेगी।

8. (1) नियम 7 के उप-नियम (3) में विनिर्दिष्ट सूचना उस रीति में कथन करेगा, जिसमें एचआईवी और एड्स नीति की प्रतियां प्राप्त की जाएंगी और स्थापन में कार्यरत अथवा सेवाओं हेतु आने वाले व्यक्ति ऐसी नीति की नि:शुल्क प्रतिलिपि पाने के हकदार होंगे।

(2) स्थापनों की एचआईवी और एड्स नीति की प्रतियां उनके द्वारा पब्लिक डोमेन में उपलब्ध कराई जाएंगी, जिनके लिए नीति उपलब्ध कराई गई है, जिसमें उनकी वेबसाइट, यदि कोई हो, और नाममात्र मूल्य पर हार्डकॉपी उपलब्ध कराना सम्मिलित है।

(3) प्रत्येक राज्य का समुचित प्राधिकारी सभी शैक्षणिक स्थापनाओं के प्रमुखों को एचआईवी तथा एड्स नीति की प्रति उपलब्ध कराएंगे, जो इन स्थापनों में प्रवेश पाने वाले विद्यार्थियों को अथवा उनके माता-पिता अथवा अभिभावकों को इन नीतियों की एक प्रति नि:शुल्क उपलब्ध कराएगा।

अध्याय – III

स्थापनाओं हेतु शिकायत निवारण प्रणाली

9. (1) सौ या इससे अधिक कर्मचारियों वाले प्रत्येक स्थापन, जिसमें कर्मचारी अथवा अधिकारी अथवा निदेशक अथवा न्यासी अथवा प्रबंधक, जैसा भी मामला हो, इस अधिनियम के लागू होने के 180 दिनों के अंदर किसी वरिष्ठ पंक्ति के व्यक्ति को, द्वारा जैसा वह उचित समझे, शिकायत अधिकारी के रूप में नियुक्त किया जाएगा, जो इन नियमों के अनुपालन में स्थापना में अधिनियम के उपबंधों के उल्लंघन की शिकायतों का समाधान करेगा।

परन्तु सौ या इससे अधिक कर्मचारियों वाले स्थापन की प्रत्येक शाखा, जिसमें कर्मचारी अथवा अधिकारी अथवा निदेशक अथवा न्यासी अथवा प्रबंधक, जैसा भी मामला हो, इस अधिनियम के लागू होने के 180 दिनों के अंदर किसी वरिष्ठ पंक्ति के व्यक्ति को, द्वारा जैसा वह उचित समझे, शिकायत अधिकारी के रूप में नियुक्त किया जाएगा, जो इन नियमों के अनुपालन में स्थापन में अधिनियम के उपबंधों के उल्लंघन की शिकायतों का समाधान करेगा।

परन्तु आगे यह कि स्वास्थ्य देखरेख स्थापनों के मामले में, इस नियम के उपबंध इस तरह से लागू होंगे जैसे "सौ अथवा इससे अधिक" शब्दों के स्थान पर "बीस अथवा इससे अधिक" शब्दों को रखा गया है।

(2) स्थापन द्वारा नियुक्ति के 30 दिनों के अंदर, रोकथाम की सूचना, देखरेख, सहयोग तथा एचआईवी संबंधित उपचार, मानव लैंगिकता, यौन अभिमुखता तथा लिंग निर्धारण, नशीले पदार्थ का प्रयोग, सेक्स वर्क, एचआईवी संभावित व्यक्तियों, कलंक तथा भेदभाव, एचआईवी पीड़ितों के साथ घनिष्ठता बनाने के सिद्धांत, जोखिम कम

करने के उपाय आदि सहित इस अधिनियम के उपबंधों पर शिकायत अधिकारियों को प्रशिक्षण दिया जाएगा। प्रशिक्षण के दौरान शिकायत अधिकारी को संरक्षित व्यक्तियों तथा एचआईवी संभावित व्यक्तियों सहित विशेषज्ञों की सहायता प्रदान की जाएगी।

10. (1) कोई भी व्यक्ति स्थापन में अधिनियम के कथित उल्लंघन की जानकारी मिलने के उपरांत तीन माह के भीतर शिकायत अधिकारी को शिकायत कर सकता है:

परन्तु शिकायत अधिकारी, लिखित में कारण अभिलेख करते हुए और तीन मास के लिए शिकायत करने की समय-सीमा बढ़ा सकता है, यदि वह संतुष्ट है कि शिकायतकर्ता कुछ परिस्थितियों के कारण निर्धारित समय में शिकायत नहीं कर सका।

(2) प्रत्येक शिकायत, इन नियमों के साथ उपबद्ध प्ररूप में, लिखित में, की जाएगी:

परन्तु यह कि जहां लिखित में शिकायत नहीं की जा सकती है, शिकायत अधिकारी, शिकायतकर्ता को सभी प्रकार की युक्तियुक्त सहायता प्रदान करेगा जिससे कि शिकायत लिखित में की जा सके।

(3) शिकायत अधिकारी व्यक्तिगत रूप में, अथवा डाक द्वारा अथवा फोन से अथवा इलैक्ट्रॉनिक रूप में शिकायत प्राप्त कर सकता है:

परन्तु यह कि स्थापन शिकायत अधिकारी नियुक्त किए जाने की 30 दिन की अवधि के भीतर समर्पित वेबसाइट, वेबपेज के माध्यम से इलैक्ट्रॉनिक रूप में शिकायत की प्राप्ति अथवा शिकायत अधिकारी को शिकायतें भेजने के लिए सरकारी ई-मेल का पते प्रदान करने की रीति तय करेगी।

(4) शिकायत अधिकारी, शिकायत की प्राप्ति पर, शिकायतकर्ता को पावती देगा और मात्र उस उद्देश्य के लिए रखे गए रजिस्टर में शिकायत दर्ज करेगा।

(5) रजिस्टर में शिकायत की प्राप्ति का समय और की गई कार्रवाई की रजिस्टर में प्रविष्टि की जाएगी।

(6) रजिस्टर में प्रत्येक शिकायत को क्रमिक संख्या दी जाएगी।

(7) शिकायत अधिकारी अधिनियम की अधीन की गई शिकायत पर उद्देश्यपरक और स्वतंत्र रीति से कार्य करेगा।

(8) शिकायत अधिकारी शिकायत पर तत्परता से और किसी भी स्थिति में सात कार्य दिवसों के भीतर निर्णय लेगा:

परन्तु यह कि आपात मामले में अथवा स्वास्थ्य देखरेख के स्थापन के मामले में जहां यह उपबंधों में भेदभाव या फिर स्वास्थ्य देखरेख सेवाओं के पहुँच अथवा सर्वाभौमिक सावधानियों के उपबंधों से संबंधित शिकायत है, शिकायत अधिकारी उसी दिन, जिस दिन उसे शिकायत प्राप्त होती है, निर्णय लेगा।

11. (1) शिकायत अधिकारी यदि संतुष्ट है कि अधिनियम का उल्लंघन हुआ है जैसा कि शिकायत में आरोप लगाया गया है-

(क) प्रथमत:, स्थापना को उल्लंघन सुधार के उपाए करने का निदेश देगा;

(ख) दूसरे, जिस व्यक्ति ने उल्लंघन किया है उसे परामर्श देगा और ऐसे व्यक्ति को एचआईवी और एड्स, अधिनियम के उपबंधों और नियमों तथा दिशा-निर्देशों, विशेषकर कलंक और भेदभाव से संबंधित प्रशिक्षण दिया जाएगा जो एक सप्ताह की अवधि का होगा और सामाजिक सेवा हेतु निर्धारित अवधि तय की जाएगी जिसमें एचआईवी और एक्वायर्ड इम्यूनोडेफिसिएंसी वायरस, संरक्षित व्यक्ति नेटवर्क हेतु कार्यरत

गैर-सरकारी संगठन के साथ कार्य करना सम्मिलित होगा, अथवा राज्य सरकार के अधीन समुचित प्राधिकारी द्वारा निगरानी रखी जाएगी और हो सकता है कि उल्लंघनकर्ता का पर्यवेक्षण करने वाले को भी ऐसा प्रशिक्षण लेना हो।

(2) उसी व्यक्ति द्वारा पुन:अधिनियम का उल्लंघन करने पर शिकायत अधिकारी, स्थापन को विधि अनुसार उसके विरुद्ध अनुशांसनिक कार्रवाई करने की सिफारिश कर सकता है।

(3) शिकायत अधिकारी, शिकायत के संबंध में की गई कार्रवाई की शिकायतकर्ता को जानकारी देगा और यदि शिकायतकर्ता की गई कार्रवाई से असंतुष्ट हो तो उसको अधिकार होगा कि वह ओम्बड्समैन के पास जाए अथवा कोई अन्य उपयुक्त विधि कार्रवाई करे।

(4) शिकायत अधिकारी, शिकायत पर निर्णय के उपरांत निर्णय की तारीख से 10 दिन की अवधि में स्थापना को तथा शिकायत से संबद्ध पक्षकारों को निर्णय के संबंध में लिखित में कारण सूचित करेगा।

12. (1) शिकायत अधिकारी सुनिश्चित करेगा कि शिकायत, इसकी प्रकार संख्या और की गई कार्रवाई की रिपोर्ट केन्द्रीय सरकार के अधीन उपयुक्त प्राधिकारी को अधिनियम की धारा 11 और इसके अधीन नियम 13 के अंतर्गत, हर छ: माह में दी जाए।

(2) शिकायत अधिकारी इस अधिनियम के नियम 13 और धारा 11 के उपबंधों के अध्ययधीन, यह सुनिश्चित करेगा कि शिकायत, शिकायत की प्रकृति, शिकायत की संख्या और की गई कार्रवाई वार्षिक आधार पर संस्थान की वार्षिक रिपोर्ट में अथवा संस्थान की वेबसाइट पर प्रकाशित हो।

13. (1) शिकायत अधिकारी, संरक्षित व्यक्ति जो किसी शिकायत का हिस्सा है, के अनुरोध पर निम्नलिखित रीति से उक्त संरक्षित व्यक्ति की पहचान के संरक्षण को सुनिश्चित करेगा, अर्थात्:

(क) शिकायत अधिकारी ऐसे दस्तावेज की एक प्रति फाइल करेगा जिसमें ऐसे संरक्षित व्यक्ति का नाम, पहचान और पहचान योग्य ब्यौरा दिया गया हो, और इसे बंद लिफाफे में शिकायत अधिकारी की सुरक्षित अभिरक्षा में रखा जाएगा;

(ख) उसके समक्ष आई शिकायतों में संलिप्त संरक्षित व्यक्ति को छद्म नाम प्रदान करेगा;

(ग) शिकायत अधिकारी के समक्ष आई शिकायतों में संलिप्त संरक्षित व्यक्ति की पहचान और उसके पहचान योग्य ब्यौरों को नियम 10 के उप-नियम 4 के तहत शिकायतों के रजिस्टर सहित शिकायतों के संबंध में शिकायत अधिकारी और संस्थान द्वारा सृजित सभी दस्तावेजों और रिकॉर्डों में छद्म नाम से प्रदर्शित किया जाएगा;

(घ) शिकायत अधिकारी के समक्ष आई शिकायत में संलिप्त संरक्षित व्यक्ति की पहचान और पहचान योग्य ब्यौरों को किसी भी व्यक्ति या सहायक और स्टाफ सहित उनके प्रतिनिधियों द्वारा प्रकट नहीं किया जाएगा।

(2) कोई भी व्यक्ति शिकायत अधिकारी के समक्ष आई शिकायत के संबंध में कोई भी मामला तब तक मुद्रित या प्रकाशित नहीं कराएगा जब तक कि शिकायत में संलिप्त संरक्षित व्यक्तियों की पहचान सुरक्षित न की गई हो।

(3) शिकायत अधिकारी इस अधिनियम की धारा 11 के उपबंधों के अनुसार आंकड़ों के संरक्षण के उपायों का अनुपालन करेगा।

14. प्रत्येक स्थापन जिसे शिकायत अधिकारी नियुक्त करने की आवश्यकता है वह-

(क) अपने कर्मचारियों को इस अधिनियम के उपबंधों के प्रति संवेदनशील बनाने के लिए वार्षिक आधार पर कार्यशालाएं और जागरूकता कार्यकम तथा शिकायत अधिकारी के लिए अभिमुखी कार्यक्रम कार्यक्रम संचालित करेगा;

(ख) शिकायत पर निर्णय लेने के लिए शिकायत अधिकारी को आवश्यक सुविधाएं प्रदान करेगा; और

(ग) ऐसी सूचना उपलब्ध कराएगा जो शिकायत अधिकारी द्वारा निर्णय लेने के लिए अपेक्षित है।

15. केन्द्रीय सरकार के अधीन समुचित प्राधिकारी-

(क) अधिनियम के उपबंधों जिसमें अधिकारों के समाधान से संबंधित उपबंध भी शामिल हैं, के प्रति सामान्य रूप से आम जनता और विशेष तौर पर संरक्षित व्यक्तियों, सिविल प्राधिकारियों और स्वास्थ्य देखभाल कर्मियों की समझ को बढ़ाने के लिए सूचना शिक्षा, संचार और प्रशिक्षण सामग्री को तैयार करेगा और इसका प्रसार करेगा;

(ख) ऐसे अभिमुखी और प्रशिक्षण कार्यक्रमों को तैयार करेगा और इनका प्रसार करेगा जिनका संस्थानों द्वारा नियम 9 के उपनियम 2 के तहत शिकायत अधिकारियों के प्रशिक्षण में और इस अधिनियम तथा नियम 11 के उपनियम (1) के खण्ड (ख) के उपबंधों का उल्लंघन करते पाए गए व्यक्तियों के परामर्श में प्रयोग किया जा सकता है;

(ग) उच्च भार वाले जिलों में संस्थानों के लिए राज्य सरकार के अधीन ऐसे जिलों में समुचित प्राधिकारी और उनके शिकायत अधिकारियों के समन्वय में उक्त अधिनियम और नियमों के क्रियान्वयन पर प्रशिक्षण प्रदान करेगा और आगे ऐसे प्रशिक्षण वार्षिक आधार पर प्रदान करेगा;

(घ) उच्च भार वाले जिलों में सिविल प्राधिकारियों और मान्यता प्राप्त सामाजिक स्वास्थ्य कर्मियों (आशा) और आंगनवाड़ी कर्मियों सहित स्वास्थ्य देखभाल कर्मियों के लिए राज्य सरकार के अधीन ऐसे जिलों में उपयुक्त प्राधिकारी के समन्वय में उक्त अधिनियम और नियमों के क्रियान्वयन पर प्रशिक्षण प्रदान करेगा और आगे ऐसे प्रशिक्षण वार्षिक आधार पर प्रदान करेगा।

16. इन नियमों में अंतर्विष्ट कुछ भी अन्य उपचारों के प्रति किसी व्यक्ति के अधिकार को प्रतिसिद्ध, सीमित या अन्यथा प्रतिबंधित करता हो परन्तु इस अधिनियम या इस अधिनियम के उपबंधों के उल्लंघन से निपटने के लिए कुछ समय के लिए बनाए गए किसी अन्य कानून के तहत उपबंधित न किया गया हो।

प्ररूप

नियम 10 के अधीन शिकायत अधिकारी को शिकायत करने के लिए प्ररूप

1. घटना की तारीख .....

2. घटना का स्थान .....

3. घटना का विवरण .....

4. घटना के लिए उत्तरदायी व्यक्ति या संस्थान.....

शिकायतकर्ता के हस्ताक्षर या अंगूठा निशान*

नाम: तारीख:

मोबाइल नं. या ईमेल या फैक्स या पता :

केवल कार्यालय प्रयोग हेतु :

शिकायत संख्या: .....

*जहां शिकायत मौखिक रूप से या टेलीफोन के माध्यम से प्राप्त होती है और शिकायत अधिकारी द्वारा लिख ली गई है वहां शिकायत अधिकारी प्रपत्र पर तारीख सहित हस्ताक्षर करेगा।

[फा. सं. टी-11020/50/1999-नाको (पी एण्ड सी)]
आलोक सक्सेना, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(National AIDS Control Organisation)

NOTIFICATION

New Delhi, the 17th September, 2018

G.S.R. 888I.—In exercise of the powers conferred by section 47 of the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 of 2017), the Central Government hereby makes the following rules, namely:—

Chapter – I

Preliminary

1. Short title and commencement.- (1) These rules may be called the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Rules, 2018.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions.-

(1) In these rules, unless the context otherwise requires,—

(a) "Act" means the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 of 2017);

(b) "appropriate authority" means;

(i) the National AIDS Control Organisation in case of Central Government; and

(ii) the State AIDS Control Society in case of State Government;

(c) "high burden district" means a district which has-

(i) more than one percent prevalence among antenatal care in Sentinel Surveillance; or

(ii) more than five percent prevalence among high-risk population in Sentinel Surveillance; or

(iii) HIV positivity of more than national average among general clients in Integrated Counselling and Testing Centre notified by the appropriate authority under the Central Government from time to time;

(2) Words and expressions used herein and not defined in these rules but defined in the Act shall have the meanings assigned to them in the Act.

Chapter – II

Manner of Notifying HIV and AIDS Policy for Establishments

3. The appropriate authority under the Central Government shall, before notifying a model HIV and AIDS policy for establishments consult -

(a) all stakeholders including representatives of HIV -positive persons;

(b) HIV -affected persons and protected persons;

(c) healthcare providers;

(d) establishments engaged in providing education, healthcare services, experts and organizations working in the field of HIV and AIDS, employers, trade unions, and other relevant stakeholders on such policy.

4. The appropriate authority under the Central Government shall notify a model HIV and AIDS policy for establishments in the Official Gazette.

5. The appropriate authority under the Central Government shall review and update from time to time the model HIV and AIDS policy for establishments in accordance with rules 3 and 4.

6. (1) The model HIV and AIDS policy applicable to an establishment, engaged in the provision of healthcare services and every other establishment where there is a significant risk of occupational exposure to HIV shall provide for a safe working environment and for informed consent for testing, treatment and research in accordance with the provisions of the Act.

(2) The model HIV and AIDS Policy applicable to an establishment consisting of one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall provide for a grievance redressal mechanism in accordance with the provisions of the Act and these rules:

Provided that in the case of healthcare establishments, the provisions of this sub-rule shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted.

7. (1) The model HIV and AIDS policy as may be applicable and as may be amended and updated from time to time by the appropriate authority under the Central Government shall be adopted by every establishment upon its notification.

(2) The text of the HIV and AIDS policy shall be communicated to all persons working in the establishment by the person in charge of or responsible to the establishment.

(3) The person in charge or responsible for the establishment shall prominently post the text of the HIV and AIDS policy as a notice in English and in the language understood by majority of persons working in or accessing such establishment on special boards to be maintained for such purpose, at or near the entrance through which the majority of the persons working in or accessing the services of the establishment enter such establishment.

(4) The establishment shall conduct annual training sessions for persons working in such establishment in understanding and implementing the HIV and AIDS policy.

8. (1) The notice referred to in sub- rule (3) of rule 7 shall state the manner in which copies of the HIV and AIDS policy shall be obtained and persons working in or accessing the services of the establishment shall be entitled to a copy of such policy free of charge.

(2) The copies of the HIV and AIDS policy of establishments shall be made available in the public domain by those to whom the policy has been made available including on their website if any and in case of hard copies for a nominal price.

(3) The appropriate authority of every State shall make available the copy of HIV and AIDS policy to heads of all educational establishments who shall further provide a copy of the policy to the learners and their parents or guardians free of charge immediately upon admission of the learner to the establishment.

Chapter – III

Grievance Redressal Mechanism for Establishments

9. (1) Every establishment having one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall within one hundred and eighty days of the commencement of the Act, designate such person of senior rank, as it deems fit, as the Complaints Officer who shall dispose of complaints of violations of the provisions of the Act in the establishment, in accordance with these rules:

Provided that every branch of an establishment having one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall within one hundred and eighty days of the commencement of the Act, designate such person of senior rank, as it deems fit, as an additional Complaints Officer for such branch who shall dispose of complaints of violations of the provisions of the Act in the establishment, in accordance with these rules:

Provided further that in the case of healthcare establishments, the provisions of this rule shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted.

(2) The establishment shall within thirty days of appointment, provide training to the Complaints Officer on the provisions of the Act including information on prevention, care, support and treatment related to HIV, human sexuality, sexual orientation and gender identity, drug use, sex work, people vulnerable to HIV, stigma and discrimination, principles of the greater involvement of people living with HIV, strategies of risk reduction, etc. During the training assistance of experts including protected persons and persons vulnerable to HIV may be provided to the Complaints Officer.

10. (1) Any person may make a complaint to the Complaints Officer, within three months from the date that the person making the complaint became aware of the alleged violation of the Act in the establishment:

Provided that the Complaints Officer may, for reasons to be recorded in writing, extend the time limit to make the complaint by a further period of three months, if he is satisfied that circumstances prevented the complainant from making the complaint within the stipulated period.

(2) Every complaint shall be made to the Complaints Officer in writing in the Form set annexed to these rules:

Provided that where a complaint cannot be made in writing the Complaints Officer shall render all reasonable assistance to the complainant to reduce the complaint in writing.

(3) The Complaints Officer may receive complaint made in person, or by post or telephonically or in electronic form:

Provided that the establishment shall within a period of thirty days of appointing the Complaints Officer, establish a method for receipt of complaints in electronic form either through dedicated website, webpage or by providing an official email address for the submission of complaints to the Complaints Officer.

(4) The Complaints Officer shall, on receipt of a complaint, provide an acknowledgment to the complainant and record the Complaint in a register to be kept solely for that purpose.

(5) The time of the complaint and the action taken on the complaint shall be entered in a register.

(6) Every complaint shall be numbered sequentially in the register.

(7) The Complaints Officer shall act in an objective and independent manner while deciding complaints made under the Act.

(8) 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 healthcare 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.

11. (1) The Complaints Officer, if satisfied that a violation of the Act has taken place as alleged in the complaint, shall-

(a) firstly, direct the establishment to take measures to rectify the violation;

(b) secondly, counsel the person who has committed the violation and require such person to undergo training in relation to HIV and AIDS, provisions of the Act, rules and guidelines, particularly in relation stigma and discrimination, for a period amounting to one week, and a fixed period of social service, which shall include working with a non-governmental organisation working on HIV and Acquired Immunodeficiency Virus, a protected person's network, or the appropriate authority under the State Government that shall be monitored, and may also require that the person supervising the violator undergo such training.

(2) Upon subsequent violation of the Act by the same person, the Complaints Officer may recommend the establishment to take disciplinary action in accordance with the law.

(3) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint and of the complainant's right to approach the Ombudsman or to any other appropriate legal recourse in case the complainant is dissatisfied with the action taken.

(4) The Complaints Officer shall, on deciding a complaint, provide brief reasons in writing for the decision to the establishment and the concerned parties to the complaint within a period of ten days from the date of decision.

12. (1) The Complaints Officer shall ensure that the complaint, its nature and number and the action taken are reported to the appropriate authority under the Central Government every six months subject to the provisions of section 11 of the Act and rule 13 of these rules.

(2) The Complaints Officer shall ensure that the complaint, the nature of the complaint, the number of the complaint and the action taken are published on an annual basis or the establishment publishes annual report or on the website of the establishment or in such annual report , subject to the provisions of rule 13 and section 11 of the Act.

13. (1) The Complaints Officer shall, if requested by a protected person who is part of any complaint, ensure the protection of the identity of the protected person in the following manner, namely:-

(a) the Complaints Officer shall file one copy of the document bearing the full name, identity and identifying details of such protected person which shall be kept in a sealed cover and in safe custody with the Complaints Officer;

(b) the Complaints Officer shall provide pseudonyms to protected person involved in complaints before him;

(c) the identity of protected person involved in complaints before the Complaints Officer and their identifying details shall be displayed in pseudonym in all documentation and records generated by the Complaints Officer and the establishment in relation to the complaints including in the register of complaints under sub-rule (4) of rule 10;

(d) the identity and identifying details of the protected person involved in a complaint before the Complaints Officer shall not be revealed by any person or their representatives including assistants and staff.

(2) No person shall print or publish any matter in relation to a complaint before a Complaint Officer unless the identity of the protected persons in the complaint is protected.

(3) The Complaints Officer shall comply with the data protection measures in accordance with the provisions of section 11 of the Act.

14. Every establishment which requires to appoint a Complaints Officer shall-

(a) on an annual basis, organise workshops and awareness programmes for sensitising its employees with the provisions of the Act and orientation programmes for the Complaints Officer;

(b) provide necessary facilities for the Complaints Officer for deciding the complaint; and

(c) make available such information as the Complaints Officer may require in deciding the complaint.

15. The appropriate authority under the Central Government shall-

(a) develop and disseminate information, education, communication and training materials to advance the understanding of the public generally and in particular of protected persons, civil authorities and healthcare workers of the provisions of the Act including relating to redressal of rights;

(b) formulate and disseminate orientation and training programmes that may be used by establishments in the training of Complaints Officers under sub-rule (2) of rule 9 and in the counselling of persons found to have violated the provisions of the Act and clause (b) of sub-rule (1) of rule 11;

(c) provide training for the establishments in high burden districts, in coordination with the appropriate authority under the State Government and their Complaints officers in such districts on the implementation of the Act and the rules and shall further provide such trainings on an annual basis;

(d) provide training for civil authorities, and healthcare workers including Accredited Social Health Activists and Anganwadi Workers in high burden districts, in coordination with the appropriate authority under the State Government in such districts on the implementation of the Act and the rules and shall further provide such trainings on an annual basis.

16. Nothing contained in these rules prohibits, limits or otherwise restricts the right of a person to other remedies provided under the Act or any other law for the time being in force to address violations of the provisions of the Act.

FORM

Form for making Complaint to Complaints Officer under rule 10

1. Date of Incident ____
2. Place of Incident ____
3. Description of incident _____
4. Person or institution responsible for the incident _____

Signature or Thumb Impression of Complainant*

Name: Date:

Mobile No. or email or Fax or Address:

For Official Use only:

Complaint Number: ____

**Where the complaint is received orally or telephonically and reduced to writing by the Complaints Officer, the Complaints Officer shall sign and date the Form.*

[F. No. T-11020/50/1999-NACO (P&C)]

ALOK SAXENA, Jt. Secy.

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ALOK KUMAR
Digitally signed by ALOK KUMAR
Date: 2018.09.22 11:16:42 +05'30'

Annexure 3: TOR of Counselor

सत्यमेव जयते

निधि केसरवानी, भा.प्र.से.
निदेशक
Nidhi Kesarwani, I.A.S.
Director

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

No. T-11025/08/2022-NACO (BSD) CB
Dated: 09/11/2022

Order

Subject: Revised integrated Terms of Reference (ToR) for the Counselor's under National AIDS Control Programme (NACP) Phase –V

In order to provide quality services to the client in a holistic manner, it has been reviewed to create synergy in the counseling support provided to clients visiting various services under NACP.

A revised ToR for the Counselor's working in wide-range of programmes under NACP-V (e.g. Help line 1097, Targeted Intervention projects, Opioid Substitution Therapy centers, Anti Retro-viral Therapy Centres, Integrated Counselling and Testing Centres, Designated STI/RTI Clinics, One Stop Centre, Sampoorna Suraksha Strategy) has been approved by the competent authority.

In this regard, all the States has to ensure the following Terms of Reference (ToR) for the counselors under all the components of program.

Revised ToR for counselor's under NACP-V

A. Essential Qualification:

Graduate degree holder in Psychology/Social Work/Sociology/ Anthropology/Human development/Nursing with 3 years of experience in counseling/educating under National Health Programme

OR,

Post-graduate in Psychology/Social Work/Sociology/ Anthropology/Human development/Nursing

If candidate is a person living with HIV/AIDS (PLHIV),

Graduate degree holder in Psychology/Social Work/Sociology/ Anthropology/Human development/Nursing with 1 years of experience in counseling/educating under National Health Programmes

B. Desirable

- Experience of working under the National AIDS and STD Control Programme (NACP) facility or community settings

Contd…

9th Floor, Chandralok Building, 36 Janpath, New Delhi-110001 Tel. : 011-23325343 Fax : 011-23325335
E-mail : dir@naco.gov.in

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

C. Knowledge and Skill:

- The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.
- Familiarity with government health policies and related programmes.
- Ability to work in teams, and flexible ways of working as per the need of programme

D. Role and Responsibilities are:

The counselor would be performing following jobs, in facility (including prison) and also in outreach/community settings through field visits in a confidential and ethical manners, as per the modalities prescribed in national guidelines/periodic instructions issued under the National AIDS and STD Control Programme

1. Counseling and educating the target audience on preventive measures, testing and treatment of HIV, STIs and related co-infections through one-to-one or group counseling, using suitable medium (Exp. posters, flip books, flyers, leaflets, audio-visual materials, tele-counselling, virtual platform etc.)
2. Undertaking the risk assessment of the target audience and offering of suitable follow-up services as per the risk level of the clients,
3. Promoting of comprehensive prevention models (Condom, Contraception, Pre-Exposure Prophylaxis, Post-Exposure Prophylaxis etc.), including condom demonstration (using penis model), for prevention of new infections,
4. Undertake HIV and Syphilis screening services in facility and field settings,
5. Undertake the counseling for people found reactive/positive for HIV, STIs and related co-infections, including but not limited to, anti-retroviral medicines, preparedness counseling, adherence counseling, opportunistic infections management, management of NCD, lifestyle modification, positive prevention, disclosures, index testing, psychosocial support, family counseling, suitable linkage and referrals, including to 1097, social protection schemes, legal aid, rehabilitation and other relevant services etc.
6. Benefits of DTG based regimen or current ART regimen which is preferred in programme.
7. Undertake the enabling environment to fight against stigma and discrimination.
8. Undertake the family planning counseling and follow-up referral and linkages among eligible HIV positive clients,
9. Undertake the counseling among adolescents and youths for sexual and reproductive health including that for prevention, testing and treatment of HIV, STIs and related co-infections Undertake the counseling and follow-up services for 'at-risk' non-reactive/negative clients, including but not limited to, comprehensive prevention models, periodic screening for HIV/STIs and suitable linkage and referrals, including to 1097, as per the national guidelines,
10. Follow-up for HIV and STIs reactive/positive people through field visit/outreach ensuring uptake of suitable services like confirmatory testing, registration to treatment facilities and adherence counseling,
11. Follow-up for HIV and STIs reactive/positive children through field visit/outreach ensuring uptake of suitable services like confirmatory testing, viral load tests, registration to treatment facilities and

Contd...

adherence counseling,

12. Follow-up for HIV and STIs reactive/positive children through field visit/outreach for ARVs/prophylaxis/suitable treatment administration
13. Coordination with various outreach workers/field functionaries/ANM/ASHA Workers/Anganwadi Workers etc. in context of HIV/STI-reactive/positive individuals ensuring uptake of suitable services like confirmatory testing, registration to treatment facilities, adherence counseling etc.
14. Promote institutional delivery of HIV infected pregnant women.
15. Counselling on exclusive breast/replacement feeding (EBF/ERF) and counsel mother for complete EID.
16. Perform the role of nodal point for Sampoorna Suraksha Strategy as suitable for the given locality,
17. Counselling on harm-reduction services for injecting drug users including on the topic of Opioid Substitution Therapy, Viral Load testing and viral suppression.
18. Administration of OST drugs to the injecting drug users as suitable,
19. Ensuring the suitable use and maintenance of kits/commodities/consumables/equipment's provided under NACP including the cold-chain maintenance of kits/drugs as per the guidelines,
20. Undertake the data recording and reporting, including the data entry in IT-enabled platforms, for the services offered as per the system prescribed under the national guidelines.
21. Undertake the specific activities in context of the programme monitoring, surveillance and research as per the instructions issued periodically,
22. Participation in reviews, trainings and capacity building activities etc. as per the instructions issued periodically.
23. Undertaking of any other related activities under NACP as per the instructions issued periodically.

This issue with the approval of competent authority.

(Nidhi Kesarwani)

To

Project Director's
State AIDS Control Societies

Copy to

1) Sr. PPS to Additional Secretary and Director General, NACO
2) Sr. PPS to Director, NACO
3) All Division Heads, NACO
4) Deputy Secretary (Admin), NACO
5) Deputy Directors-NACO

Annexure 4: ToR of Lab Technician

BSD

Position	Essential Qualification	Essential Experience	Desirable	Job responsibilities (All SACS, district and facility level staff will work in accordance to the operational and technical guidelines of NACO issued from time to time focussing on but not limited to the following activities)
LT	B.Sc in Medical Laboratory Technology (BMLT) or BMLS Diploma in Medical Laboratory Technology (DMLT) or DMLS with the course duration of at least 2 years recognised by State Government/ Central Government	1) Two years of experience of working in diagnostic laboratory for those with B.Sc/ Diploma in Medical Laboratory Technology (course duration of 2 years) 2) One year experience for those working in diagnostic laboratory for candidates having M.Sc in Medical Laboratory Technology 3) Candidates with experience of working in accredited labs or those labs who have applied for accreditation will be preferred.	M. Sc in Medical Laboratory Technology/ MMLS	❑ Draw blood for and undertake HIV and Syphilis screening and testing according to standard laboratory procedure and its QC. ❑ Undertaken Dual HIV Syphilis testing ❑ Ensure that adequate stock of consumables, rapid HIV diagnostic kits, RPR test kits and Dual HIV/Syphilis RDT are available in the ICTC. ❑ Keep a record of HIV and syphilis test results as well as a stock record of rapid HIV diagnostic kits, RPR test kits, Dual HIV/Syphilis test kits and consumables. ❑ Ensure the maintenance of all laboratory equipment. ❑ Scrupulously follow internal and external quality assurance procedures. ❑ Follow universal safety precautions and strictly adhere to hospital waste management guidelines. ❑ Perform testing in field setting and camp settings. ❑ Any other activity assigned under the Programme

Annexure 5:
Integrated 10 point Counselling tool on TB/Drug resistant TB

Integrated 10 points counselling tool on TB/drug resistant TB

1. Tuberculosis (TB) is the most common opportunistic Infection in people living with HIV (PLHIV) and leading cause of death in PLHIV.
2. Tuberculosis is an infectious disease caused predominantly by Mycobacterium Tuberculosis. The infection occurs most commonly through droplet nuclei generated by coughing, sneezing etc., inhaled via the respiratory route. TB usually affects the lungs, but may affect other parts of the body as well.
   - *An HIV negative person infected with TB has a 10% life-time risk of developing TB disease.*
   - *HIV increases the risk of progression from TB infection to TB disease and PLHIVs have a 60% lifetime risk of developing TB disease.*
3. Persons having cough of 2 weeks or more, with or without other symptoms, are referred to as pulmonary TB suspect (Presumptive TB case). They should have 2 sputum samples examined at Designated Microscopy Centre (DMC).
4. A person with extra-pulmonary TB may have symptoms related to the organs affected along with symptoms like enlarged cervical lymph modes, chest pain, pain and swelling of the joints, etc. Extra-pulmonary TB can be confirmed by other investigations.
5. All people living with HIV should be regularly screened for TB using a clinical symptom-based algorithm consisting with any one of the symptoms of cough of any duration, fever, weight loss or night sweats at the time of initial presentation for HIV care and at every visit to a health facility or contact with a health-care worker afterwards.
6. Diagnosis and treatment services for TB are available free of cost through National Tuberculosis Elimination Program (NTEP)
   - *2 sputum smear examinations are necessary for the diagnosis of pulmonary TB. During the course of treatment, the progress is monitored by means of follow up sputum examinations.*
   - *Anti TB drugs are provided as Fixed Dose Combinations (FDCs) as weight band*
   - *Treatment is provided by "Treatment Provider" at a place near the patient's home.*
   - *Cure from TB can only be ensured by taking complete and regular treatment. Without correct and complete treatment, a patient can become very ill or develop Drug resistant TB.*
7. PLHIV diagnosed with TB should be linked to ART services at earliest, irrespective of CD4Count. Cotrimoxazole preventive therapy should be provided to all HIV-TB co-infected patients to prevent opportunistic infection.
8. An HIV/TB co-infected patient should be referred to nearest NTEP certified Culture and Drug sensitivity laboratory facility/CBNAAT facility for diagnosis of Drug resistant TB. These cases will be managed as per latest guidelines on "Programmatic management of Drug Resistant TB in India under NTEP.
9. The client's information is to be kept confidential and this information is not furnished under any circumstances to any other person except 'Shared confidentiality' with the treating physician and public health system DOT provider for better case management & to get benefit of prophylactic/treatment options available for him.
10. All TB/Drug resistant TB patients should maintain cough hygiene (putting a cloth on nose & mouth while coughing or sneezing) to prevent transmission of TB/DRTB.

Source: Handbook for HIV and STI Counsellors, NACO, 2023

Annexure 6:
Interim Guidance for Confirmation of HIV diagnosis, if Testing kits are in short supply

P-11014/16/2013-NACO/BSD/ICTC-PartFle-1
Government of India
Ministry of Health and Family Welfare
National AIDS Control Organization
(Basic Service Division)

6th floor, Chandralok Building,
36 Janpath, New Delhi-110001
Date: 03/03/2023

Subject: Revised algorithm for Confirmation of HIV diagnosis -reg.

Dear Sir/Madam.

Confirmation of HIV diagnosis is a critical step for early initiation on ART. The present algorithm requires three test kits of different principles to be positive in sequence before a diagnosis of HIV can be established.

At present, HIV kit 1 supplies are being managed centrally, but for HIV test kit 2 & 3, letters have been sent to SACS to procure locally. This is an interim arrangement till the further procurement of HIV kit 1, 2, and 3 is completed through CMSS, based on indents already placed with due approvals.

We appreciate States for initiating this state level procurement of HIV kit 2 and 3. However, few States who are facing shortage of either kit 2 or 3 have requested for guidance from NACO on revised algorithm for confirmation of HIV diagnosis. In view of the situation, a meeting was held on 27th Feb. 2023 of Technical sub group created and facilitated by Lab Service Division, NACO to discuss the same. The minutes of the meeting are enclosed herewith.

Based on the recommendation mentioned in the minutes, all SACS are requested to implement and disseminate the interim guidance for confirmation of HIV diagnosis through SRLs and ICTC so that appropriate actions are taken for timely confirmation of the HIV reactive cases.

Alongside it is requested that, all SACS expedite the local procurements of HIV kit 2 and 3 at-most priority.

This is issued with the approval of the competent authority.

Warm regards.

Yours faithfully,

(Dr. Shobhini Rajan)
DDG (BSD), NACO

Enclosed: Minutes of the Meeting
To,
Project Director (s), State AIDS Control Societies

Annexure 7:
Whole blood finger prick sample collection for Adults and Children above the age of 18 months for HIV test

Point of care test (POCT) kits that use whole blood from finger-prick samples are used at HIV screening facilities and in the community for mobile outreach. Each POCT user must complete initial training and orientation on each test method prior to initiation of testing and following any changes or update in instrumentation, kits, or test methods.

Procedure for whole blood finger prick sample collection

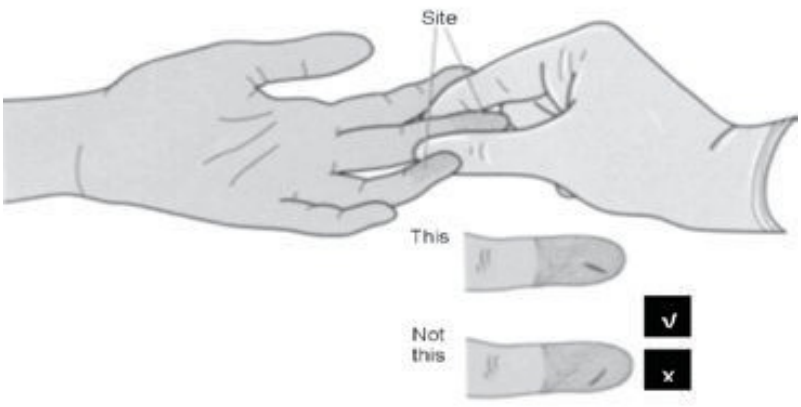
Material: (To be arranged by LT/ concerned HCW from local ICTC/Screening sites /Health System/ TI/ LWS/Mobile ICTC/VHSND)

- Test kits in cold chain (Please note the TTI indicator and expiry date of the kit.)
- Alcohol swabs
- Pair of gloves
- Soap or hand wash
- Lancets/ needles
- Biohazard bags
- First aid kit

The nine steps in collecting the blood sample are as follows:

1. Make the client/ patient to sit or lie down comfortably and lower the arm from which the sample is to be taken. Ensure that the fingers are lower than elbow of the same arm.
2. Choose the fingertip of the middle or ring finger.

Recommended sites for finger puncture

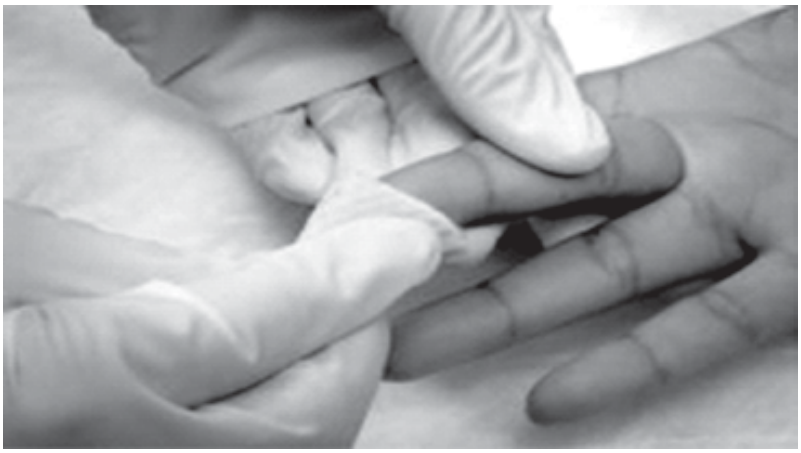


Selecting the site to be pricked



3. Clean the fingertip with alcohol. Allow the area to air dry. Do not touch the area.

Cleaning the fingertip with alcohol



4. Gently squeeze and release the area to be pricked until it is red.
5. Position the hand palm side up. Place the lancet or needle away from the centre of the fingertip. Firmly press the lancet or needle against the skin and puncture the skin. Dispose of the lancet or needle in a puncture proof container

Pricking the finger



6. Wipe away the first drop of blood with a sterile gauze pad and then discard it as per biomedical waste disposal guidelines.
7. Hold the finger lower than the elbow and apply gentle intermittent pressure to the base of the punctured finger a few times.
8. Using the disposable pipettes supplied with the test kit, draw up the required amount of whole blood specimen from the fingertip. Do not use any other pipette and do not reuse the pipette.
9. Once the required amount of whole blood specimen has been collected, gently apply pressure at the puncture site with gauze to ensure that there is no further bleeding from the site. Request the client to continue pressing with the gauze until bleeding stops.

It is important to correctly follow the steps for drawing blood because painful or repeated attempts can cause discomfort and result in collection of a poor quality or quantity of sample.

DOs and DON'Ts of rapid HIV screening test

DOs

- Do store the test kit as per the manufacturer's instructions
- Do follow the package insert instructions.
- Do use a new disposable pipette and device for testing each new specimen.
- Do use the supplied pipette to drop the blood specimen from the finger prick onto the device.
- Do use a control specimen at least once after taking the kit from the ICTC.
- Do run the test immediately after removing the test cassette from the foil pouch.
- Do follow the given instructions while interpreting the test results. The reading may show a reactive result if the sample is checked or read after prescribed time period as mentioned in the package insert.
- After reading, confirming and recording the test result, discard the used material, including the used HIV test card, into the discard jar.

DON'Ts

- Do not use the kit or any kit components after the expiry date.
- Do not freeze the kit.
- Do not use the same disposable pipette and device for multiple samples.
- Do not pipette by mouth.
- Do not use any device if the pouches are perforated.
- Do not mix reagents from different kits.
- Do not drop blood droplets directly from the patient's fingertip onto the device of the kit insert. A disposable pipette must be used to transfer the specimen from the fingertip to the specimen pad on the rapid card device.

DONT's of finger puncture

- Do not puncture the side or the tip of the finger.
- Do not puncture parallel to the grooves of the fingerprint.
- Do not puncture the index finger.
- Do not puncture the little finger.
- Do not puncture the fingers of a child less than 12 months of age. (Any blood sample from babies less than 12 months or weighing less than 10 kg is collected through a heel prick.)

Annexure 8:
HIV Test Report Form

Name and address of ICTC centre: (Form to be filled in duplicate)

Name: Surname _____ **Middle name** _____ **First name** _____

Gender: M / F / H/TG **Age:** _____ Years **PID #** _____)_____ **Lab ID #**_____

Date and time blood drawn: _____ (DD/MM/YY) _____ (HH:MM)

Test Details:

Specimen type used for testing: Serum / Plasma / Whole Blood

Date and time specimen tested: _____ (DD/MM/YY) _____ (HH:MM)

Note:

- Column 2 and 3 to be filled only when HIV 1 & 2 antibody discriminatory test(s) used
- No cell has to be left blank; indicate as NA where not applicable.

Column 1				Column 2	Column 3	Column 4
Name of HIV test kit	**Batch No.**	**Expiry Date**	**Principle of test (Tick as appropriate)**	**Reactive/ Nonreactive (R/NR) for HIV-1 antibodies**	**Reactive/ Nonreactive (R/NR) for HIV-2 antibodies**	**Reactive/ Nonreactive (R/NR) for HIV antibodies**
Test I:			1. Dot Immunoassay 2. Immunochromatography 3. Immuno-concentration 4. Any other			
Test II:			1. Dot Immunoassay 2. Immunochromatography 3. Immuno-concentration 4. Any other			
Test III:			1. Dot Immunoassay 2. Immunochromatography 3. Immuno-concentration 4. Any other			

Interpretation of the result: Tick (√) relevant

☐ Specimen is negative for HIV antibodies

☐ Specimen is positive for HIV-1 antibodies

☐ *Specimen is positive for HIV antibodies (HIV 1 and HIV 2; or HIV 2 alone)

☐ Specimen is indeterminate for HIV antibodies. Collect fresh sample in two weeks.

** Confirmation of HIV 2 sero- status at identified referral laboratory through ART centres*

Name & Signature
Laboratory Technician

Name & Signature
Laboratory In-charge

Date: _____

Seal

-- End of report --

Annexure 9:
Checklist to review Quality Management Systems at ICTC

Checklist to review Quality Management Systems at ICTC

Name of the ICTC	
Name of the Reviewer(s):	
Signature of Reviewer	
Date of Review	

The final percentage score and the grades to be filled by the reviewer				
Operational (O) :			Total Score :	
Technical (T) :			..... Percentage (%)	
Monitoring & Evaluation (M&E) :			:	
Logistics (L) :			.....	
★	★★	★★★	★★★★	★★★★★
Grade 1 Poor Immediate remediation needed (0-29%)	**Grade 2** Below Average (30-54%)	**Grade 3** Average (55-74%)	**Grade 4** Above average (75-89%)	**Grade 5** Excellent (90-100%)

Annexure 10:
Checklist for Assessment of Screening Sites

Checklist for Assessment of Screening Facilities

Name of Facility:	
Address:	
Name of In Charge	
Person designated for HIV Testing	Name: _____ Designation: _____
Name of Nodal ICTC	
Name of Assessor	
Date of assessment	

S.N.	Attributes	Maximum Score	Score Obtained	% Score
A	Personnel and Training	06		
B	Physical Facility	16		
C	Safety	18		
D	Pre-analytical	06		
E	Analytical	14		
F	Post Analytical	06		
G	Quality Assurance	06		
H	Inventory Management	08		
I	Document and records	12		
	Total Score	**92**		

Scoring:
The score given against individual clause can be as follows;

a. Non-compliance – Score zero if a complete non-compliance is identified.
b. Partial – To be scored as 1 if a partial compliance is observed by the assessor
c. Compliance – To be scored 2 if all parameters required for the clause are met.

Signature of Assessor:	Signature of In-charge / Medical Officer of Screening Facility:

Sr. No	Questions	Maximum Score	Score Obtained	Comments
A	**Personnel and Training**			
1	Is there a designated staff available for HIV testing and release of reports	2		
2	Is there a backup arrangement available for HIV testing in the absence of the designated staff	2		
3	Has the designated staff received hands-on training in Whole Blood Finger Prick and HIV Testing by rapid test? (Check for training evidence of the designated staff)	2		
B	**Physical Facility**			
1	Is there an adequate space available for HIV testing with adequate lightning? (Check for designated testing area/Table and adequate lighting for reading the results.)	2		
2	Is the testing area clean and clutter free for rapid HIV testing?	2		
3	Is there a refrigerator/s available for kit storage? Is the space adequate for kit storage? (Map the Supplies required based on the average monthly testing and indent practices)	2		
4	Check for overfilled refrigerator, frosting. Check kit are not stored at the door compartment	2		
5	Is glass/ digital thermometer available for monitoring of temperature of refrigerator?	2		
6	Are refrigerator temperature monitored and recorded twice daily?	2		
7	If there sufficient and secure storage space is available for storage of consumables?	2		
8	If there sufficient and secure storage space is available for storage of records and documents?	2		
C	**Safety**			
1	Is the testing facility labeled with appropriate signage (Bio hazard, No food & drinks)?	2		
2	Are lab safety practices being followed?			
	a. Hand washing station	2		
	b. Use of PPE including respiratory protection	2		
	c. Hepatitis-B vaccination	2		
	d. Availability of Spill kit	2		
	e. First aid kit	2		
	f. Is an appropriate disinfectant available to clean the work area and disinfection? (70% ethanol & 1 % hypochlorite)	2		
3	Is the BMW segregated as per the regulation? (Sharps, soiled solid plastic and non-plastic waste segregated in appropriate colour coded bins)	2		

Sr. No	Questions	Maximum Score	Score Obtained	Comments
4	Are containers/bins for infectious waste emptied regularly within 24 hours for final disposal?	2		
D	**Pre-analytical Phase**			
1	Has informed consent been taken from each patient before screening?	2		
2	Are the sample collection flow charts available and displayed?	2		
3	Are test kits labeled with date received and opened?	2		
E	**Analytical**			
1	Is the testing SOP or work instruction available and accessible?	2		
2	Are test kits used within the expiration date and first-expiry, first-out [FEFO] principle followed?	2		
3	Are test cartridges properly labelled (i.e. client ID) during use?	2		
4	Are test results interpreted as per manufacturer instructions? (Staff Interview/Observation)	2		
5	Do you have stop watch to measure the time for reading the results? If no, how do you monitor the time?	2		
6	Are invalid tests recorded in a register/logbook and repeated?	2		
7	Is testing halted in last six month due to non-availability of testing personnel? (specify No of days testing halted)	2		
F	**Post Analytical Phase**			
1	For reactive on HIV screening, does the individual referred to the Nodal ICTC for confirmation of HIV diagnosis.	2		
2	Is linkage form in triplicate used for referral of reactive individual?	2		
3	For non-reactive on HIV screening, does duly signed report given to the individual on the same day? (Report must be duly signed by the medical officer)	2		
G	**Quality Assurance**			
1	Is there information on lot to lot verification conducted at ICTC available at facility?	2		
2	Is IQC data recorded in lab register?	2		
3	Is the facility is visited regularly by ICTC staff on monthly basis? (Check for record of visit including purpose of visit, Issues observed and suggestion)	2		
H	**Inventory management**			
1	Is there adequate stock of kits, condoms?	2		
2	Is stock register available and updated?	2		

Sr. No	Questions	Maximum Score	Score Obtained	Comments
3	Is indent of the kits sent before stock out of existing kit? (Review the inventory management procedure)	2		
4	Was there interruption in the testing services on account of non-availability of kit in last six months?	2		
I	**Documents and Records**			
1	Are linkage form available at the Screening Site? Are the linkage forms complete and accurate? (Review last 3 months month)	2		
2	Is there a form/register available for recording and reporting? (Check for Patient ID, results and referral details)	2		
3	Are all prescribed records and registers at the Screening sites, maintained regularly and reviewed by Nodal ICTC Staff? (Lab register, Stock Register, Copy of referral slips)	2		
4	Are test results properly maintained for confidentiality, accessible, archived and retrievable? (Check whether the records and registers are kept in cupboard with lock and key. Who is the custodian of the keys)	2		
5	Is there IEC materials available at the Screening Sites	2		
6	Are monthly reports dispatched regularly? (Describe briefly what are standard practice followed in the facility)	2		

Annexure 11:
Testing Kits principles, specifications and Advisories

Technical Specifications of HIV Test kits 1, 2 & 3 for detection of Antibodies against HIV by either of the Principles: Dot Immuno Assay / Immunochromatography (Lateral Flow) / Immunoconcentration

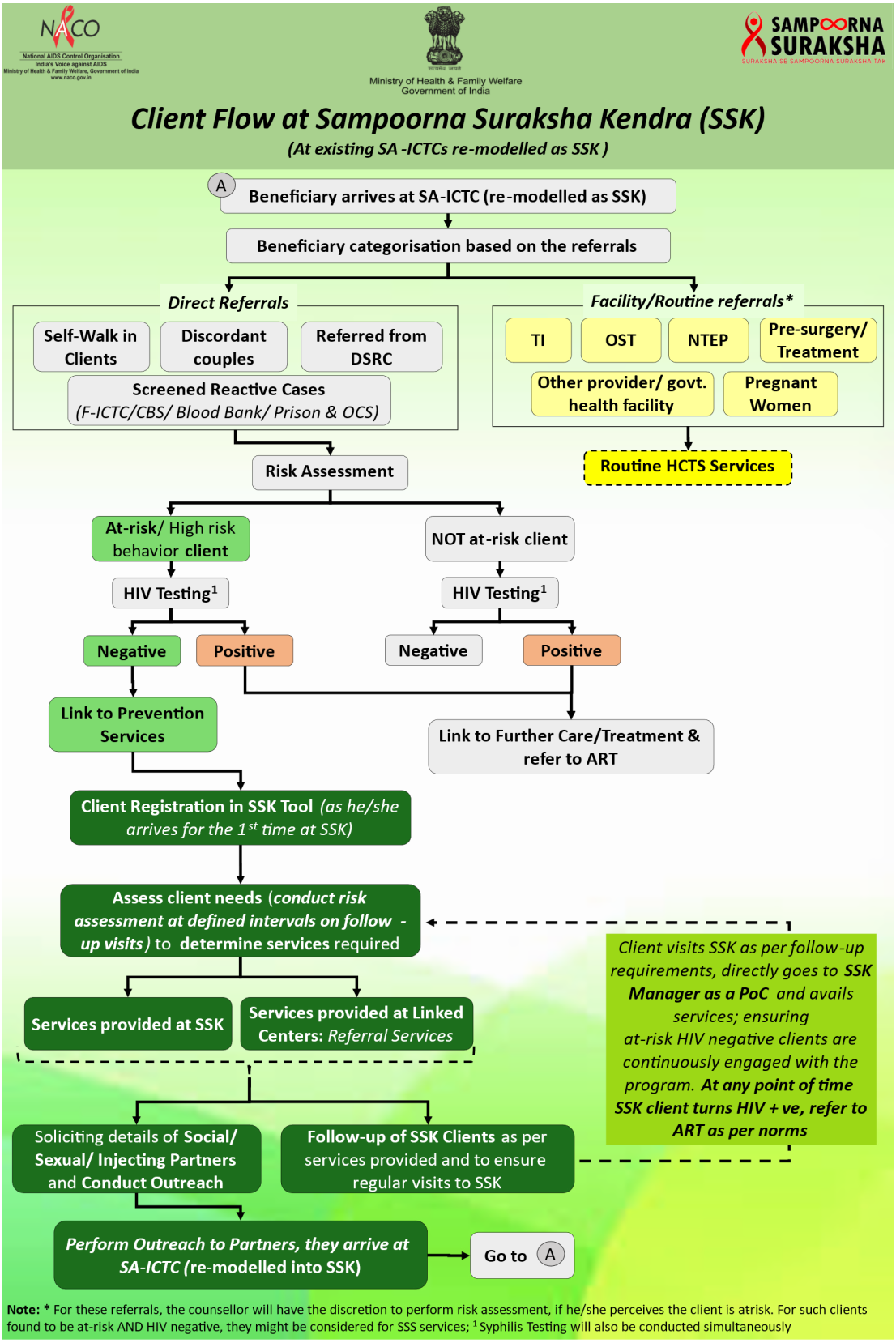
1. HIV test kit should have either of the following principles:
   a) Dot immuno Assay
   b) Immunochromatography (lateral flow)
   c) Immunoconcentration
2. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
3. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
4. Adequate documents detailing the Principle component, detail of antigen for antibody detection of HIV 1 & 2, bio safety precautions to be undertaken, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
5. The product insert should have the pictorial representation of the test methodology.
6. The kit should have approval of the statuary authority from the country of origin.
7. Imported and Indigenous kits should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
8. The time required for performing the test should not be more than 30 minutes.
9. The kits should have a shelf life of 24 months and at least 5/6th of the minimum shelf life must remain at the time of receipt by the consignee.
10. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the Principle of lateral flow.
11. The assay should have sensitivity of 100% and specificity of ≥98%.
12. The manufacturer should ensure that:

    a. The test kit should be packed such that there is a provision to conduct the single test at a time.
    b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
    c. The pack size of HIV rapid test kits should be not more than 50 tests per kit.

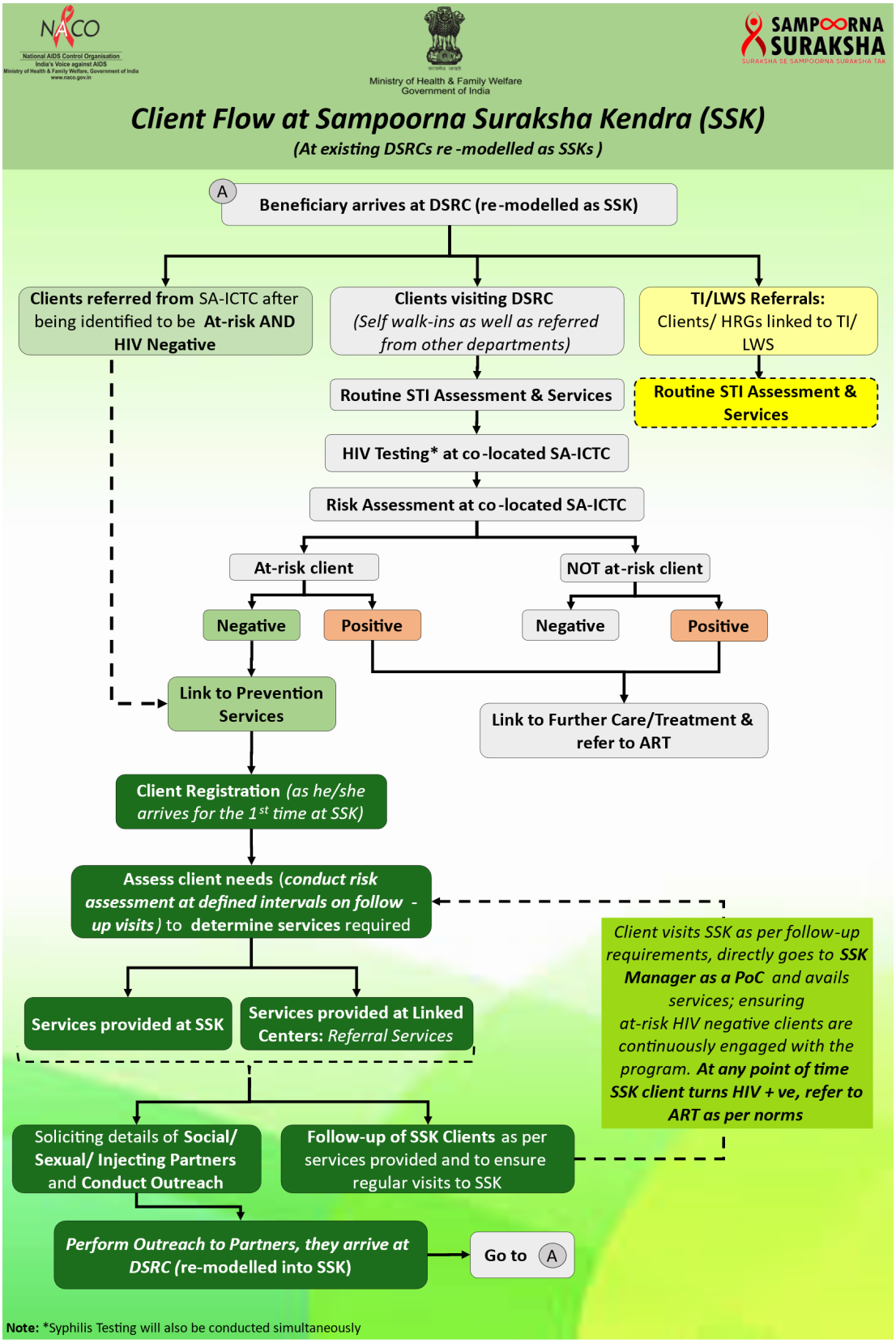
13. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport of the kits at 2 - 8^{0} C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

****

Annexure 12:
Client Flow at ICTC remodeled as SSK



Annexure 13:
Client Flow for a DSRC remodeled as SSK



Annexure 14:
Referral/Linkage slip for the HIV Counselling & Testing Services

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-2
(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 derails:
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 by 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 15:
Office Memorandum dated 28th July 2023 on 'Rollout of revised HMIS format in NACP Facilities for data entry-reg'

Z-17018/04/2015/NACO (Monitoring & Evaluation)
Government of India
Ministry of Health and Family Welfare
National AIDS Control Organisation

6th and 9th Floor, Chanderlok Building
36, Janpath, New Delhi - 110001
Dated: 28th July 2023

To

The Project Directors
State AIDS Control Societies/Mumbai DACS

Subject: Rollout of revised HMIS format in NACP Facilities for data entry-reg

Dear Sir/Madam,

HMIS is a system of consolidated monthly reporting of progress made by government facilities on NHM indicators. The HMIS formats have been rationalized and revised to include the new programmes and schemes of MoHFW, Govt of India. The revised HMIS formats have been rolled out across the country since April 2023. The data entry portal for the same is fully operational.

In the revised format, 45 indicators pertaining to HIV testing, STI/RTI management, and syphilis screening have been included. The new formats (facility type-wise), along with draft data definitions is enclosed.

In view of the above, you are requested to ensure the followings:

1. Complete transition of the reporting for NACP-related indicators from the facility integrated-ICTCs (FI-ICTC) through HMIS. No reporting from the FI-ICTC shall be now done through the SOCH Mobile App.
2. Inclusion of the monthly performance of the NACO's supported stand-alone ICTC and Designated STI/RTI Clinics (DSRCs) in the HMIS report of the health facility. Stand-alone ICTC and Designated STI/RTI Clinics (DSRCs) under NACO would continue to do the reporting in SOCH.
3. Engage with a suitable officer of NHM in your State/UT for the creation of the login credential for the SACS SI officer in the HMIS portal.
4. Close monitoring of the NACP-related data being reported in the HMIS portal by the SI team and related program divisions at SACS. If any data quality issues (non-reporting or otherwise) are observed, the same may be shared with the concerned State HMIS team, with a copy to the NACO's SI-M&E Team.

You are welcome to reach out to Dr. P Sujith (Consultant, SI-M&E, NACO, Mobile:7838401158, email ID: sujith.naco2022@gmail.com) for all related queries.

This issue with the approval of the competent authority.

Yours faithfully

Dr. Chinmoyee Das
HoD,SI Division, NACO

Enclose: As above

Copy for information to:

1) PSO to AS&DG, NACO
2) Sr.PPS to Director (NK), NACO
3) All HoD's NACO

Annexure 16:
Comprehensive list of monitoring Indicators for HCTS services

Testing Details of At-Risk Clients					
1	**ICTC Testing Indicators for clients other than pregnant women**				
No	**Indicator**	**Numerator**	**Denominator**	**Source**	**Reporting Frequency**
1.1	Percentage of at-risk clients identified at the ICTC	Number of at-risk clients identified based on risk assessment	Total number of clients underwent risk assessment	SOCH	Monthly
1.2	Percentage of clients who have been tested for HIV	Number of clients tested for HIV during the reporting period	Annual target during the reporting period[8]	N: SOCH D: Annual Target provided by NACO	Monthly
1.3	Percentage of clients confirmed HIV positive	Number of clients confirmed HIV positive during the reporting period	Number of clients tested for HIV during the reporting period	SOCH	Monthly
1.4	Percentage of HIV positive clients who have been linked for ART	Number of clients linked for ART during the reporting period.	Number of clients confirmed HIV positive during the reporting period	SOCH	Monthly
1.5	Percentage of HIV positive clients who have been initiated on ART	Number of at-risk clients initiated on ART during the reporting period	Number of at-risk clients HIV Positive during the reporting period	SOCH	Monthly
1.6	Percentage of clients tested for Syphilis	Number of clients screened for Syphilis during the reporting period	Total number of HCTS attendees (excluding pregnant women) during the reporting period	SOCH	Monthly
1.7	Percentage of clients found syphilis reactive	Number of clients found syphilis reactive during the reporting period	Number of at-risk clients (excluding pregnant women) screened/tested for Syphilis during the reporting period	SOCH	Monthly

8. Refer to state and population wise targets provided

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
2	**Indicators for HIV and Syphilis Screening at all sites (other than pregnant women)**				
2.1	Percentage clients screened for HIV at screening Sites	Number of clients Screened/tested for HIV at all Sites (ICTC, all screening sites) during the reporting period	Annual target during the reporting period[9]	N: HMIS D: Annual Target	Monthly
2.2	Percentage of clients screened HIV reactive	Number of clients found reactive at Screening Sites during the reporting period	Number of clients Screened for HIV at Screening Sites during the reporting period	HMIS	Monthly
2.3	Percentage of clients who are reactive to HIV are linked to ICTC for Confirmation	Number of clients who were reactive and linked to ICTC for confirmation during the reporting period	Number of clients found reactive at screening sites during the reporting period	HMIS	Monthly
2.4	Percentage of clients who were linked to ICTC for confirmation and underwent HIV confirmation	Number of clients who were reactive, underwent HIV confirmation during the reporting period	Number of clients women who were reactive and linked to ICTC for confirmation during the reporting period	HMIS	Monthly
2.5	Percentage of clients confirmed as HIV positive	Number of clients confirmed as HIV positive during the reporting period	Number of clients who were reactive, and underwent HIV confirmation during the reporting period	HMIS	Monthly
2.6	Percentage of clients screened for syphilis	Number of clients screened for syphilis during the reporting period	Annual target during the reporting period[10]	HMIS	Monthly
2.7	Percentage of clients found syphilis reactive	Number of clients found syphilis reactive during the reporting period	Number of clients screened for syphilis during the reporting period	HMIS	Monthly

9. Refer to state and population wise targets provided
10. Refer to state and population wise targets provided

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
3	**DSRC Clients (HIV and Syphilis Screening for DSRC clients screened at ICTC)**				
3.1	Percentage of DSRC attendees screened for HIV	Number of DSRC attendees screened for HIV during the reporting period	Total DSRC attendees during the reporting period	SOCH	Monthly
3.2	Percentage of DSRC attendees confirmed HIV positive	Number of DSRC attendees confirmed HIV positive during the reporting period	Number of DSRC attendees screened for HIV during the reporting period	SOCH	Monthly
3.3	Percentage of DSRC attendees screened for Syphilis	Number of DSRC attendees screened for Syphilis during the reporting period	Total DSRC attendees during the reporting period	SOCH	Monthly
3.4	Percentage of DSRC Clients found syphilis reactive	Number of DSRC Clients found syphilis reactive during the reporting period	Number of DSRC clients screened for Syphilis during the reporting period	SOCH	Monthly
HIV & Syphilis screening of Pregnant Women and HIV/Syphilis positive pregnant women					
4	**Syphilis screening of Pregnant Women at all screening sites including ICTC**				
4.1	Percentage of Pregnant Women screened for Syphilis	Number of Pregnant Women screened for Syphilis during the reporting period	Estimated Pregnant Women during reporting period	HMIS	Monthly
4.2	Percentage of Pregnant Women screened Syphilis Reactive	Number of Pregnant Women found Syphilis Reactive during the reporting period	Number of Pregnant Women screened for Syphilis during the reporting period	HMIS	Monthly
4.3	Percentage of Pregnant Women initiated for Syphilis Treatment	Number of Pregnant Women initiated for Syphilis Treatment during the reporting period	Number of Pregnant Women found Syphilis Reactive during the reporting period	SOCH	Monthly
4.4	Percentage of Pregnant Women monitored for syphilis treatment	Number of pregnant women tested for follow-up RPR/VDRL titers in the reporting period	Number of Pregnant Women completed 3 months of treatment for syphilis in the reporting period	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
5	**HIV Screening of Pregnant Women from Screening Sites**				
5.1	Percentage of Pregnant Women Screened for HIV	Number of Pregnant Women Screened for HIV during the reporting period	Annual target during the reporting period[11]	N: HMIS D: Annual targets	Monthly
5.2	Percentage of Pregnant Women Reactive for HIV	Number of Pregnant Women Reactive for HIV during the reporting period	Number of Pregnant Women Screened for HIV during the reporting period	HMIS	Monthly
5.3	Percentage of Pregnant Women Reactive for HIV linked for HIV confirmation	Number of Pregnant Women Reactive for HIV linked at confirmatory site for HIV confirmation during the reporting period	Number of Pregnant Women Reactive for HIV during the reporting period	N: SOCH D: HMIS	Monthly
5.4	Percentage of Pregnant Women Confirmed HIV Positive	Number of HIV Reactive Pregnant Women Confirmed HIV Positive during the reporting period	Number of Pregnant Women Reactive for HIV linked at confirmatory sites for HIV Confirmation during the reporting period	N: SOCH D: HMIS	Monthly
6	**HIV testing of Pregnant Women at ICTC**				
6.1	Percentage of Pregnant Women tested for HIV at health facility where ICTC is situated	Number of Pregnant Women tested for HIV at health facility where ICTC is situated during the reporting period	Estimated Pregnant Women during the reporting period	N: SOCH D: Annual Targets	Monthly
6.2	Percentage of pregnant women confirmed HIV Positive	Number of Pregnant Women confirmed HIV Positive during the reporting period	Number of Pregnant Women tested for HIV at health facility where ICTC is situated during the reporting period	N: SOCH D: HMIS	Monthly
6.3	Percentage of Newly Identified HIV Positive Pregnant Women linked to ART centre	Number of Newly Identified HIV Positive Pregnant Women linked to ART centre	Number of Pregnant Women confirmed HIV Positive during the reporting period	SOCH	Monthly

11. Refer to state and population wise targets provided

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
6.4	Percentage of Newly Identified HIV Positive Pregnant Women Initiated On ART	Number of Newly Identified HIV Positive Pregnant Women Initiated on-ART during the reporting period	Number of newly identified HIV positive pregnant women during the reporting period	SOCH	Monthly
6.5	Percentage of Pregnant WLHIV (New + Known) On ART	Number of Pregnant WLHIV (New + Known) on ART during the reporting period	Estimated HIV positive pregnant women during the reporting period	N:SOCH D: Annual HIV Estimation	Monthly
6.6	Pregnant WLHIV: Time of diagnosis of HIV infection				
6.6.1	Percentage of Pregnant Women Identified HIV Positive in the 1st Trimester	Number of Pregnant Women Identified HIV Positive in the 1st Trimester during the reporting period	Total number of newly identified HIV positive pregnant women during the reporting period	SOCH	Quarterly
6.6.2	Percentage of Pregnant Women Identified HIV Positive in the 2nd Trimester	Number of Pregnant Women Identified HIV Positive in the 2nd Trimester during the reporting period	Total number of newly identified HIV positive pregnant women during the reporting period	SOCH	Quarterly
6.6.3	Percentage of Pregnant Women Identified HIV Positive in the 3rd Trimester	Pregnant Women Identified HIV Positive in the 3rd Trimester during the reporting period	Total number of newly identified HIV positive pregnant women during the reporting period	SOCH	Quarterly
6.6.4	Percentage of Pregnant Women Identified HIV Positive in the Direct in Labour (DIL)	Pregnant Women Identified HIV Positive in the Direct in Labour (DIL) during the reporting period	Total number of newly identified HIV positive pregnant women during the reporting period	SOCH	Quarterly
6.6.5	Percentage of pregnant Women newly identified as HIV positive	Total number of pregnant newly identified(including DIL) as HIV positive during the reporting period	Total number of pregnant WLHIV identified during the reporting period (Known plus Newly identified)	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
6.6.6	Percentage of pregnant women identified HIV Positive prior to current pregnancy (Known HIV Positive pregnant Women)	Total number of pregnant women Identified as HIV Positive prior to current pregnancy during the reporting period	Total number of pregnant WLHIV identified during the reporting period (Known plus Newly identified positive pregnant women)	SOCH	Monthly
6.6.7	Percentage of Women Identified HIV Positive in the Post Natal Care (PNC) and Breast-feeding mother	Total number women Identified HIV Positive in the PNC and Breast-feeding mother during the reporting period	Total number of pregnant WLHIV identified during the reporting period (Known plus Newly identified)	SOCH	Monthly
6.7	No of Pregnant WLHIV Tested for Viral Load Testing at 32-36 weeks				
6.7.1	Percentage of Pregnant WLHIV tested for Viral Load at 32-36 weeks	Total number of Pregnant WLHIV tested for Viral Load at 32-36 weeks of pregnancy during the reporting period	Total number of Pregnant WLHIV Eligible for Viral Load Testing at 32-36 weeks of pregnancy during the reporting period	SOCH	Monthly
6.7.2	Percentage of Pregnant WLHIV with suppressed viral load(<1000 copies)	Number of Pregnant WLHIV Virally suppressed at 32-36 weeks of VL test during the reporting period	Total number of Pregnant WLHIV tested for Viral Load at 32-36 weeks of pregnancy during the reporting period	SOCH	Monthly
7	**HIV/Syphilis Exposed Babies**				
7.1	HIV Exposed Babies: Coverage of ARV Prophylaxis				
7.1.1	Percentage of HIV exposed babies received ARV Prophylaxis (NVP/ ZDV)	Total number of HIV exposed babies received either single or dual ARV prophylaxis during the reporting period	Total number of live births to the HIV Positive Pregnant Women during the reporting period	SOCH	Monthly
7.1.2	Percentage of HIV exposed babies initiated on CPT	Total number of HIV exposed babies initiated on CPT during the reporting period	Total number of live births to Pregnant WLHIV during the reporting period	SOCH	Monthly
7.2	Syphilis Exposed Babies: Follow up				

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
7.2.1	Percentage of syphilis-exposed infants received RPR/VDRL testing at Birth	Number of Syphilis-exposed infants tested for RPR/VDRL at birth in the reporting period	Number of live births to syphilis reactive pregnant women in the reporting period	SOCH	Monthly
7.2.2	Percentage of syphilis-exposed infants received RPR/VDRL testing at 14 weeks	Number of Syphilis-exposed infants tested for RPR/VDRL at 14 weeks in the reporting period	Number of eligible syphilis-exposed infants for RPR/VDRL testing at 14 weeks in the reporting period	SOCH	Monthly
7.2.3	Percentage of syphilis-exposed infants received RPR/VDRL testing at 6 months	Number of Syphilis-exposed infants tested for RPR/VDRL at 6 months in the reporting period	Number of eligible syphilis-exposed infants for RPR/VDRL testing at 6 months in the reporting period	SOCH	Monthly
7.2.4	Percentage of infants diagnosed with congenital syphilis	Number of babies diagnosed with congenital syphilis.	The number of surviving syphilis exposed infants tested for congenital syphilis.	SOCH	Monthly
7.2.5	Percentage of syphilis-exposed infants received complete treatment of congenital syphilis	Number of cases of syphilis-exposed infants received complete treatment in the reporting period	Number of syphilis-exposed infants diagnosed as congenital syphilis in the reporting period	SOCH	Quarterly
8	**HIV Exposed Babies: EID testing**				
8.1.	EID Testing at 42-Days (6 weeks)				
8.1.1.	Percentage of babies screened for HIV at 6 weeks	Number of babies screened for HIV between 6-8 weeks during the reporting period	Number of HIV exposed babies eligible for 6 weeks EID during the reporting period	SOCH	Monthly
8.1.2.	Percentage of babies confirmed HIV positive using two DBS tests	Number of babies confirmed HIV positive at 6 weeks through two DBS test during the reporting period	Number of babies who underwent HIV testing at 6 weeks during the reporting period	SOCH	Monthly
8.1.3.	Percentage of babies confirmed HIV positive at 6 weeks initiated on-ART	Number of confirmed positive babies at 6 weeks initiated on-ART during the reporting period	Number of babies confirmed HIV positive using two DBS test during the reporting period	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
8.2.	EID testing at 6 -12 months (Patients should be prioritized for getting testing in 6-7 Months of age)				
8.2.1.	Percentage of babies screened with HIV Antibody Test at 6 months	Number of babies screened with Antibody Test at 6 months during the reporting period	Number of HIV exposed babies eligible for 6 months EID	SOCH	Monthly
8.2.2.	Percentage of babies found reactive in any one of three antibody tests for HIV	Number of babies found reactive in any one of three antibody tests during the reporting period	Number of babies screened with Antibody Test at 6 months during the reporting period	SOCH	Monthly
8.2.3.	Percentage of babies confirmed HIV positive using two DBS test at 6 months	Number of babies confirmed HIV positive using two DBS at 6 months during the reporting period	Number of babies found reactive in any one of three antibody tests during the reporting period	SOCH	Monthly
8.2.4.	Percentage of babies confirmed HIV positive initiated on-ART at 6 months	Number of confirmed positive babies initiated on-ART during the reporting period	Number of babies confirmed HIV positive using two DBS test at 6 months during the reporting period	SOCH	Monthly
8.3.	EID Testing during 12-18 months (Patients should be prioritized for getting testing in 12-13 Months of age)				
8.3.1	Percentage of HIV exposed babies screened with Antibody Test at 12-18 months	Number of HIV exposed babies screened with Antibody Test at 12-18 months during the reporting period	Total number of HIV exposed babies eligible for EID at 12 months during the reporting period	SOCH	Monthly
8.3.2.	Percentage of babies found reactive on either 3, any 2 or any one of three test at 12-18 months	Number of babies found reactive on either 3, any 2 or any one of three test at 12-18 months during the reporting period	Number of HIV exposed babies screened with Antibody Test at 12-18 months during the reporting period	SOCH	Monthly
8.3.3.	Percentage of babies confirmed HIV positive using two DBS test at 12-18 months	Number of babies confirmed HIV positive using two DBS test at 12-18 months during the reporting period	Percentage of babies found reactive on either 3, any 2 or any one of three test at 12-18 months during the reporting period	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
8.3.4	Percentage of babies confirmed HIV positive at 12-18 months initiated on-ART	Number of babies confirmed HIV positive at 12-18 months initiated on-ART during the reporting period	Number of babies confirmed HIV positive using two DBS test at 12-18 months during the reporting period	SOCH	Monthly
8.4.	EID Testing after 18 months (Patients should be prioritized for getting testing in 18-19 Months of age)				
8.4.1.	Percentage of HIV exposed babies screened after 18 months	Total number of HIV exposed babies screened using all 3 Antibody Test during the reporting period	Total number of eligible babies for 18 months EID	SOCH	Monthly
8.4.2.	Total number of babies confirmed HIV positive after 18 months EID	Total number of babies confirmed HIV positive after 18 months by all 3 Antibody Test during the reporting period	Total number of HIV exposed babies screened using all 3 Antibody Test at 18 months during the reporting period	SOCH	Monthly
8.4.3.	Percentage of babies confirmed HIV positive after 18 months initiated on-ART	Number of babies confirmed HIV positive after 18 months initiated on-ART during the reporting period	Total number of babies confirmed HIV positive after 18 months by all 3 Antibody Test during the reporting period	SOCH	Monthly
DSRC Reporting Format					
9	**Number of patients availed STI services at DSRC**				
9.1	Percentage of STI attendees counselled	Total number of STI attendees counselled	Total DSRC attendees during the reporting period	SOCH	Monthly
9.2	Percentage of STI attendees received condoms	Total number of STI attendees received condoms during the reporting period	Total DSRC attendees during the reporting period	SOCH	Monthly
9.3	Percentage of at-risk clients identified at the DSRC	Number of at-risk clients identified based on risk assessment	Total number of clients were underwent risk assessment	SOCH	Monthly
9.4.	STI/RTI Syndrome diagnosed at DSRC				

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
9.4.1	Percentage of DSRC attendees reported with STI/ RTI syndromes	Number of DSRC attendees reported with STI/RTI syndromes during the reporting period	Total number of DSRC attendees during the reporting period	SOCH	Monthly
9.4.2	Percentage of syphilis reactive provided with treatment (excluding pregnant women)	Number of eligible syphilis -reactive cases provided with treatment (excluding pregnant women) during the reporting period	Total number of syphilis reactive cases (excluding pregnant women) eligible for treatment reported during the reporting period	SOCH	Monthly
9.4.3	Percentage of people living with HIV(PLHIV) diagnosed with STI/RTI at DSRC	Number of people living with HIV(PLHIV) diagnosed with STI/ RTI during the reporting period	Number of PLHIV referred to DSRC during the reporting period	SOCH	Monthly
9.4.4	Percentage of partners of STI/RTI cases managed[12]	Number of partners of STI/RTI cases managed during the reporting period include services)	Number of partner notification undertaken for STI/ RTI cases during the reporting period	SOCH	Monthly
10	**Testing Details of HRG (FSW, MSM, H/TG, PWID, Prison inmates) and Bridge (Migrant, Transport worker) population**				
10.1	Percentage of HRG (except Prison inmates) screened for HIV	Total number of HRGs (except Prison inmates) screened for HIV either in ICTC or TI during the reporting period	Total number of HRG (except Prison inmates) active[13] during the reporting period	Program data/ SOCH	Monthly
10.2	Percentage of Bridge population screened for HIV	Total number of bridge population screened for HIV either in ICTC or TI during the reporting period	Total number of bridge population contacted during the reporting period	Program data/ SOCH	Monthly
10.3	Percentage of HRG (except Prison inmates) undergone HIV confirmatory test at ICTC	Number of HRG (except Prison inmates)undergone HIV confirmatory test at ICTC during the reporting period	Total cases found reactive during the reporting period	Program data/ SOCH	Monthly

12. Counselling, risk assessment, clinical examination, screening for HIV & syphilis and treatment
13. Provided at least one service in 6 months

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
10.4	Percentage of Bridge population undergone HIV confirmatory test at ICTC	Total Bridge population undergone HIV confirmatory test at ICTC during the reporting period	Total cases found reactive during the reporting period	Program data/ SOCH	Monthly
10.5	Percentage of HRG (except Prison inmates) confirmed HIV positive	Number of HRG(except Prison inmates) confirmed HIV positive during the reporting period	Number of HRG(except Prison inmates) undergone HIV confirmatory test at ICTC during the reporting period	Program data/ SOCH	Monthly
10.6	Percentage of bridge population confirmed HIV positive	Number of bridge population confirmed HIV positive during the reporting period	Total Bridge population undergone HIV confirmatory test at ICTC during the reporting period	Program data/ SOCH	Monthly
10.7	Percentage of HRG(except Prison inmates) linked with ARTC	Number of HRG (except Prison inmates)linked with ARTC during the reporting period	Number of HRG (except Prison inmates)tested HIV positive	Program data/ SOCH	Monthly
10.8	Percentage of bridge population linked with ARTC	Total bridge population linked with ARTC during the reporting period	Number of bridge population tested HIV positive during the reporting period	Program data/ SOCH	Monthly
10.9	Percentage of HRG (except Prison inmates) initiated on ART	Total number of HRG (except Prison inmates) initiated on ART out of linked to ART during the reporting period	Number of HRG(except Prison inmates) linked with ARTC during the reporting period	Program data/ SOCH	Monthly
10.10	Percentage of bridge population initiated on ART	Number of bridge population HRG initiated on ART out of the linked to ART during the reporting period	Total bridge population linked with ARTC during the reporting period	Program data/ SOCH	Monthly
10.11	Percentage of HRG (except Prison inmates)screened for syphilis	Number of HRG(except Prison inmates) screened for syphilis during the reporting period	Total number of HRG (except Prison inmates)active during the reporting period	Program data/ SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
10.12	Percentage of HRG (except Prison inmates)tested syphilis reactive	Number of HRG (except Prison inmates)tested syphilis reactive during the reporting period	Number of HRG (except Prison inmates) screened for syphilis during the reporting period	Program data/ SOCH	Monthly
10.13	Percentage of HRG (except Prison inmates) initiated on treatment for syphilis	Number of HRG (except Prison inmates)initiated on treatment for syphilis during the reporting period	Number of HRG (except Prison inmates) tested syphilis reactive during the reporting period	Program data/ SOCH	Monthly
11	**Index testing of PLHIV**				
11.1	Percentage of PLHIV offered Index Testing	Number of PLHIV offered Index testing during the reporting period	Number of PLHIV eligible for index testing during the reporting period	SOCH	Monthly
11.2	Percentage of contacts elicited from index cases	Number of contacts elicited	Number of PLHIV accepted for Index Testing during the reporting period	SOCH	Monthly
11.3	Percentage of eligible contacts provided consent for testing	Number of eligible contacts provided consent for testing	Number of contacts elicited	SOCH	Monthly
11.4	Percentage of contacts tested for HIV	Number of contacts tested for HIV during the reporting period	Number of contacts found eligible and provided consent for testing during the reporting period	SOCH	Monthly
11.5	Percentage of confirmed HIV positive among contacts	Number of contacts identified as confirmed HIV positive during the reporting period	Number of contacts tested during the reporting period	SOCH	Monthly
11.6	Percentage of HIV positives contacts linked with ART	Number of HIV positive contacts linked successfully for ART services during the reporting period	Number of contacts identified as HIV positive during the reporting period	SOCH	Monthly

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
11.7	Percentage of HIV positives contacts initiated on ART	Number of HIV positive contacts initiated on ART during the reporting period	Number of HIV positive contacts linked successfully for ART services during the reporting period	SOCH	Monthly
12	**Outreach services**				
12.1	Percentage of unregistered HRGs (except Prison inmates)screened for HIV through Community Based Screening	Total number of unregistered HRGs(except Prison inmates) reached during camps under revamp strategy and are screened for HIV during the reporting period	Total number of unregistered HRG (except Prison inmates) reached through camps	N: SOCH D: Annual target	Monthly
12.2	Percentage of HRGs (except Prison inmates) found reactive for HIV	Total number of HRGs(except Prison inmates) found reactive for HIV during the reporting period	Number of HRGs (except Prison inmates)screened for HIV during camps during the reporting period	Program data/ SOCH	Monthly
12.3	Percentage of positive HRGs(except Prison inmates) linked with ART	Number of positive HRGs(except Prison inmates) linked with ART during the reporting period	Total number of HRGs(except Prison inmates) found positive of the screened cases during the reporting period	Program data/ SOCH	Monthly
12.4	Percentage of Clients[14] Tested for HIV at mobile ICTC	Total clients Tested for HIV at mobile ICTC during the reporting period	Annual target assigned during the reporting period	N:SOCH D: Annual target	Monthly
12.5	Percentage of Clients confirmed HIV positive at mobile ICTC	Total clients confirmed HIV positive at mobile ICTC during the reporting period	Total clients tested for HIV at mobile ICTC during the reporting period	SOCH	Monthly
12.6	Percentage of clients confirmed HIV positive linked to ART Centre	Number of clients confirmed HIV positive linked to ART Centre during the reporting period	Total clients confirmed HIV positive at mobile ICTC during the reporting period	SOCH	Monthly

14. Mainly includes high-risk and other vulnerable population

No	Indicator	Numerator	Denominator	Source	Reporting Frequency
12.7	Percentage of clients confirmed HIV positive initiated on ART	Number of clients confirmed HIV positive initiated on ART	Number of clients confirmed HIV positive linked to ART Centre during the reporting period	SOCH	Monthly
13	**Prison and Other Closed Setting**				
13.1	Percentage of inmates tested for HIV against estimation	Total inmates tested for HIV during the reporting period	Estimated inmates during the reporting period	SOCH	Monthly
13.2	Percentage of inmates confirmed HIV positive	Total inmates confirmed HIV positive during the reporting period	Total inmates tested for HIV during the reporting period	SOCH	Monthly
13.3	Percentage HIV positive inmates put on ART	Total HIV positive inmates put on ART during the reporting period	Total inmates found HIV positive during the reporting period	SOCH	Monthly
13.4	Percentage of Inmate screened for Syphilis	Total inmates who have been screened for syphilis during the reporting period	Estimated inmates during the reporting period	SOCH	Monthly
13.5	Percentage of Inmate found Syphilis reactive	Total inmates who have been detected syphilis reactive during the reporting period	Total inmates who have been screened for syphilis during the reporting period	SOCH	Monthly
13.6	Percentage of inmates initiated for Syphilis treatment	Total inmates who have been initiated on treatment during the reporting period	Total inmates who have been detected syphilis reactive during the reporting period	SOCH	Monthly
14	**TB screening and testing**				
14.1	Percentage of clients screened for TB	Number of clients screened for TB(4S)	Total no. of ICTC attendees	SOCH	Monthly
14.2	Percentage of clients identified as Presumptive TB cases among those screened for TB	Number of clients identified as Presumptive TB cases among those screened for TB during the reporting period	Number of clients screened for TB(4S) during the reporting period	SOCH	Monthly

14.3	Percentage of clients identified as Presumptive TB referred for TB testing	Number of clients identified as Presumptive TB referred for TB testing during the reporting period	Number of clients identified as Presumptive TB cases among those screened for TB during the reporting period	SOCH	Monthly
14.4	Percentage of clients identified as Presumptive TB case tested for TB	Number of clients identified as Presumptive TB case tested for TB during the reporting period	Number of clients identified as Presumptive TB referred for TB testing during the reporting period	SOCH	Monthly
14.5	Percentage of clients diagnosed as TB among tested for TB	Number of clients diagnosed as TB among tested for TB during the reporting period	Number of clients identified as Presumptive TB case tested for TB during the reporting period	SOCH	Monthly
14.6	Percentage of clients diagnosed as TB, put on TB treatment	Number of clients put on TB treatment during the reporting period	Number of clients diagnosed with TB during the reporting period	SOCH	Monthly
14.7	Percentage of clients completed TB treatment	Number of clients completed TB treatment during the reporting period	Number of clients put on TB treatment during the reporting period	SOCH	Quarterly



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