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Ministry of Health
Government of India

National Operational Guidelines for ART Services

2021

NACO
National AIDS Control Organisation

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सत्यमेव जयते
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Additional Secretary

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FOREWORD

Provision of Anti-Retroviral Therapy for People Living with HIV (PLHIV) under the National AIDS Control Programme has been a game changer in our fight against HIV/AIDS in the country. Since the launch of free Antiretroviral treatment under NACP in April 2004, continuous efforts have been made to ensure universal access to comprehensive, equitable and stigma free treatment to all people living with HIV/AIDS in the country.

In the last decade, there has been massive scale-up and decentralization of ART services with the aim of universal access and lifelong retention on ART for all. Over the years, HIV care support and treatment related services have responded to the changes in programme planning, monitoring and delivery as well as treatment regimens. PLHIV have access to free diagnostic facilities, free antiretroviral therapy, prevention and management of opportunistic infections including Tuberculosis through a single window approach. Keeping the PLHIV at centre, NACP has also introduced differentiated service delivery models to ensure services nearer to their place of residence, to improve retention in care, adherence to Antiretroviral Therapy (ART) for favourable long-term outcomes. As we move forward, we will continue to ensure that all people living with HIV, and those at risk, receive a comprehensive package of life-saving services for treatment and care.

I am extremely happy to present the updated and revised "Operational Guidelines for ART Services, 2021" under the National AIDS Control Programme.

The revised guidelines include detailed SOP for recent initiatives under the programme like differentiated service delivery models, management of opportunistic infections and co-morbidities, rapid initiation of ART, tele-SACEP, routine viral load monitoring, treatment services for vulnerable/ at-risk key population and adolescents, access to ART in case of natural calamities/epidemic scenarios, etc.

I would like to congratulate the team of experts, partner agencies, SACS Officials, community representatives and the CST division of NACO for having diligently worked together in updating the Operational Guidelines for ART services under NACP.

These guidelines would serve as ready reckoner for programme managers at all levels, staff of ART centres and other related facilities regarding operational aspects of treatment and care services for PLHIV under NACP, and they will find this document useful for ensuring optimal utilisation of available resources under the programme.

(Alok Saxena)

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PREFACE

The ART programme in India has been hailed as one of the best national healthcare initiatives that has saved thousands of lives and prevented catastrophic outcomes for PLHIV. The care, support and treatment. Services provided under the National AIDS Control Programme (NACP) have been instrumental in providing access to free treatment and quality services, including psycho-social support, to the people living with HIV/AIDS.

India was the first country to develop the operational guidelines for ART services in 2007 with the aim of ensuring minimum quality of care standards for ART services, not only in terms of service delivery but also in terms of monitoring and supervision framework. These were updated again in 2013 to accommodate the programmatic changes as the number of facilities and PLHIV on ART increased significantly. Many countries globally have developed similar guidelines on this pattern.

ART services have undergone an enormous scale up and decentralization along with significant changes in the policies. Programme has implemented various innovative strategies and initiatives across the country like "Treat All", treatment optimization, viral load monitoring, integrated HIV TB care, differentiated service delivery models, rapid ART initiation, advanced disease management etc. These recent advances in the treatment guidelines and expansion of services as well as innovative practices called for revision in the existing ART operational guidelines (2012). Standardized and unifonn national ART Operational guidelines remain the mainstay to standardize HIV treatment services across the country and thereby improve the quality of HIV care.

These updated ART operational guidelines provide detailed Standard Operating Procedures (SOPs) for provision of care as well as for planning, implementing, and monitoring the programme for effective service delivery. These guidelines describe the various service delivery mechanisms adopted under national program to ensure comprehensive patient-centric care, including differentiated care packages, expansion of Link ART centre to community sites and ART services for special groups, comorbid conditions. These guidelines also describe the program management aspects such as setting up of service delivery points, monitoring and mentoring mechanisms, data management, supply chain management of drugs and various other facets that are essential to ensure quality treatment for people living with HIV/ AIDS.

The efforts of Dr Chinmoyee Das and entire Care Support and Treatment (CST) team at NACO in making this document a success are highly commendable. The technical assistance provided by Dr Reshu Agarwal in coordination with other experts and NACO team towards finalization of this document is highly appreciated. These Guidelines will serve as a reference document for all cadres of service providers to provide stigma-free, high quality and patient centric care and treatment services to all PLHIV in a comprehensive and equitable manner.

(Dr. Naresh Goel)

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MESSAGE

The HIV prevalence among the adult population in India has substantially declined to 0.22% (2019) with a decline in annual new HIV infections by 37% (from baseline in 2010) in comparison to the global average of 23% in the sap1e period. With an estimate 2.3 million people living with HIV in India, the country is committed to achieving the target 3.3 of Sustainable Development Goal of Ending the AIDS epidemic as a public health threat by 2030. With the aim to achieve the UNAIDS 95-95-95 targets, various initiatives have been planned and implemented by the National AIDS Control Program (NACP) in India to improve the quality of care and treatment services and to enhance retention and adherence to Antiretroviral Therapy (ART).

The care, support and treatment component under the National AIDS Control Programme (NACP) has been instrumental in providing access to free treatment and quality services, including psycho-social support, to the people living with HIV/AIDS. The free ART initiative launched in April 2004, has witnessed several changes in programme planning, monitoring and delivery as well as treatment regimens over the years. From being limited to the tertiary care centres, to the massive scale-up and decentralization, ART services in India have come a long way in implementing and accelerating the efforts towards improving access to treatment and retention. With community playing a crucial role, strategic changes have been made to further strengthen patient centric care through 'Differentiated Care Models', which include multi month dispensing of ART, decentralise ART dispensation through peripheral health systems and community-based ART refill through Targeted Interventions, Opioid Substitution Therapy centres and Care Support Centres etc. To further expand the coverage and strengthen care, national programme has also seen major changes with newer interventions and policies are also being implemented, which include viral load monitoring, treatment optimisation through roll-out of more potent treatment regimens, advanced disease management and rapid ART initiation as part of standard of care for all PLHIV.

With the inclusion of these newer treatment and care strategies, the revised ART operational guidelines provide detailed insights on the planning, implementing, and monitoring of the programme for effective service delivery. The probable challenges in programme implementation have been well anticipated and strategies have been developed to make treatment services more patient friendly, leading to improved retention in HIV care. These revised ART Operational Guidelines will guide the programme staff on the changes in the programme policies with recent updates and inclusions. The guidelines also include the service delivery models for care support and treatment, patient centric differentiated care packages, ART services for special groups including key population, processes for the public and private sector engagement, systems for efficient data management and financial management and many other aspects that are essential to ensure quality treatment for people living with HIV/ AIDS.

NACO is proud to publish these national guidelines which include a compilation of all the latest updates and initiatives in the National AIDS Control Program. I hope that these updated ART Operational Guidelines will serve as a guiding document for the ART centres in providing quality comprehensive HIV care and saving lives of thousands of PLHIV.

(Dr. Anoop Kumar Puri)

ACKNOWLEDGEMENT

Recent changes in ART service delivery, mechanism, planning and monitoring processes needed to be updated in the Operational Guidelines for ART services. For reviewing the Operational Guidelines, inputs were sought from all divisions at NACO, representatives from SACS, Centres of Excellence, ART centres, community representatives, experts from the Technical Resource Group (TRG) and partner organisations. After series of consultations with all stakeholders this document has been developed.

The overall guidance provided by Shri Alok Saxena, AS & DG, NACO has been instrumental in making this document comprehensive and user friendly to ensure high quality services to PLHIV. Constant guidance as well as programmatic and technical leadership of Dr Naresh Goel (Ex-DDG, NACO) has provided stewardship in shaping this document. Valuable insights from Dr A.K. Puri (DDG, NACO) have been critical in completion of these guidelines. All the components of NACO provided inputs on cross cutting areas under the guidance of Dr Shobini Rajan (DDG, NACO) and all the Deputy Directors –Dr Bhawani Singh, Dr Saiprasad Bhavsar, Dr Bhawna Rao. Valuable insights and coordination efforts led by Dr Chinmoyee Das (DD CST, NACO) have been critical in completion of these guidelines.

The valuable inputs of the entire team of CST Division, NACO – Dr Maninder Manihani, Dr Purnima Parmar, Mr Archit Sinha, Mr Mathew Sebastian and Mr Bijo P. Abraham and Dr Saima Furqan and the efforts taken for coordination with all the members in making this document a success is highly commendable.

Technical assistance provided by Dr Reshu Agarwal (CDC), who led and coordinated the process of drafting the revised guidelines, is duly acknowledged. Support provided by Dr Srikala Acharya (APD, Mumbai DACS), Dr Samina Nadeem (RC, NACO), Dr Ravi Kumar (RC, NACO), Dr Sudhir Chawla (ex-JD, Gujarat SACS), Late Mr Prashant Malaiya (Ex DD, MP SACS), Dr Anwar Parvez (I-TECH), Dr Ramesh Allam (CDC) and Dr B Ravi (SHARE India) in completion of the guidelines is also appreciated.

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This document would not have been possible without the support of communities, ART centre staff, SACS officials and all stakeholders who have been providing valuable inputs to the program constantly.

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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ADM	advanced disease management
AHD	advanced HIV disease
AIC	airborne infection control
AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral drugs
ATT	anti TB treatment
CARG	community ART refill groups
CBNAAT	cartridge based nucleic acid amplification test
CBO	community-based organization
CD4	cluster of differentiation 4
CHC	community health centre
CLHIV	children living with HIV
CoE	centre of excellence
CPT	cotrimoxazole prophylactic therapy
CSC	care and support centres
CST	care support and treatment
CQI	continuous quality improvement
DAPCU	district AIDS prevention and control unit
DBS	dried blood spot
DMC	designated microscopy centre
DPM	district program manager
DSD	differentiated service delivery
DTG	dolutegravir
EID	early infant diagnosis
FEFO	first expiry/first out
FSW	female sex worker
HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health care workers
HIV	human immunodeficiency virus

ICTC	integrated counselling and testing centre
ICF	intensified case finding
IMS	information management system of NACP (currently being referred to as SOCH)
IPC	infection prevention and control
IRIS	immune reconstitution inflammatory syndrome
KP	key population
LAC	link ART centre
LFU	lost to follow-up
MIS	missed for ART refill
MMD	multi-month dispensation
SMO/MO	senior medical officer/medical officer
MOHFW	Ministry of Health and Family Welfare
MSM	men who have sex with men
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NACEP	National AIDS Clinic Expert Panel
NCD	non-communicable diseases
NDLS/RDLS	national/regional distance learning session
NGO	non-governmental organization
NPCDCS	National Program for Prevention and Control of Cancer, Diabetes, CVD and Stroke
NTEP	National Tuberculosis Elimination Programme
NVHCP	National Viral Hepatitis Control Programme
OI	opportunistic infections
ORW	outreach worker
OST	opioid substitution therapy
pCoE	pediatric centre of excellence
PEP	post-exposure prophylaxis
PHC	primary health centre
PLHIV	people living with HIV
PPE	personal protective equipment
PPTCT	prevention of parent to child transmission
PWID	people who inject drugs
SACEP	state AIDS clinical expert panel
SACS	State AIDS Control Society
SGRC	State Grievance Redressal Committee
SOP	standard operating procedure
STI	sexually transmitted infections
TB	tuberculosis
TG	transgender
TI	targeted intervention
TPT	tuberculosis preventive treatment
VL	viral load

INTRODUCTION

India is committed to 'Ending the AIDS' epidemic as a public health threat by 2030 in line with Sustainable Development Goals (SDG). The vision of the National AIDS Control Programme (NACP) is that of 'Paving the way for an AIDS free India' through 'attaining universal coverage of human immunodeficiency virus (HIV) prevention, treatment to care continuum of services that are effective, inclusive, equitable and adapted to needs. The goals remain those of the 'Three Zeros'-i.e. zero new infections, zero AIDS-related deaths and zero discrimination which form the basis of the national strategic plan.

The Government of India is committed to providing universal access to comprehensive, equitable, stigma-free, quality care, support and treatment services to all PLHIV through an integrated approach. The lifesaving antiretroviral therapy (ART) has improved millions of lives and significantly averted infection. In 2019, there were an estimated 23.49 lakh (17.98 lakh–30.98 lakh) people living with HIV (PLHIV) in the country, with an adult (15–49 years) HIV prevalence of 0.22% (0.17–0.29%). There were 69.22 thousand (37.03 thousand–121.50 thousand) new infections in 2019 which has declined by 37% since 2010 and by 86% since reaching the peak in 1997. There were 58.96 thousand (33.61 thousand–102.16 thousand) AIDS related deaths in 2019, which has declined by 66% since 2010 and by 78% since attaining peak mortality in 2005.

The free ART initiative began on the 1st April 2004 in 8 tertiary level hospitals across 6 high prevalence states and the NCT of Delhi. Since then, there has been a massive scale-up and decentralization of ART services with the aim of universal access to life saving ART for all PLHIV, along with lifelong retention and sustained viral load suppression. PLHIV have access to free diagnostic facilities; free first-line, second and third-line ART; prevention of parent to child transmission of HIV (PPTCT) services; prevention, diagnosis and management of opportunistic infections including management of Tuberculosis (TB) with daily anti-TB treatment through a single window approach. As part of comprehensive care, the national programme also provides psychosocial support and follow-up services, individualized thematic counselling, positive living and positive prevention services with appropriate referral linkages to various social beneficiary schemes. Currently, HIV care and treatment services are being delivered through a network of 620 Antiretroviral Therapy centres and 1264 Link ART centres along with 310 care and support centres to approximately 1.4 million PLHIV across the country (June 2021).

Standardized and uniform national ART operational guidelines remain the mainstay to standardize HIV treatment services across the country and thereby improve the quality of HIV care across all sectors of health care in our country context. NACP has updated its guidelines with regards to programmatic and technical aspects of ART from time to time. In addition to the evidence-based scale-up of facilities, there have been regular updates in the programmatic and technical guidelines, keeping pace with new evidence, global developments, and recommendations.

Over the years, national program has witnessed several changes ranging from adoption of 'treat all' policy; dolutegravir based regimens for treatment optimization; introduction of viral load (VL) testing for monitoring of PLHIV on ART; implementation of patient centric differentiated care models including multi-month dispensation (MMD); expansion of Link ART centre (model for provision of decentralised ART) to include community sites; revision of recording and reporting systems; adoption of IT-enabled Information Management System (IMS). These guidelines herein encompass all the updates and initiatives under the national program and include

compilation of all office memorandums (OM) issued by NACO from time to time with respect to ART service delivery. These operational guidelines for ART services are written based on the national recommendations that have been finalised grounded on national and global experiences and recommendations and taking into consideration the feasibility for implementation in country context. The current guidelines are based on the recommendations of the Technical Resource Group (TRG) for Antiretroviral Therapy comprising of technical as well as programmatic experts from the public and private sectors, Government of India, World Health Organization (WHO) and other UN agencies, bilateral partners, network of positive people and non-governmental organizations (NGOs) involved in the care and treatment of PLHIV. The inputs and best practices received from the field from time to time have been taken into consideration in the revision of the operational guidelines.

Objectives of operational guidelines for ART services:

- To standardise HIV care and treatment services across all the facilities in the country with the aim of achieving the goal of 95:95:95 to 'end the AIDS epidemic' as a public health threat by 2030 in line with **Sustainable Development Goals**
- To provide comprehensive, consolidated and most updated guidance for implementation of ART services in the country
- To serve as reference document for all service providers and programme managers for implementation and monitoring of HIV care support and treatment services
- To support provision of comprehensive, equitable, stigma-free, quality and patient centric care and treatment services to all PLHIV

Organization of the guidelines: These updated ART operational guidelines are divided into two main parts

Part I (Guidelines for ART service provision): Provides detailed Standard Operating Procedures (SOPs) for provision of care to PLHIV. This part describes the various service delivery mechanism adopted under national program to ensure comprehensive patient-centric care, including differentiated care packages, decentralised services through Link ART centre, ART services for special groups and PLHIV with comorbid conditions etc.

Part II (Guidelines for implementation of service delivery models): Provides insights for planning, implementing, and monitoring the programme for effective service delivery. This part describes the program management aspects such as setting up of service delivery points, infrastructure, human resource (HR), monitoring and mentoring mechanisms, data management, supply chain management of drugs and various other facets that are essential to ensure quality treatment for people living with HIV/ AIDS.

"National Operational Guidelines for ART Services 2021" embrace as well as supersede all the office memoranda issued by NACO on programmatic aspects of ART till the date of release of these guidelines. These guidelines are a living document and will continue to evolve and will be revised and updated on regular basis as per national and global evidence and recommendations. These guidelines are to be used in conjunction with National Guidelines for HIV care and Treatment 2021.

PART I :

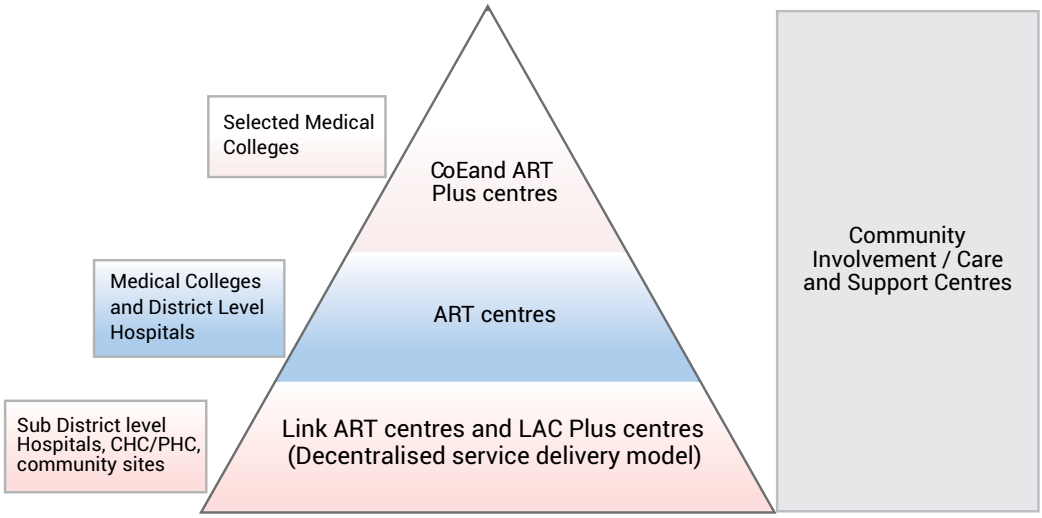
GUIDELINES FOR ART SERVICE PROVISION TO PLHIV

CHAPTER 1

SERVICE DELIVERY MODEL FOR CARE SUPPORT AND TREATMENT

National AIDS Control Programme (NACP) is committed to universal coverage across the HIV prevention to treatment continuum of services, which are effective, inclusive, equitable and adapted to needs of the community. One of the key objectives of NACP is to provide care, support and treatment to all PLHIV and ensure lifelong retention and sustained viral load suppression. NACP aims to facilitate sustainable and patient centric service delivery through a three-tier structure for delivery of care support and treatment services to all PLHIV. This service delivery model for HIV care and treatment comprises ART centres, Centres of Excellence and Link ART centre. The network of service delivery points is being expanded to ensure universal access to ART. Community involvement has been one of the core pillars of care and treatment services. ART centres are also linked with care and support centres (CSC) for providing a comprehensive package of services.

Figure 1. Service delivery model for HIV care, support and treatment



1.1 ART Centres

The free ART services in India were rolled out on 1st April 2004 under NACP in eight government hospitals. Since then, the services have been scaled up to 620 centres providing ART to nearly 14 lakhs PLHIV on ART across the country (June 2021).

The ART centres are established mainly in the medicine departments of medical colleges and district hospitals. However, some ART centres are functioning in the sub-district and block hospitals also mainly in high prevalence states. The centres are set up based on prevalence of HIV in the district/region, capacity of the facility to deliver ART related services. In addition to government sector, NACO is also engaging with private sector for setting up of ART centres. As per the Gazette of India notification dated 28th October 2020, every teaching college should have ART centre by the time of 3rd renewal (admission of 4th Batch of MBBS students).

1.1.1 Objectives of ART centre

The main objective of ART Centre is to provide comprehensive package of care, support and treatment services that are effective, inclusive, equitable and adapted to needs of PLHIV.

1.1.2 Functions of ART centre

ART centres are mandated to give comprehensive and holistic care to PLHIV. Functions of ART centre can be categorised as medical, psycho-social and programmatic as indicated below:

a. Medical functions

- Provide ART to all PLHIV
- Provide baseline and follow up investigations to PLHIV, including CD4 cell count and viral load testing
- Provide prophylaxis and management of opportunistic infections
- Provide TB preventive and management services as per guidelines
- Identify PLHIV with advanced HIV disease for appropriate management and refer to higher level of care as needed to reduce mortality
- Provide patient-centric differentiated care to PLHIV
- Monitor, manage and follow up PLHIV for adherence, retention and adverse effects (if any)
- Provide treatment education and counselling on 100% adherence to therapy and retention for long term effectiveness of ART
- Facilitate linkage to specialist care /in-patient care, as and when necessary
- Referral/e-referral of PLHIV with treatment failure to SACEP for review for second line/third ART and complicated adverse effects
- Provide appropriate interventions for PPTCT and care of exposed child
- Provide linkages with other health services, including non-communicable diseases and other comorbidities

b. Psychosocial functions

- Provide psychological support to PLHIV and caregivers
- Provide counselling for adherence to ARV drugs
- Educate PLHIV on proper nutrition and healthy living
- Assist in the disclosure of HIV results to spouse/family
- Counselling for testing of spouse/partners/children
- Step up counselling to PLHIV who have poor adherence and are virally unsuppressed
- Counsel for risk reduction behaviour including safe sex practices
- Provide appropriate counselling to PLHIV belonging to special groups (key population, children, adolescents, migrants, pregnant women etc.)
- Facilitate linkages with care and support centres to improve:
  - Retention for sustained viral suppression; and
  - Access to social protection schemes provided by various line ministries under central and state government.

c. Programmatic functions

- Contribute to achieving goal of 95:95:95 to 'End the AIDS' epidemic as a public health threat by 2030 in line with Sustainable Development Goals (SDG)
- Proper recording and timely reporting as per national guidelines
- Tracking of missed for ART refill (MIS) and lost to follow-up (LFU) cases in coordination with DAPCU, CSC, ICTC, link workers, TI NGO and other NGO approved by NACO/SACS
- Coordination with National Tuberculosis Elimination Programme (NTEP) for management of HIV-TB coinfected patients and to ensure availability of drugs for anti-TB treatment (ATT) and TB preventive treatment (TPT)

- Mentoring the LAC and co-ordination with LAC staff for ARV drug indent, monthly reporting CD4, and viral load test
- Sensitize the hospital staff on care support and treatment (CST) services

1.2 Link ART Centres and LAC Plus Centre (LAC plus)

This is a differentiated service delivery model for decentralized ART services near the patient's residence rolled out in 2008. These sites could be community health centres, primary health centres, opioid substitution therapy centres; care and support centres and targeted intervention sites and other community level sites at NGOs/ CBOs/ CSOs. The goal of this model is to make the treatment services easily accessible to PLHIV and promote adherence by addressing the barriers associated with inconvenience due to frequent visits, 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 patients on ART, treatment of minor OIs, identification and management of adverse effects and reinforce adherence on every visit. Over time, the number of LAC has been expanded to more than 1200 centres, providing services to 1,16,000 PLHIV to support drug adherence and retention in care.

With the adoption of 'treat all' policy in 2017, all PLHIV need to be initiated on ART at the earliest after diagnosis or as soon as possible based on other considerations such as concurrent opportunistic infections (OIs). Therefore, LAC plus scheme is being revised to expand the scope to include ART initiation. LAC Plus centres shall also be authorized to initiate ART after written approval from NACO/SACS. This will help in integrating HIV care into general health system; making ART more accessible and convenient to PLHIV; bridging the gap between HIV testing and treatment services.

The detailed functions and SOPs of LAC Plus centres are described in **Section 5****.** As a step towards patient centric care and ensuring uninterrupted ART services to PLHIV, programme plans to set up Community ART Refill Groups (CARG), particularly in difficult terrains and hard to reach areas. Details are provided under Section 4.4.3.3.

1.3 Centres of Excellence and ART Plus Centres

1.3.1 Centres of Excellence (COE)

The HIV/AIDS epidemic is complex, necessitating comprehensive care, effective health delivery systems, trained and motivated workforce and operational research. PLHIV have a varying need ranging from management of advanced disease, complicated OIs, immune reconstitution inflammatory syndrome (IRIS), non-infectious HIV related illnesses, coinfections and comorbidities. Therefore, HIV care requires a comprehensive care approach that meets the multitude of care challenges. HIV providers need to be up to date with the latest HIV treatment guidelines and patient management protocols. Hence, the model of Centres of Excellence (CoE) in HIV care was developed in 2008 with an objective that these centres shall be model treatment centres, impart high quality training and would be primary sites for undertaking operational and clinical research on a larger scale. Currently, eleven Centres of Excellence (CoE) are functioning and are providing comprehensive HIV care over the years including ART, support and treatment and have been involved in training and research. In addition, there are seven paediatric Centres of Excellence (pCoE) providing high quality care to children. These centres also serve as model centres in diagnosis, treatment, care continuum of HIV/AIDS, opportunistic infections other HIV/AIDS-related conditions, recording reporting, infection control practices and pharmacy practices.

Functions of Centres of Excellence: In addition to routine functions of ART Centres, CoE are mandated to perform the following functions:

- **Providing comprehensive care which includes** management of complex OIs/HIV associated illness/ART related adverse effects/complications; and conducting State AIDS Clinical Expert Panel (SACEP) to review PLHIV for second line/third line ART (both adults and paediatric).
- **Training and mentoring**

- **Research**
- **Technical support to national programme**

Please refer to Section 12 for detailed guidelines for CoE/pCoE.

1.3.2 ART Plus centres

The concept of ART plus centre has evolved to expand the access to 2nd Line ART beyond the centres of excellence. Select ART centres across the country have been identified as ART Plus centres. These ART plus centres have been capacitated to conduct SACEP to review PLHIV for second line/third line ART (both adults and paediatric) following the same referral procedure as adopted for the Centres of Excellence. Presently, a total of 94 ART plus centres are functional in the country.

1.4 Care and Support Centres

The care and support centres (CSC) since its inception in April 2013 serves as a comprehensive unit for treatment support for retention, adherence, positive living, referral, linkages to need-based services, and strengthening an enabling environment for PLHIV. CSC are community-based service delivery points and play a vital role to reduce stigma and discrimination through effective treatment literacy activities in coordination with local PLHIV networks. These community-based CSCs are an integral part of the national response to meet the needs of PLHIV, including those from high-risk groups and women and children living with HIV. The goal of CSC is to improve the survival and quality of life of PLHIV. Major objectives of CSC are as follows:

- Early linkage of PLHIV to care, support and treatment services
- To improve treatment adherence and education for PLHIV
- To leverage positive prevention activities
- To improve social protection and wellbeing of PLHIV

For details on care and support centres, please refer to Guidelines for Care and Support Centres, 2018.

CHAPTER 2
ART INITIATION

This chapter describes the detailed SOPs for ART initiation, including management of patients with advanced HIV disease. This chapter serves as guidance to the staff of ART centre for patient monitoring and follow up.

NACO adopted "Treat All" policy in May 2017 which means that all persons diagnosed with HIV infection are eligible for ART initiation regardless of CD4 count or WHO clinical staging. Steps involved in ART initiation are as follows:

- Registration in HIV care
- Preparedness counselling
- Initial evaluation
- OI prophylaxis and management of PLHIV with advanced HIV disease
- Timely ART initiation

2.1 Registration in HIV Care

All persons detected HIV positive at an ICTC should be referred to the nearest (based on convenience of PLHIV) ART centre/LAC plus for ART initiation. Post-test counselling session at an ICTC should adequately emphasise on benefits of ART and importance of adherence, positive living, the need to involve caregiver and regular follow up (such that it helps in preparedness of the patient for ART).

ICTC counsellor should provide guidance to the PLHIV to carry the following documents while going to ART centre, along with address, telephone number of ART centre:

1. ICTC report
2. A valid address proof
3. Passport size photographs (2)

In order to ensure good adherence, it is desirable that patient is enrolled at an ART centre nearest to his current place of stay; however, the decision about the preferred ART centre for enrolment is to be taken by the patient. The information about the available options for the same must be provided by the ICTC counsellor.

Once the HIV positive person reaches the ART centre, s/he should be enrolled in HIV care register and patient's demographic and other relevant information recorded in **patient treatment record (white card)** and a **green book** is issued to him/her. The ART counsellor should get full contact details of the patient and one caregiver, including phone numbers while enrolling in HIV care. Any information that is not available or not complete should be updated in subsequent visits. A documentary evidence of address proof in the form of aadhar card/ voter card/ ration card/ electricity or telephone bill etc. should be obtained. For patients from rural areas, a letter from the panchayat chief (Sarpanch) will suffice as address proof. For patients who are street dwellers, CSC or some NGO/CBO may take the responsibility of following them regularly. However, registration/treatment should not be denied even if the patient does not carry a valid identity proof. Instead, s/he should be registered and asked to bring the address proof during the subsequent visit. In case of migrants, full contact details of current residence and native place should be obtained. Similarly, in case of pregnant woman full contact details of in-laws, parent home and current residence all may be collected with care and assurance of maintaining the confidentiality of the patient.

2.2 ART Preparedness Counselling

ART preparedness counselling is a critical part of the ART initiation process. Antiretroviral treatment should be started based on the patient's informed decision and preparedness to begin ART. Preparedness counselling comprises a stepwise approach, which includes establishing rapport, providing basic information about HIV and ART, providing treatment education (lifelong treatment, dosages and timings, importance of adherence for VL suppression, adverse effects), guidance on positive living and prevention, encouraging disclosure and developing an individual treatment plan fitting ART to the patient's lifestyle. Detailed behavioural/ psychosocial assessment needs to be carried out which should include information about education level, employment status, financial status, social support and family / household structure and identification of primary care giver. Besides this, nutritional and mental health assessment should also be done. Treatment education and adherence support should be provided to the patient without delaying treatment initiation. Caregivers must also be counselled and trained to support treatment adherence, follow-up visits and shared decision-making. ***In addition to counsellor, medical officer should also support the process of preparedness counselling to ensure long-term retention and viral load suppression in PLHIV.***

Since the guidelines for ART eligibility, initiation, monitoring and follow up have evolved over the years, it is very important for ART staff to familiarize themselves to new counselling messages around ***treat all policy, rapid ART initiation, VL monitoring, differentiated care especially advanced disease management, undetectable =untransmissible (U=U)*** which means that persons with an consistently undetectable viral load has minimal chance of transmitting the virus sexually to their contacts, if adherent to ART.

High degree of adherence is essential for optimal virologic suppression and therefore counsellors should identify PLHIV having risk factors associated with poor adherence or poor retention such as financial/ distance related issues, migration, lack of understanding, mental health, comorbidity/coinfection, advanced HIV disease, alcoholism, substance abuse etc., and must provide the individualized focused counselling to these patients. **Peer counselling** should also be a part of the initial counselling where an HIV positive person will talk to PLHIV on importance of ART adherence and the importance of furnishing correct contact details for further follow-up and support. For this, support from **care coordinator/CSC** staff should be taken. At least one counselling session should also be provided to the caregiver in first three months of ART initiation. Patient centric focused counselling should be provided for special groups such as key populations, children, adolescents, pregnant women, etc (refer to Section 7 for details on best practices for provision of ART services to special groups). PLHIV should also be counselled and supported for disclosure and testing of spouse/sexual partners and children (Index testing services which is a voluntary case-finding approach, with the consent of the HIV positive person, focus on the elicitation of the sexual and/or needle sharing partners and biological children of consenting HIV positive individuals and offer them HIV testing services).

Preparedness counselling requires reinforcement approach. Post-initiation support is vital for the first few months of treatment initiation. Patients need extra support to ensure they do not disengage early in their treatment journey. Therefore, **quality counselling sessions for preparedness should be continued even after ART initiation, especially, during the first three months of starting ART.** Patients should be assisted to develop an individualized adherence plan by addressing the potential barriers for adherence. **A minimum of four sessions should be done as part of preparedness counselling as per details below:**

Session 1: Day of registration in care/day of initiation

- Provide education on HIV and its management
- Explain importance of ART adherence and prepare an adherence plan

Counsellors should use **seven Point counselling tool for ART preparedness** (Figure 2) which shall guide them through the process.

Step 1: Education about HIV and ART

Step 2: Identify the patient's motivation to stay alive and healthy

Step 3: Identification of caregiver

Step 4: Identify the potential barriers to adherence or retention

Step 5: Identify strategies to ensure good adherence

Step 6: Devise a treatment plan that suits the patient the best

Step 7: Plan for the next appointment

Session 2: First follow up visit after ART initiation

- Review and recap the patient's understanding about previous session/ visit
- Review the patient's adherence of the previous month and assess if the patient managed to apply the strategies agreed upon last time
- Encourage and motivate
- Explain treatment pathway ahead: At 6 months, a viral load test will be done which will measure how well you are taking your treatment and whether it is working to suppress the HIV virus
- Explain importance of adherence for healthy life, achieving viral load suppression and reduction in transmission risk (using U=U message)
- Explain risks associated with non-adherence, including illness and unsuppressed viral load
- Review and revise the adherence plan based on patient's feedback or any new issue identified
- Explain to the patient that if they take their treatment well, they will be eligible for multi month dispensations and ARV refill from Link ART centres

Session 3: Second follow up visit after ART initiation

- Review and recap the patient's understanding about previous session/visit
- Review the patient's adherence of the previous month
- Review and finalise the adherence plan based on patient's feedback or any new issue identified

Session 4: Third follow up visit after ART initiation

- Restate goals of viral load suppression and treatment pathway ahead if assessment result normal

"ART Preparedness Counselling Checklist" (Annexure 1) should be used and filled by the counsellors in the ART centre and kept in white card of PLHIV. The first section should be filled at the time of first visit of PLHIV to the ART centre. All details of this section may not be available during the first visit itself. Counsellors must try and get all the details in the subsequent visits. The follow up sections will be filled after one, two and three months of ART initiation, respectively. This form will help the counsellors to identify the various potential barriers to treatment adherence and develop appropriate strategies with the patient to overcome these barriers. This checklist will also help to identify any other issue(s) faced by PLHIV in taking ART.

Begin follow up sessions by reviewing the patient's adherence in the previous month. Review and recap the patient's understanding about what was discussed in the previous session. If the patient's adherence is more than 95%, appreciate/motivate the patient to maintain the same and discuss about what strategies worked for him/her. If the patient's adherence is less than 95%, identify the reason for the same and enquire if the strategies which were discussed in previous visit were implemented or not. It is important to actively probe and identify any new issue or barrier to adherence has occurred in this visit and devise strategies to tackle the same. Each session must conclude with devising a treatment plan in consultation with the patient and a reminder about the next due date to visit the ART centre. This will include convenient time to take the drug, how to store ART, what reminder tools can be used and how to space drugs if the patient is on medication for any other concomitant illness. The counsellor shall then schedule the date for the next visit in consultation with the patient and reinforce the importance of regular follow-ups.

Figure 2. Seven-point counselling tool for ART preparedness

Explain the purpose of the session: Acknowledge that as facility staff you are there to support patients. Explain that you will assist them by discussing together any barriers they may have and to assist them in creating an individualized adherence plan to help them take their treatment correctly. Be open and alert to any personal difficulties and struggles with aspects of the information

STEP-1: Education about HIV and ART	• Ask questions to assess understanding of HIV and ART • Provide education on HIV and ART using the pointers provided in the checklist (HIV is a chronic manageable disease which require lifelong medication) • Explain benefits of ART (ART stops HIV from making more virus, allowing you to be healthier, U=U) • Explain importance of adherence and lifelong treatment
STEP-2: Identify patient's motivation to stay alive and healthy	• Ask patient to think about things that make them want to stay healthy and to live fully • Ask them to think about the important people in their lives • Ask them to identify specific things that they really want to have in life, for example go to school or work or taking care of family or anything that is specific to the person
STEP-3: Identify caregiver	Assist the patient to identify support system by asking the following questions: • Who could support you in taking your treatment? family/friends or others • How important do you think it is to disclose your health status? • Counsel the caregiver about importance of treatment adherence and follow-up visits • Discuss any social or personal issues that the patient may have and support the patient to address the same
STEP-4: Identify the potential barriers to adherence or retention	• Encourage the patient to be frank about personal issues (as per checklist) that may affect their adherence and help them to address issues • Acknowledge common barriers that other patients have experienced to make the space safe and avoid judgments • Invite patient to express beliefs or concerns that may interfere with their treatment • Provide patient with appropriate information/support (counselling, peer support, treatment buddy, need-based referral) which will help them address the issue/s that have been identified
STEP-5: Identify strategies to ensure good adherence	• Ask: What could help you to remember to take the treatment? • Discuss treatment reminders and adherence options based on the specific needs of the patient: phone calls by treatment buddy, SMS, ICT based tools, alarm, calendar, TV shows etc.
STEP-6: Devise a treatment plan that suits the patient the best	• Advise the patient to take ART at a fixed time everyday, preferably at night. However, if this is not feasible, ask for the best time to take ART as per the schedule of the patient? • Many PLHIV do not have any private place to ***store*** their medicines and are not able to take them in privacy. Ask: What safe place could you identify to store your ART? How can you always carry 1 or 2 doses with you? • How will the patient remember or who will remind him/her to take the medication if he/she forgets? What ***reminder tools*** will the PLHIV use? • What will you do in case you ***forget to take a dose?*** If the pill of the once daily regimen of TLD is missed, then it should be taken as soon as patient remembers within 12 hours. Missed doses can be taken up to 6 hours later in a twice-daily regimen. Are any other ***family members*** on ART? If yes, try to align the due dates for family centric approach • Is the patient on ***medication*** (including prevention or management of OI) for any other illness? If yes, explain about the adherence, duration, drug-drug interactions and timing/spacing of medications • Visit/contact the ART centre if you have new symptoms (IRIS/adverse effects)
STEP-7: Plan for the next appointment	• Schedule due date for next visit in consultation with the patient • Remind PLHIV about the next due date to visit the ART centre and explain the importance of regular clinic attendance for monitoring of efficacy, adverse effects and adherence

Note: Assess the patient's readiness to start ART. If the patient is not ready, repeat the counselling session/s as required. This tool should be kept with each counsellor for ready reference

2.3 Initial Evaluation

A comprehensive clinical and laboratory assessment should be done for all PLHIV. This helps to determine:

- WHO clinical stage of the HIV infection and to identify the **PLHIV with advanced HIV disease**
- Need for OI prophylaxis
- Optimal ART regimen
- Psycho social and nutritional needs

The following steps should be followed for initial evaluation of PLHIV:

Step 1: Clinical assessment and history

Step 2: Physical examination

Step 3: Baseline laboratory evaluation

Step 1: Clinical assessment and medical history

Assessment and history taking should include:

- 4 symptom screening for TB (**Adults and adolescents:** fever, cough, weight loss, night sweats; **Children:** fever, cough, poor weight gain, h/o contact with a TB patient)
- Any persistent symptoms-headache, poor concentration, seizures
- General medical history for comorbid conditions–diabetes, hypertension etc.
- History of tuberculosis in past/family
- Any prior exposure to ARVs in the past
- Any sexually transmitted infection (STI)
- HIV risk behaviour–multiple partners, key populations, injecting drug use
- Substance abuse–alcohol, tobacco, oral or injecting drugs
- Pregnancy and contraception
- Allergies/medication/vaccines
- Nutritional status
- Psychosocial assessment

Step 2: Physical examination

It is essential to conduct a thorough physical examination for clinical staging and screening. A detailed physical examination should be done at the first visit which should include measurement and recording of vital signs (temperature, pulse rate, blood pressure, respiratory rate), body weight and height (paediatric). Besides this a detailed examination of the oral cavity, lymph nodes, skin, genital ophthalmic and systemic examination need to be carried out. For more details refer to **"National Guidelines for HIV care and Treatment 2021".**

Step 3: Baseline laboratory work up of PLHIV

Essential/mandatory tests for all patients registering in HIV care

- Haemogram/CBC
- Fasting blood sugar
- Blood urea, serum creatinine
- Serum bilirubin, ALT (SGPT)
- CD4 count
- Urine for routine and microscopic examination
- X-ray chest PA view (digital, if possible)

Additional tests in the baseline as per the physician's decision

- Symptoms and signs directed investigations for ruling out opportunistic infections, including M. tuberculosis by testing sputum/appropriate specimen by molecular diagnostics (nucleic acid amplification test-NAAT) for TB (CBNAAT/TrueNAT) and/or other required investigations
- Complete LFT (liver function test) for those being initiated on ATT and for patients with Hepatitis B or C coinfection
- USG whole abdomen
- Rk 39 strip test to confirm or rule out leishmaniasis in PLHIV having fever >2 weeks' duration, hepatosplenomegaly and pancytopenia residing in or h/o visit to endemic areas (Bihar, eastern Uttar Pradesh, Jharkhand and West Bengal)
- Pregnancy test (if applicable) •For women, cervical PAP smear / visual inspection with acetic acid (VIA) or other method of cervical cancer screening
- Lipid profile (if available)
- HBsAg and anti-HCV antibodies (especially for key populations and high-risk groups) (if available)
- Fundus exam for those with CD 4 count≤100 cells/cmm (if available)
- VDRL (if available)
- Anal PAP smear for MSM (if available)

Non-availability/non-feasibility of any of above tests should not delay the initiation of ART

2.4 Initiation of ART

After the assessment of treatment readiness by the counsellor, PLHIV should be initiated on ART by the medical officer.

- Treatment should be started based on the person's informed decision and preparedness to initiate ART with information and understanding of the benefits of treatment, lifelong course of medication with good adherence.
- An informed consent should be obtained from the patient or from the caregiver in-case the patient is a minor, before initiating HIV care and ART (Annexure 2: Consent form. Should be printed in local languages)

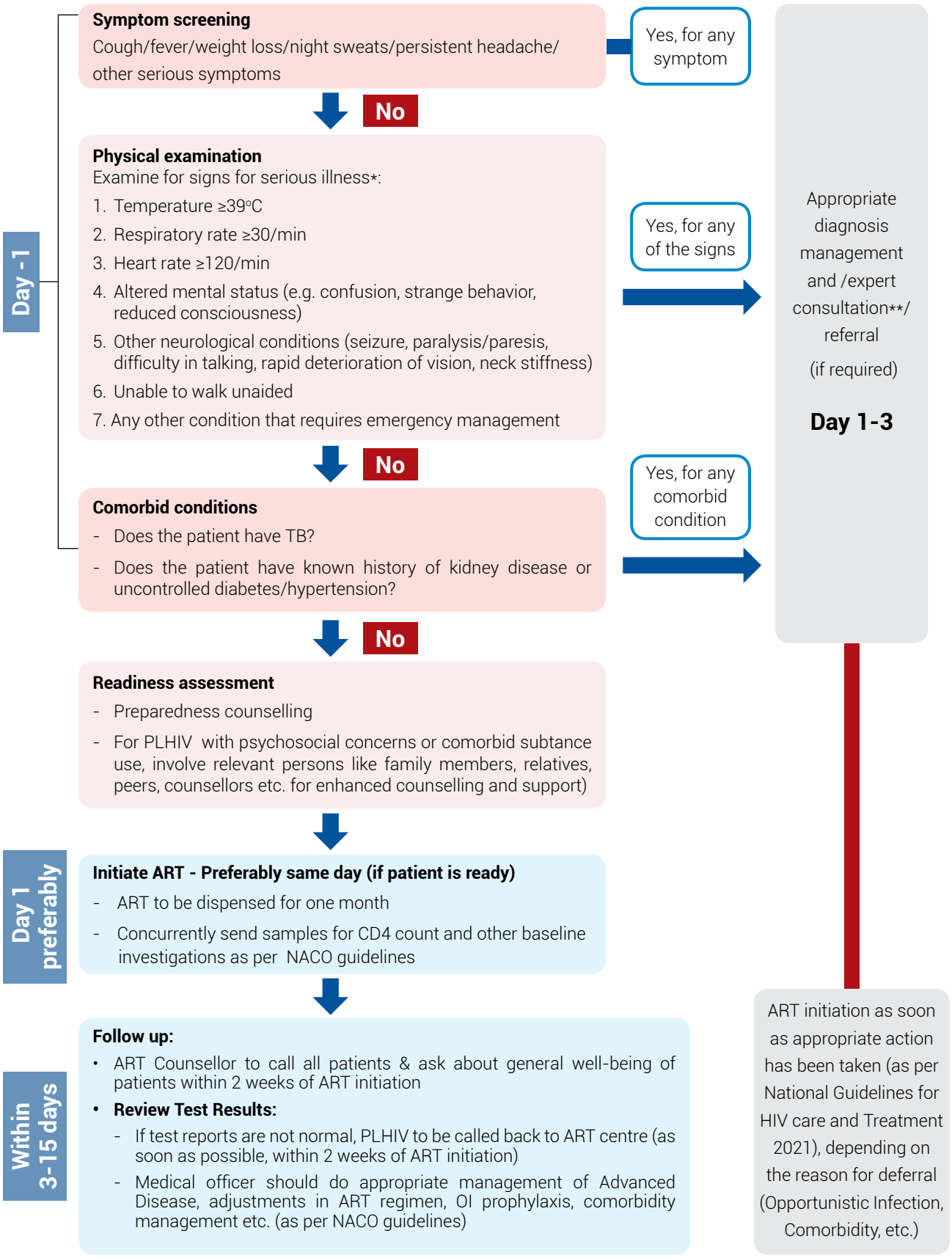
The introduction of the "Treat All" recommendation supports the **rapid initiation** of ART, including the offer of **same-day** initiation where there is no clinical contraindication. ***Following a confirmed HIV diagnosis and clinical assessment, same day /rapid ART initiation (at the earliest) should be offered to all people living with HIV, adequately prepared and ready for initiation.*** However, if an active OI is present, ART initiation may be deferred as required.

PLHIV should be assessed to readiness for ART initiation using the algorithm provided at Figure 3 below (with concurrent sample collection for CD4 testing and baseline investigation). This algorithm focusses on clinical screening of PLHIV for potential presence of common opportunistic infections/advanced HIV disease/co-morbid conditions:

- PLHIV who do not have any such conditions can be fast tracked for ART initiation giving them the benefits of timely ART initiation, such as reduction in incident TB and other OIs, achieving quick VL suppression, prevention of transmission and better health outcomes. Additionally, it will also reduce travel inconvenience and financial burden for PLHIV.
- PLHIV who have any such symptoms would require further evaluation for diagnosis and management common opportunistic infections/advanced HIV disease/co-morbid conditions before ART initiation. Detailed management of PLHIV with advanced HIV disease is discussed in Section 2.6

PLHIV who become LFU in the preparedness phase should be followed up as per details given in Section 3.5 of these guidelines

Figure 3. Algorithm for fast tracking ART initiation and identification of PLHIV with advanced HIV disease



* A seriously ill child is defined as having any of the following danger signs: lethargy or unconsciousness; convulsions; unable to drink or breastfeed; repeated vomiting.

** In case, expert opinion is not available in the local facility, virtual consultation from CoE/ART plus Centres may be taken.

2.5 OI Prophylaxis/Preventive Treatment

Co-trimoxazole prophylaxis (CPT)

- PLHIV (adults, adolescents and children >5 years of age) with WHO clinical stage 3 and 4 or CD4 count <350/cmm must be provided CPT. It should be continued till the time patient has CD4 count ≥350/cmm on two different occasions 6 months apart with an ascending trend and devoid of any WHO clinical stage 3 and 4 conditions.
- HIV-infected infants and children up to 5 years of age should also be provided CPT irrespective of CD4 count or % and WHO staging.

TB preventive treatment (TPT): 6 months of Isoniazid preventive treatment should be given to all PLHIV (>1 year of age). For more details on OI prophylaxis refer to the National Guidelines for HIV care and Treatment 2021

2.6 Management of PLHIV with Advanced HIV Disease

HIV-associated mortality in India has declined largely due to the scale-up of anti-retroviral therapy (ART). However, it is estimated that nearly 40% of patients present late to HIV care with an AIDS-defining illness or advanced immunosuppression. HIV-associated morbidity and mortality remains high in this group. Even after initiating ART, people with advanced immune suppression or CD4<200 at baseline have a 50% higher rate of mortality as compared to people with a CD4>200 at the time of ART initiation.

Advanced Disease Management (ADM) package: A package of services shall be provided to PLHIV with advanced HIV disease to reduce morbidity and mortality by early diagnosing, treating or preventing appropriate causes of opportunistic infections.

Definition of advanced HIV disease

- For adults and adolescents, and children older than five years, advanced HIV disease is defined as CD4 cell count <200cells/mm3 or WHO stage 3 or 4 event.
- All children younger than five years (who are not already receiving ART and clinically stable) are considered to have advanced HIV disease.

Components:

1. Management of common Opportunistic Infections

- Screen for signs and symptoms of opportunistic infections (including TB)
- Evaluate those with symptoms of severe infections (or who are seriously ill) with the appropriate tests such as molecular diagnostics (CBNAAT/TrueNAT) and Urine TB lipoarabinomannan (TB- LAM)* for TB; and for cryptococcal disease using cryptococcal antigen testing (CrAg LFA)*.

  **as and when included in the national program. Health facilities where serum CrAg is available are encouraged to use this test for PLHIV.*
- Treat OI, according to National Guidelines for HIV care and Treatment 2021

2. Give prophylaxis and preventive (pre-emptive) treatment for prevention of serious OIs

- TB preventative treatment (TPT) to prevent development of TB disease
- Co-trimoxazole prophylaxis to prevent severe bacterial infections and PCP
- Fluconazole pre-emptive treatment to prevent the development of cryptococcal meningitis (if CrAg positive without meningitis) or fluconazole primary prophylaxis when CrAg screening test is not available and CD4≤100 cells/cmm

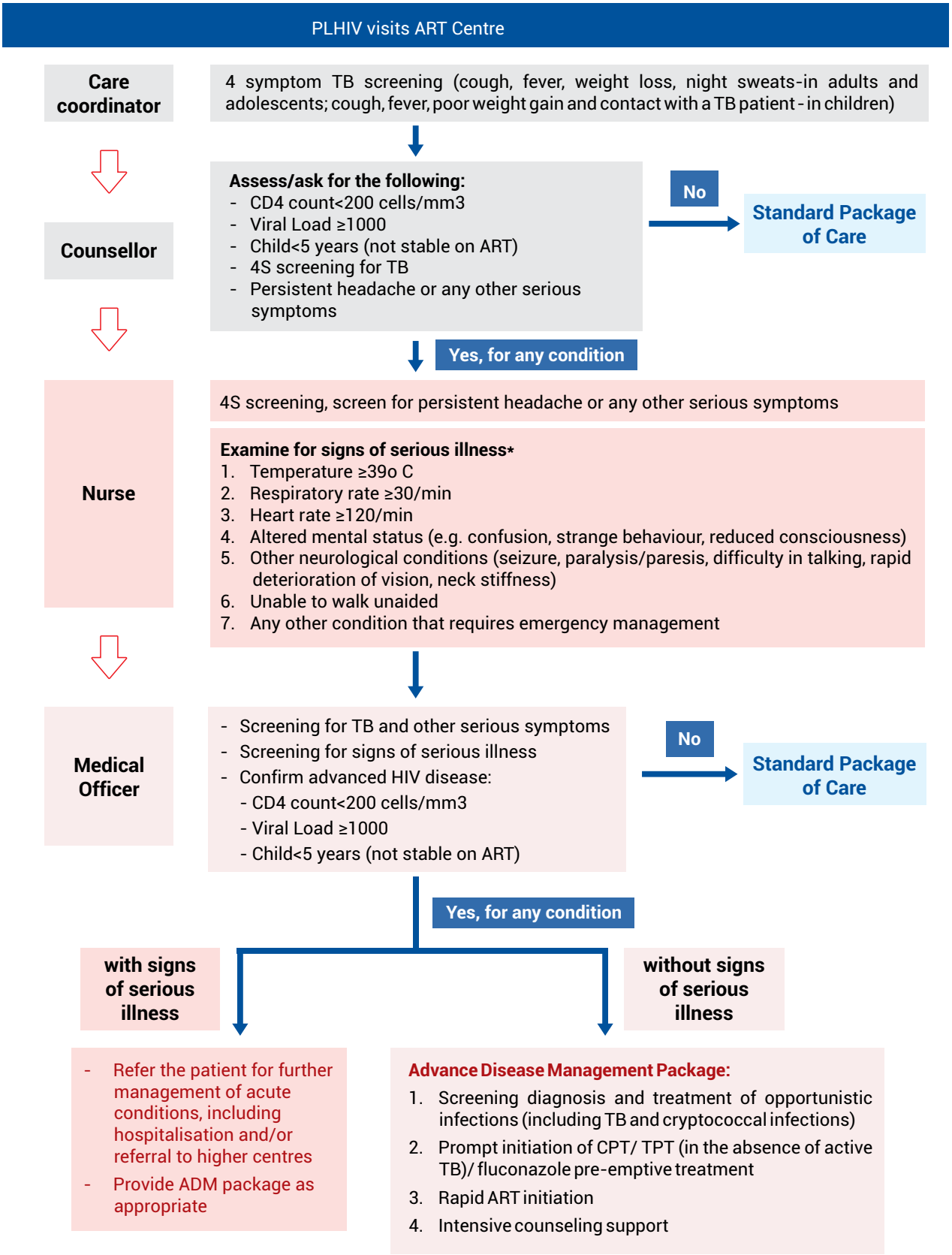
3. Rapid ART, if opportunistic infection is ruled out or managed as per t National Guidelines for HIV care and Treatment 2021

4. Give tailored and intensified counselling to people with advanced HIV disease to support their care

All children younger than five years (who are not already receiving ART and clinically stable) are considered to have advanced HIV disease and require early referral for diagnosis and management. Please refer to Section 7.5.9 for details regarding ADM in children below 5 years

Operational part for advanced disease management (ADM) package are given in detail in Figure 4.

Figure 4. Flow chart of operational part of advanced disease management package



*A seriously ill child is defined as having any of the following danger signs: lethargy or unconsciousness; convulsions; unable to drink or breastfeed; repeated vomiting.

Brief description duties of ART staff with regards to ART initiation:

Roles and responsibilities for ART staff with regards to ART Initiation are described below:

Care coordinator

1. Be the first interface with patient at centre
2. Peer education
3. Psychosocial support including preparedness and adherence support
4. 4 symptom screening & stamping
5. Support PLHIV in linkages, within the hospital (OP and IP)
6. Coordinate for linkage with the CSC
7. Documentation: patient visit register, stamping for 4S in green book

Counsellor

1. Registration in HIV care
2. Preparedness counselling
3. Identification & counselling of caregiver
4. Identification of potential barriers to adherence and prepare adherence plan
5. Verification of mobile number
6. 4 symptom screening
7. Readiness assessment for "Rapid ART Initiation"
8. Identify PLHIV with advanced HIV disease
9. Coordinate with staff nurse for ADM package
10. Counsel and support PLHIV for disclosure and testing of spouse/sexual partners and children (index testing services)
11. Provide family centric care by aligning due dates with other family member on ART
12. Obtain an address proof/verification of the patient through ORW of CSC and other ORWs
13. Consent form to be signed by the PLHIV for ART
14. Inform the patient about tracing and support system, in case PLHIV doesn't come back for follow-ups
15. Documentation: HIV care register, relevant sections of white card, ART enrolment register, green book, ART preparedness counselling checklist
16. Documentation: HIV registers, white card & green book

Staff nurse

1. TB screening, referral for TB diagnosis in consultation with medical officer
2. Monitor vital signs such as temperature, pulse, BP, respiratory rate and record weight and height at baseline
3. Assess PLHIV for advanced HIV disease and coordinate with medical officer for management
4. Initiation TB treatment in coinfected PLHIV, in consultation with medical officer
5. Follow up in indoor patient department and other specialty departments for ADM
6. Screening of PLHIV non-communicable diseases especially diabetes, high blood pressure and common cancers
7. Ensure baseline laboratory investigations
8. Preparedness and adherence support
9. Documentation: Green book, white card, HIV-TB line list, HIV-TB register

Laboratory technician

1. Facilitate baseline investigations of samples from institution
2. Ensure CD4 testing
3. Track investigations of PLHIV with advanced HIV disease
4. Coordinate with ART Staff e.g. staff nurse & counsellor for reports of baseline investigations
5. Documentation: lab registers, entry in IMS

Medical officer

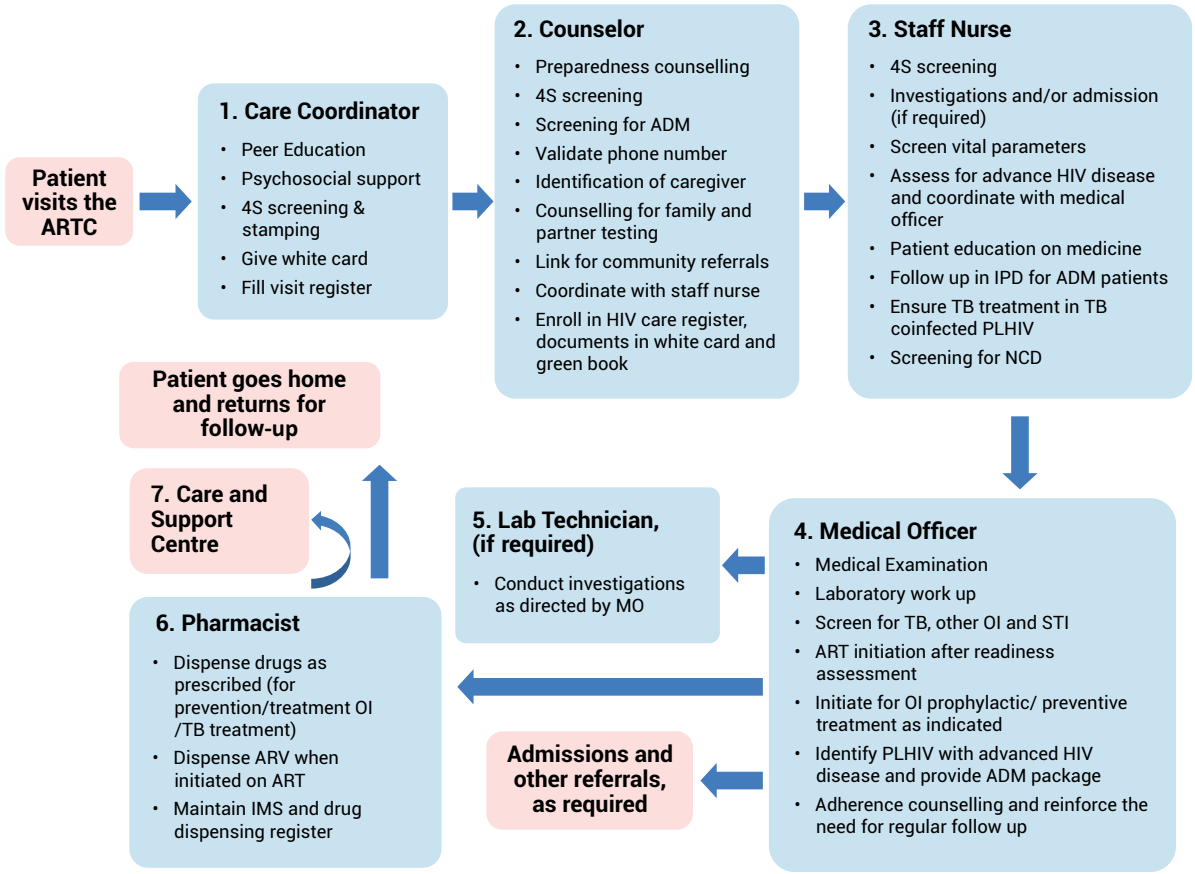
1. Complete history taking, clinical examination, review of signs and symptoms (including 4 symptoms for TB), assess for advanced HIV disease
2. Determine WHO clinical staging
3. Prescribe appropriate laboratory investigations
4. Provide prophylaxis (Cotrimoxazole prophylaxis therapy-CPT) and preventive (pre-emptive) treatment for prevention of OIs to all eligible PLHIV
5. Screening and management/referral for STI
6. Treatment for active OI, including TB
7. Rapid ART initiation unless clinically contraindicated based on National Guidelines for HIV care and Treatment 2021
8. Reinforce preparedness counselling by emphasizing on importance of ART, adherence, treatment continuation and maintaining a healthy lifestyle
9. Management/referral of PLHIV with advanced HIV disease
10. Identification and referral of PLHIV with comorbidities, including non-communicable diseases and mental health issues
11. Documentation: appropriate sections of white card and green book

Pharmacist

1. Dispensation of drugs as prescribed (for prevention/treatment OI/TB treatment)
2. Dispensation of ARV when initiated on ART
3. Explain about dosage and timing of ART and reinforce about adherence
4. Documentation: IMS and drug dispensing register

ART staff should fulfil their roles and responsibilities (as described above) and work as team for initiation of ART. Patient flow at ART centre for PLHIV to be initiated on ART is described in Figure 5.

Figure 5. Patient flow at ART centre for PLHIV to be initiated on ART



CHAPTER 3

MONITORING AND FOLLOW-UP OF PLHIV

The goal of ART is to achieve maximal and durable suppression of viral load leading to immune reconstitution with improvement in quality life for PLHIV. Monitoring and follow up of PLHIV is important to ensure adherence and retention on lifelong ART. This chapter describes the definitions of programme indicators and SOPs for PLHIV monitoring and follow up.

3.1 Programme Definitions

3.1.1 First line, second line and third line ART regimens

First line ART: First line ART is the initial regimen prescribed for an ART naïve patient.

Second line ART: Second line ART is the subsequent regimen used in sequence immediately after first line therapy has failed.

Third line ART: Third line ART is the subsequent regimen used in sequence immediately after second line therapy has failed.

3.1.2 Substitution and switch

Substitution: Substitution refers to replacement of ARV drug(s) PLHIV due to adverse effects of drug, drug-drug interactions or programme policy. This does not indicate change of regimen due to treatment failure.

Switch: Treatment failure refers to the loss of antiviral efficacy to the current regimen. When the entire regimen is changed because of treatment failure, it is referred to as the switch.

3.1.3 Patient status or treatment outcomes

On ART lost to follow up (LFU): PLHIV on ART with no clinical contact or ARV pick-up for 90 days or more since last due date (missed appointment).

Mechanism to give due date: PLHIV should be given due date in such a manner, that s/he should always be left with drugs for 2 days at any given time.

When the patient is initiated on ART for the first time, s/he is given drugs for 30 days but should be called on the 28th day. If his adherence has been 100%, s/he should be left with the drugs for 2 days. Henceforth, s/he should always be given drugs for 30 days and his next due date of visit should always be on the 30th day.

How to label a PLHIV as LFU: A patient "On-ART" will be labelled as **"Missed (MIS)"** if the patient does not turn up for pill pick up any time within 90 days of due date. After that if the patient does not come to the centre even on 90th day or after, the patient will be termed as "LFU".

Reporting: Reporting in MPR would be done based on the status of PLHIV on the last day of the reporting month. Reporting should be done using IMS.

Example of MIS and LFU is given below:

- For a patient on ART who collected his ARV drugs for the first time on 6th January, the next scheduled visit shall be on 3rd February.
- If s/he does not come on 3rd February, the tracking measure shall be initiated same day.

- If s/he does not come for pill pick up within 90 days of due date, then s/he shall be termed as 'MIS' and measures to track the patient shall be continued.
- If s/he does not to come for 90 days or more since last due date, then s/he shall be termed as 'LFU'.
- For reporting in MPR, the status of PLHIV on the last day of the reporting month would be considered.

Pre-ART LFU: PLHIV not initiated on ART and with no clinical contact or visit to health facility for more than or equal to 28 days.

Opted out: If a PLHIV is contacted through outreach (home visit) and expresses his/her unwillingness to continue ART services under national program (after adequate counselling) and provides in writing about the same, outcome of the visit will be reported as 'opted out' in the tracker sheet.

Once such information is received from outreach staff by ART centre, counsellor and medical officer will reach the patient through phone call and try to counsel to continue ART services. If not reachable, another visit through project coordinator/peer counsellor of CSC should be attempted. Such patients would be labelled as "Opted Out" in white card and IMS/MLL, at least after 3 documented attempts by CSC/ART centre to retrieve patient back and resolve the reason for not continuing ART services under national programme. Patients taking treatment from private or taking alternate medicines shall also be considered as "Opted Out"

Stopped treatment: PLHIV on ART whose treatment is stopped on medical advice (in discussion with the clinical team). The reasons for stopping treatment should be documented in white card.

Note: *Missed, LFU, opted out and stopped treatment are dynamic outcomes and may change at any point of time, if the patient comes back.*

Died: If death of a patient is confirmed by family members/relatives/local authorities during outreach and valid documentation such as death certificate (or any other document, which can prove the death) is provided then upon submission of the same, it could be updated in white card/MLL/IMS as "death" by the data manager of ART centre.

In case death certificate or a valid documentation is not available, documentation can be obtained by outreach workers/CSC staff in writing either from the village headman or close family members who are ready to give their contact details for verification by ART centre. If outreach is not possible and family member/relative, declare death over phone, medical officer of the ART centre shall take details of the same over phone and document on white card (e.g. date of death, probable reason of death).

Transferred out: Transferred out refers to a situation when a patient seeks transfer from one ART centre under the national program to another. However, PLHIV will be labelled as 'transferred out' only when patient reaches recipient ART centre and transfer has been accepted in IMS by recipient ART. After confirmation of transfer by recipient ART centre, the parent ART centre will change status in their MLL/IMS as "transferred out" and the receiving ART centre will label this patient as "transferred in."

For details on procedure for transfer out, please refer to Section 8.2.2.4 of this guideline.

3.1.4 Stable PLHIV:

Adults and adolescents (≥10 years): PLHIV (adult/adolescent) shall be termed "stable", if fulfilling all the following criteria:

- On ART for at least 6 months;
- No adverse effects of ART that requires regular monitoring;
- No current illness/opportunistic infection/medical condition which requires management or regular monitoring; and
- Suppressed viral load (in the absence of viral load monitoring, rising CD4 cell counts or CD4 cell counts exceeding 200 cells/mm^3 and adherence ≥95% consecutively over the last 3 months)

Children (>2 years): Children (>2 years age) shall be termed "stable", if fulfilling all the following criteria:

- On ART for at least 6 months;
- Suppressed viral load;

- Treatment adherence >95% in each of last 3 months;
- On the same regimen (with no dose or formulation change) for at least 3 months;
- With no current illnesses/medical condition (including malnutrition*) which requires further management

**defined as weight for age is less than -2SD OR weight for height/length is less than -2SD*

Key points:

- *Definition of stable patient shall be applicable for patients on any ART regimen (1st, 2nd and 3rd line) after being on that line of regimen for at least 6 months.*
- *This definition shall be applicable across various differentiated care models like multi-month dispensation, decentralized and community-based dispensations (such as LAC, CARG).*
- *Benefits of MMD may also be extended to patient availing services at LAC and LAC plus.*
- *PLHIV on TB Preventive Therapy (TPT) who have completed 3 months on TPT could also be provided benefits of service delivery models for stable PLHIV, if fulfilling above criteria. They should be provided after proper counselling on adherence and adverse effects.*

3.2 Objectives of Monitoring

The main aim of monitoring is ensuring retention and achieving durable viral load suppression to improve health outcomes and minimize risk of transmission. Objectives of monitoring are as follows:

- Optimize the benefits of ART
- Monitor the response to ART
- Timely identification of adverse events, comorbidities/coinfections
- Timely identification of treatment failure

3.3 SOP for Monitoring PLHIV on ART

PLHIV should be monitored for the following events during first 6 months of ART initiation.

- Clinical and immunological improvement and viral suppression
- Immune reconstitution inflammatory syndrome (IRIS)
- Early adverse drug reactions, such as drug hypersensitivity

Programme data shows that first 3 to 6 months after ART initiation are most crucial with a higher likeliness of LFU or deaths. Therefore, it is important to emphasize adherence and retention as well as identify any adverse events, opportunistic infection, comorbidities/coinfections, IRIS. Monitoring response to ART by VL testing at 6 months is critical for timely identification of treatment failure.

The most important factor for success of ART is high level of adherence to treatment. ***Adherence should be assessed and routinely encouraged by doctors, counsellors, nurses, pharmacist, workers for every patient visiting the ART centre.*** Adherence counselling is important for understanding barriers and possible reasons of non-adherence in a patient and then providing guidance to develop an individualized adherence plan. The counsellor should try to review factors like psychological, behavioural, emotional and socio-economic that may lead to non-adherence in a patient and provide customized counselling with the objective of improving adherence to treatment. **Certain PLHIV may have higher probability of becoming LFU due to financial/ distance related issues, migration, lack of understanding, mental health, comorbidities/coinfections, advanced HIV disease, alcoholism, substance abuse etc. Such PLHIV should be monitored closely and given additional time to discuss their personal and social issues/challenges in maintaining the adherence of the ART.**

Monitoring of individual PLHIV on ART is important during subsequent visit for early identification of issues like adherence, adverse effects of drugs, development of OIs including TB, follow-up investigations and more importantly immunological and virological monitoring. The following table provides a snapshot of follow-up activities during subsequent visits after ART initiation.

Table 1. Key monitoring tools for PLHIV on ART.

Monitoring Tool	When to Monitor?
Body weight	Every visit
Height (in children)	Every visit
Treatment adherence	Every visit
Clinical monitoring, T-staging	Every visit
Symptom screening for mental health related issues	Every visit
4 symptom screening for TB	Every visit
Screening for common NCD	Every 6 months or symptom directed
Lab evaluation based on ART regimen	Every 6 months or symptom directed
CD4 Count	Every 6 months*
Viral Load	At 6 months, 12 months and then every 12 months**

**CD4 Count: 1. As and when routine virologic monitoring becomes available, CD4 testing should be done every 6 months and can be discontinued for PLHIV (except those with HIV 2 infection) when CD4 count ≥350 cells/mm³ and viral load is less than 1000 copies/ml 2. CD4 monitoring should be re-started for any patient if (a) the patient has been switched due to treatment failure i.e. virologic failure (VL≥1000 copies/ml) or (b) when deemed necessary for clinical management by the clinician at any point in time*

***For patients on second/third line ART, VL testing to be done every 6 months*

Information regarding follow up visits and results of all lab investigations should be documented in relevant section of white card treatment card of PLHIV.

3.3.1 First follow up visit

First follow up visit is very important to reassure the patient about benefits of ART and to identify any new event.

- Assess the PLHIV for adherence, new OI, IRIS, drug related adverse effect
- 4 symptom screening for TB
- Continue preparedness/adherence counselling sessions
- Counsellor should validate mobile numbers and update address
- Laboratory monitoring as per guidelines
- For admitted patients and newly initiated on ART, visit by staff nurse will be made every day till patient is discharged
- All patients should also be counselled to report to ART centres in case of any symptoms prior to their scheduled visits
- Follow up on disclosure and testing of spouse/partner and children (Please refer to Annexure 3 on index testing services)

3.3.2 Subsequent follow up visits

During every visit, PLHIV should be assessed for the following:

i. An intensive monthly follow up for adherence, adverse events, development of OI should be done for all PLHIV during first 6 months of ART initiation and patients are given drugs for one month on every visit.
ii. 4 symptom screening for TB should be done all visits
iii. PLHIV newly initiated on ART should be followed up telephonically by counsellor every fortnightly for first 3 months, in addition to monthly visits. List of such PLHIV should also be shared with CSC for intensified follow up.
iv. Counsellor should validate mobile numbers and update the contact details (including full address during every visit)
v. PLHIV on TPT should be monitored for adherence and adverse effects of Isoniazid and should be provided adherence counselling for TPT (PLHIV who are already on ART and have not been received TPT earlier should be provided 6 months of Isoniazid)

vi. PLHIV who are sick, having respiratory symptoms, pregnant women, children and elderly should be fast tracked

vii. Laboratory monitoring as per guidelines

viii. Viral load testing should be done at completion of 6 months on ART

PLHIV who fulfils the criteria for stable PLHIV at 6 months should be considered for differentiated care (3 months dispensation/ link out to LAC) and followed up for retention. PLHIV who do not fulfil the criteria for stable PLHIV would need a rigorous follow up even after 6 months in terms of step-up counselling, e-referral to SACEP for review for second line, management of advanced HIV disease etc. It may be noted that stable and unstable criteria is dynamic and may interchange during the course of treatment and should, therefore, be assessed for during every visit to plan for appropriate care. Please refer to Section 4.4.2 for details.

3.4 Laboratory Monitoring

3.4.1 Laboratory monitoring to assess response to ART

The goal of ART is to have a maximal and durable suppression of viral load and an increase in CD4 counts. **Suppressed viral load and increase in CD4** count indicate that PLHIV is taking ART well and that ART is working effectively.

Viral Load Testing:

- For PLHIV on first line ART, viral load testing should be done at 6 months, 12 months of ART initiation and thereafter at every 12 months.
- For PLHIV on second/third line ART, viral load testing should be done every six months
- Laboratory technician of ART centre should regularly do entries for VL testing in IMS. Due list for viral load testing should be prepared every month and shared with counsellor and MO for VL testing on the next mentioned visit of the patient.

Interpretation of VL testing results

- PLHIV with viral load report <1000 copies/ml should continue the same ART regimen. Next viral load testing should be done as per guidelines
- PLHIV with viral load report ≥1000 copies/ml should undergo step-up adherence counselling for three months. ART centre counsellor should provide intensive support to improve adherence
- Repeat viral load testing should be done once treatment adherence is >95% for three consecutive months
  - If repeat viral load report is <1000 copies/ml, patient should be continued on same ART regimen
  - If repeat viral load report is ≥1000 copies/ml, patient should be referred to SACEP for further management
- In case of PLHIV with high viral load, declining CD4 counts and poor clinical conditions, ART medical officer (MO) may refer the patient to SACEP, even based on single viral load report, for further management

CD4 testing: CD4 count is essential for monitoring the patients on ART for immunological failure, for CPT and monitoring of PLHIV with HIV-2 infection. CD4 testing should be done every 6 months. However, as routine virologic monitoring becomes available, CD4 testing can be discontinued for PLHIV (except those with HIV-2 infection) when CD4 count ≥350 cells/mm^3 and viral load is less than 1000 copies/ml. CD4 monitoring should be re-started for any patient if: (a) the patient has been switched due to treatment failure i.e. virologic failure (VL≥1000 copies/ml) or (b) when deemed necessary for clinical management by the clinician at any point in time.

3.4.2 Routine laboratory investigations for monitoring patients on ART (follow up tests) based on ART regimen

Routine laboratory investigations for monitoring patients on ART (follow-up tests) based on ART regimen are described in table 2.

Table 2. Routine laboratory investigations for monitoring patients on ART

Hb, TLC, DLC need to be done once in every six months for all patients on ART								
Monitoring PLHIV based on ART Regimen	**Monitoring Test**	**Baseline**	**15th Day**	**First Month**	**Third Month**	**Sixth Month**	**Then Every 6 Months**	**Every 12 Months**
Tenofovir Based ART	Serum creatinine, urine examination	Yes	--	--	--	Yes	Yes	--
DTG containing ART	ALT (SGPT) Blood Sugar	Yes	--	--	--	Yes	Yes	--
Zidovudine based ART	CBC	Yes	Yes	Yes	Yes	Yes	Yes	--
Efavirenz containing ART	Lipid profile	Yes	--	--	--	--	--	Yes
Atazanavir containing ART	LFT, Lipid profile	Yes	--	--	--	Yes	Yes	--
Lopinavir containing ART	Lipid Profile & Blood sugar	Yes	--	--	--	Yes	Yes	--

3.5 Prevention and Tracking of Lost to Follow Up

3.5.1 Measures to be taken to prevent patients from being missed/lost to follow-up

Programme data shows that for every two new PLHIV initiated on ART, one is lost to follow up. Therefore, ART centres should take adequate measures to prevent patients from being missed/lost to follow up rather than tracing them after becoming LFU.

- Adequate preparedness counselling is most effective way of preventing missed and LFU (Refer to Section 2.2)
- Identification of caregiver and counselling of caregiver on adherence and treatment education
- Identification of PLHIV with advanced HIV disease and appropriate management
- Identification of barriers to adherence and developing an adherence plan
- **Focused and customized counselling to PLHIV belonging to special groups** (KP, pregnant women, children, adolescents, PLHIV with advanced HIV disease/coinfections/comorbidities)
- Family-centred approach by actively asking the PLHIV about details of all the family members on ART; aligning their pill pick up dates; referring them to same DSD models and addressing the barriers to adherence/retention for the entire family in a more holistic manner
- Providing information about available options for MMD and ART pick-up from LAC, once s/he is suppressed/stable at 6 months
- Providing information on preventive benefits of being adherent to ART using U=U message
- Effective adherence counselling and reassurance on adverse effects (if any)
- Intensified follow-up for the first three month in coordination with CSC

3.5.2 Mechanism to track and trace PLHIV who are missed/LFU

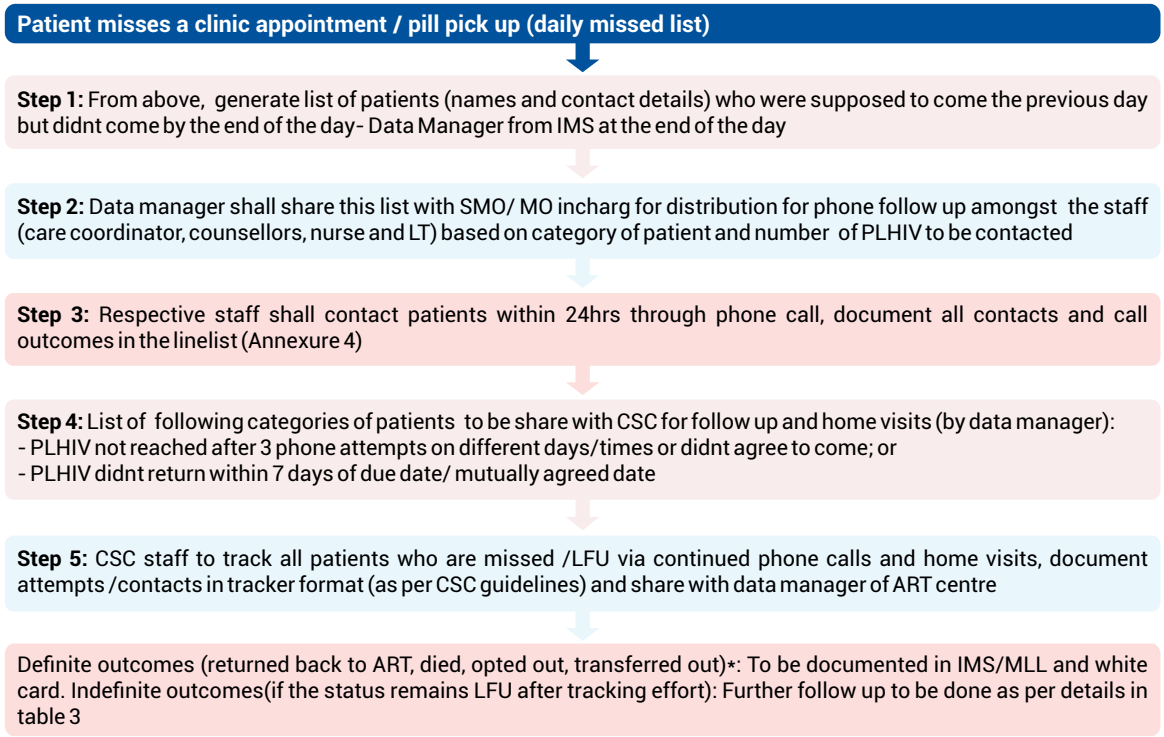
In preparedness phase:

- A line list of all patients who are not initiated on ART within 7 days of registration should be generated on daily basis by data manager and reviewed at ART Centre by medical officer and counsellor.
- If there are no contraindications for rapid ART and PLHIV is not referred/managed for any OI/comorbid condition, measures to contact these patients through phone calls should be initiated immediately.
- List of PLHIV who are not reachable through phone or didn't agree to come or didn't return within 7 days of mutually agreed date should be share with CSC or referring ICTC/NGO/CBO for follow through home visits.
- Similarly, for PLHIV where ART is deferred (for management of opportunistic infection, comorbidity, etc.), ART initiation should be ensured as soon as the appropriate action has been taken/completed (depending on the reason for deferral). If such PLHIV are not initiated within 7 days of given timeline (as per National Guidelines for HIV care and Treatment 2021), appropriate measures (as detailed above) to track them should be taken.
- DAPCU/cluster meetings should be utilised to review and address the gaps in ART initiation.

On ART:

- It is essential that a "daily missed list" is prepared at all centres. All the patients who were supposed to come to the ART centre on a particular day but have not come, need to be listed at the end of the day. This list can be prepared in two ways:
  - Ideally, this list should be auto generated through IMS software as per appointments given to the patients.
  - This list can also be generated from the MLL, if MLL is being updated on daily basis.
- If PLHIV does not turn up next day, s/he should be contacted by phone in afternoon on the same day (i.e. maximum within 48 hours of missed appointment) by the counsellor or care coordinator. At least 3 attempts of calling the patients at different times should be made and documentation done in the template given at Annexure 4.
- Line list of the following categories of patients should be prepared (by data manager) and shared with CSC on a weekly basis for follow up and home visits by outreach workers:
  - PLHIV not reached after 3 phone attempts on different days/times or didn't agree to come; or
  - PLHIV didn't return within 7 days of due date/ mutually agreed date
- After receiving the list, CSC will initiate tracking efforts through phone. Home visits should be planned for PLHIV not reachable through phone or not reached back to ART centres within 7 days of missed pill pick up (for details on microplanning for outreach activity, please refer to CSC guidelines 2018)
- If the patients are beyond the catchment area of the CSC, this list is to be given to the District Program Manager (DPM) (where DAPCU exists)/District Nodal Officer for HIV who are supposed to share this list with the ICTC supervisor/link workers/other outreach workers in NACP or health systems/TI partners for field visits.
- DPM/District Nodal Officer for HIV will then get back to the respective ART centres on outcome of field visits on a monthly basis during monthly meeting of ICTC counsellors. SACS officer in-charge of CST activities (AD/DD/JD/Consultant) with support of Regional Coordinator (RC)/Technical Expert (TE) will help to coordinate for inter-district/interstate MIS/LFU patient.
- The mechanism for tracking of LFU cases is the same as that of the tracking of "MIS" cases.
- Outcomes should be documented in IMS/MLL and white card, as per details given in Table 3

Figure 6. Tracking and tracing missed appointments



**Please refer to guidance under Section 3.1.3 for definitions of outcomes*

Table 3. Follow up actions based on tracking feedback

MIS/LFU tracking feedback	Action to be taken at CSC before providing feedback*	Action to be taken by ART centre after receiving feedback	Outcome (reported by ART centres in IMS/white card/ MPR)
1. Agreed to visit ART centre	1. PLHIV should agree to come on a mutually decided date 2. CSC to ensure that PLHIV visits on the mutually decided date	Check whether PLHIV turned on specified date. If not, follow up in next week with CSC CSC should follow up with PLHIV and explore reasons for not turning up (at least 3 attempts with possible solutions as per reason should be taken by CSC to retrieve the patient)	- If didn't return to ART centre, s/he will remain as LFU as per guidelines*
2. Physically taken to ART centre	1. CSC staff should bring the PLHIV to ART centre	Confirm that PLHIV has returned to ART centre	If already not initiated on ART, Active in HIV care If on ART, Alive and on ART)
3. Died	1. Valid documentation such as death certificate (or any other document, which can prove the death) is provided. 2. In case death certificate/valid documentation is not available, refer to Section 3.1.3 for details	Confirm that a valid document is submitted along with death outcome	Died
4. Taking ART at other NACO ART centre/ Transferred out	1. Get ART number and name of centre where PLHIV is taking medicine	Ensure e-transfer out PLHIV in IMS to the recipient centre as per details in Section 3.1.3 Receive confirmation from recipient centre	Transferred out, after receive confirmation
5. Opted out of the programme /taking alternate medicine/ taking ART from private sector	1. If patient is contacted through outreach (home visit) and patient expresses his/ her opinion of not continuing services at ART Centre and provides in writing about the same will be reported under "Opted Out" category in tracker sheet. 2. Minimum 3 attempts should be made to counsel the patient and resolve the reason for not continuing ART services under national programme.	Once such information is received from outreach staff to ART centre, counsellor will validate the same through telephonic call and try to counsel the patient to continue services. If not reachable, another visit through peer counsellor should be attempted.	Opted Out (at least after 3 documented attempts by CSC/ART centre to retrieve patient back)
9. Reported back to ART centre or already reached	Confirm with ART centre if PLHIV reached ART centre in actual	check records and update status	- If not initiated on ART, Active in HIV care - If on ART, Alive and on ART)
10.Incorrect address*	1. Minimum 3 attempts to get the correct address (verify with ART centre, ICTC, CSC records), check Aadhar number, or any other source for the correct current address, without disclosing the status of PLHIV 2. Submit report to ART centre of all efforts and reasons	Take/recommend appropriate action, follow up in subsequent months. All efforts to be taken to retrieve PLHIV	LFU*
11. Migrated	1. Minimum 3 attempts to get the correct address (verify with ART centre, ICTC, CSC records), check Aadhar number, or any other source for the correct current address, without disclosing the status of PLHIV 2. Submit report to ART centre documenting all efforts and reasons	Take/recommend appropriate action, follow up in subsequent months. All efforts to be taken to retrieve PLHIV	LFU*
12. Others*	1. Minimum 3 home visits to meet and counsel patient. 2. Submit report to ART Centre with all the efforts and reasons for still in other category	Take/recommend appropriate action, follow up in subsequent months. All efforts to be taken to retrieve PLHIV	LFU*

** Intensive tracking efforts should be done for 6 months after PLHIV is labelled as LFU. After adequate efforts have been made to track the LFU by telephonic calls and at least 3-4 properly documented visits have been made by ORW, then active tracking may be discontinued, however PLHIV will be counted as LFU.*

Note: 1. CSC should confirm/ update the address and phone number during the home visit regardless of the outcome.
2. All outcomes except LFU will be treated as definite outcomes

Brief description of responsibilities of various ART staff during monthly follow-up visits

Care coordinator

1. Peer education
2. Psychosocial support
3. Keep track of drug adherence of patients on ARV, counselling them on the importance of regularity of visits and ARV dosage
4. Augment the efforts of the counsellor and other staff of the centre in promoting adherence positive living
5. Assist in patient retrieval
6. 4 symptom screening for TB & stamping
7. Gives white card
8. Support PLHIV in linkages, within the hospital (out-patients and in-patients)
9. Coordinate for linkage with the CSC
10. Documentation: patient visit register, stamping for 4S in green book

Staff nurse

1. 4 symptom screening, referral for TB diagnosis in consultation with medical officer
2. Ask for symptoms of any adverse effects of drugs, any OI, IRIS
3. Monitor vital parameter such as temperature, pulse, BP, respiratory rate and document height (in children) and weight
4. Assess PLHIV for advanced HIV disease and coordinate with medical officer for management
5. Triaging of PLHIV for patient centric packages (new, stable/unstable)
6. Facilitate for follow up investigations
7. Patient education on medicine and adherence support
8. Initiation and completion of TB treatment in coinfected PLHIV, in consultation with medical officer
9. Ensure TB preventive treatment and follow up for completion in all PLHIV
10. Screening of PLHIV non-communicable diseases especially diabetes, high blood pressure and common cancers
11. Documentation: HIV-TB line list; HIV-TB register, relevant columns in the patient treatment record (white card) and green book

Counsellor

1. Continue preparedness counselling in PLHIV newly initiated on ART
2. Adherence counselling and monitoring; identify potential barriers to adherence and prepare adherence plan
3. Patient-centric counselling and provide specific DSD packages of care as needed
4. Follow up and facilitate for HIV testing of spouse/partner and children
5. Counselling of guardian/care giver
6. Advise/explain treatment and follow up care
7. TB screening
8. Screening for mental health related issues
9. Confirm/update the address and contact details of the patient and validates phone number during each visit
10. Step-up counselling
11. Phone follow up of MIS/LFU
12. Facilitate appropriate linkages (a) early referral to CSC (b) TI NGOs (c) treatment for substance abuse/rehabilitation (c) management of comorbid psychiatric illness. Patient should be informed the patient about various support groups.
13. Documentation: Relevant columns in the patient treatment record (white card), ART register and green book

Laboratory technician

1. Ensure VL and CD4 testing
2. Track investigations of PLHIV with advanced HIV disease
3. Coordinate for follow up lab investigations
4. Coordinate with ART staff e.g. staff nurse & counsellor for reports of CD4 and VL testing and other follow up investigations
5. Documentation: lab registers, entry in IMS

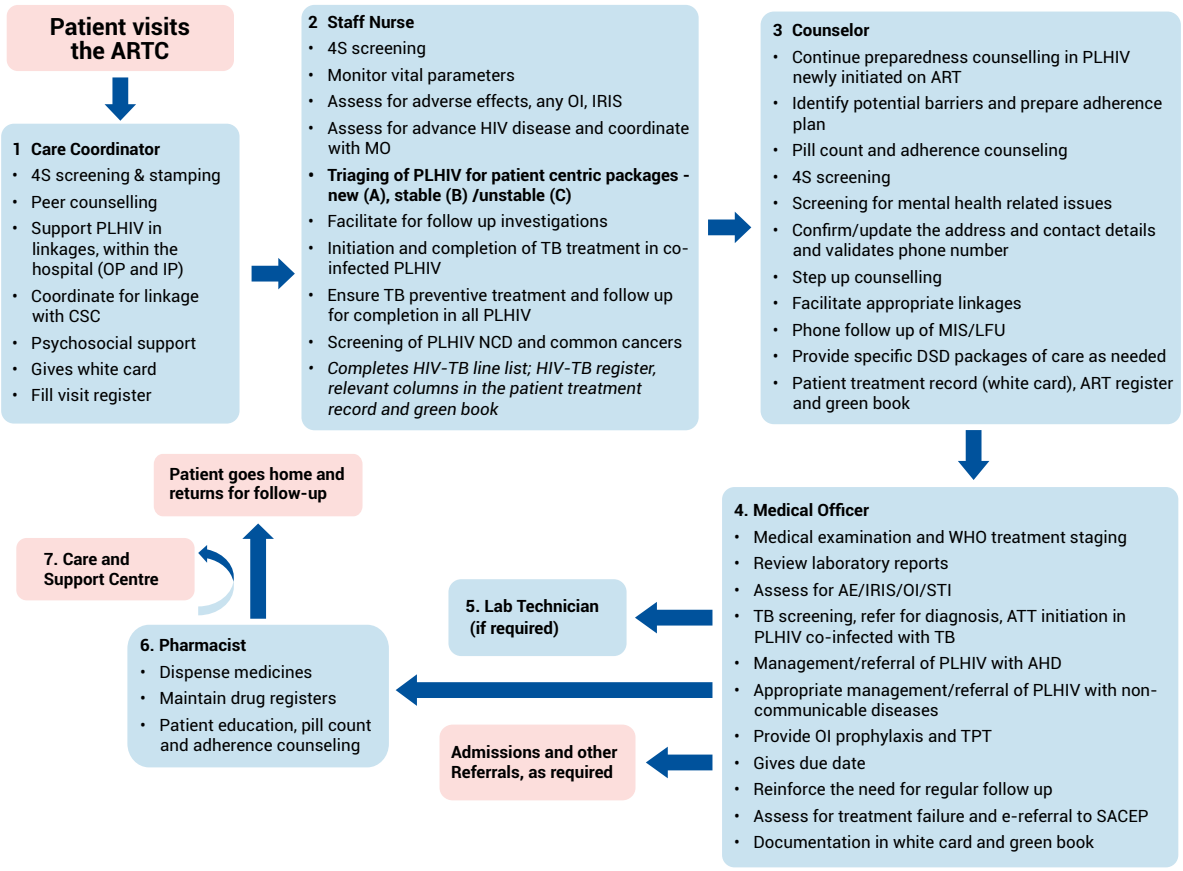
Medical officer

1. Perform clinical examination
2. Determine WHO treatment staging
3. Assess for adverse effects, OIs and IRIS
4. Patient education and adherence counselling
5. Management/referral of PLHIV with advanced HIV disease
6. Perform TB Screening, refer for diagnosis, ATT initiation in PLHIV coinfected with TB
7. Screening and referral for STI (sexually transmitted infections)
8. OI prophylaxis and TPT
9. Prescribe appropriate laboratory investigations
10. Assess for treatment failure
11. Make any required referrals including e-referral to SACEP
12. Appropriate management/referral of PLHIV with non-communicable diseases
13. Give follow up date for monthly visit
14. Reinforce the need for regular follow up
15. Documentation: relevant section of white card and green book

Pharmacist

1. Dispensation of drugs as prescribed (for prevention/treatment OI/TB treatment)
2. Dispensation of ARV drugs
3. Explain about dosage, timing of medicines and due date
4. Documentation: Maintain IMS and drug dispensing register

Figure 7. Patient flow at ART centre for patients already on ART



Note: *In ART Centres, where position of staff nurse is not sanctioned/not available, triaging to packages shall be done by care coordinator/ counsellor*

CHAPTER 4

PATIENT CENTRIC DIFFERENTIATED CARE PACKAGES FOR RETENTION

This chapter describes the strategies for enhancing retention of PLHIV in care and SOPs for implementation of patient centric differentiated care.

4.1 Enhancing Retention in Care

Retention in HIV Care is defined as continuous engagement of People Living with HIV (PLHIV) in package of services for prevention and care and support from the time of diagnosis. Retention in HIV care aims at ensuring delivery of a variety of services like prevention, treatment, care and support services on a regular basis. The various stages of treatment cascade where loss can happen are:

Stage 1: Diagnosis of HIV to enrolment in care

Stage 2: Enrolment in HIV care at the ART centre to ART initiation

Stage 3: Any time during the course of ART

Steps to prevent 'lost to follow up' at each stage of treatment cascade

It is important to prevent loss of patients of at each stage to ensure maximal retention in care with the eventual goal of enhancing patient survival and quality of life by achieving faster and durable viral load suppression.

Table 4. Strategies to reduce loss to follow-up at each stage

Stage-1 ICTC-ART linkage	Stage-2 Registration in HIV care to ART initiation	Stage-3 Any time during the course of ART
• After confirmation of HIV diagnosis at the ICTCs, efforts should be made to ensure PLHIV registers at ART centre • Optimal post-test counselling with adequate emphasis on benefits of ART and importance of adherence, positive living, need to involve caregiver and regular follow up	• Effective preparedness counselling (all aspects of the ART shall be discussed and explained to the patient, specifically its benefits, lifelong duration, preventive role, possible adverse effects, and disclosure) • Rapid ART initiation after readiness assessment • Screening for TB and other OI and management advanced HIV disease • Minimizing needs for multiple visits to ART centre before ART initiation • Identification of caregiver	• Effective adherence counselling • Intensified follow-up for the first three month of ART initiation in coordination with CSC • Patient centric differentiated care based on: - clinical characteristics (stable, unstable, comorbidity/coinfection - sub-population type (e.g. children and adolescents, pregnant and breastfeeding women, key population) and - context (hard to reach areas)

• ICTC counsellor should provide guidance to the PLHIV to take address proof and passport size photo while going to ART centre, along with address, telephone number of ART centre • Feedback on PLHIV registered at ART centre to be shared with respective ICTCs • Where possible (particularly in special groups), and if acceptable to the PLHIV, peer navigation should be encouraged to support PLHIV in linkage and early case management	• Verification the phone number and address (through CSC support) • Optimal follow up and counselling of in-patients who are diagnosed as HIV positive • Peer counselling on importance of ART adherence and the importance of furnishing correct contact details for further follow-up and support • Identification of PLHIV having risk factors associated poor adherence or poor retention (such as financial / distance related issues, migration, lack of understanding, mental health, advanced HIV disease, alcoholism, substance abuse etc) with efforts to resolve challenges • Individualised focused counselling for special groups such as key populations, children, adolescents, pregnant women, etc	• Family-centred care approach • Providing welcoming, non-judgemental, friendly and stigma- free care • Focussed and individualised care, particularly to specific groups • Realtime updation of records • Daily due list to be generated every day • If PLHIV do not turn up on due date, they need to be called up through telephone within in the 48 hours. • Line list to track "On-ART" patients who have missed their appointments (MIS) shall be prepared on a weekly basis and shared with the ORWs/CSC for tracking and retrieval • PLHIV who return to ART should be provided friendly and welcoming environment

4.2 Differentiated Care for Retention in Care

A "one size fits all" approach may not result in optimal care and therefore, adopting a differentiated care model of service delivery will improve the quality of services provided to PLHIV and to optimize the patient outcomes as well as resources.

Differentiated care is a patient-centred approach that simplifies and adapts HIV services across the treatment cascade and takes into consideration the preferences and expectations of various groups of PLHIV while reducing unnecessary burden on the health system. **By providing differentiated care, stable patients can visit the health centre less frequently, and the health system can focus resources to those most in need.** Since each patient's specific need are central, differentiated care aims to improve the patient's experience and treatment outcomes while ensuring that the health system is functioning both in a medically accountable and an efficient manner. Differentiated ART delivery is responsive to the needs of PLHIV and therefore results in increased levels of treatment adherence, patient satisfaction, and patient empowerment. For example, PLHIV who are adherent and virally suppressed do not require frequent clinical visits. By revising the models of delivery for such patients, their retention on ART and viral suppression could be maintained while reducing the burden of frequent visits to ART centres on patients as well as on the health care systems. As a result, the available resources could be allocated to enhance the quality of care for PLHIV most in need.

The benefits of differentiated care include:

- **Improves patient outcomes:** Under differentiated care, the emphasis is on designing interventions after taking into consideration patient needs and profiles, which over long-term improves patient outcomes.
- **Motivates and empowers patients to take responsibility:** Differentiated service delivery model can also be leveraged in shifting the onus of disease management to patients with the core support of the healthcare system.
- **Enhances quality of care and access to treatment for PLHIV:** The implementation of differentiated care can also be used to improve access to underserved populations and address issues surrounding stigma and discrimination that PLHIV may often face when accessing health services.
- **Effective resource management:** One key benefit of differentiated care is that it differentiated care allows utilization of limited resources to prioritize interventions for PLHIV with special needs

General considerations for differentiated ART service delivery:
Models of ART delivery should be differentiated according to the following three elements.

1. The clinical characteristics of the patient (e.g. stable, unstable, comorbidity/coinfection)
2. The sub-population (e.g. adults, children and adolescents, pregnant and breastfeeding women, key populations, men)
3. The context (e.g. difficult terrains and hard to reach areas)

4.3 Differentiated Service Delivery Models under NACP

NACP has always been ahead in implementing patient-centric differentiated care models for PLHIV with introduction of Link ART centre model in 2008 and two-month ARV dispensation in 2010. Currently, the following differentiated care models for ART delivery are functional in the country. These models serve to ensure convenience of stable PLHIV by minimizing their visits to ART centres and prioritizing the PLHIV with special needs

4.3.1 Multi-month dispensation (MMD): Under this model, stable PLHIV are provided ARVs drugs for three months at a time, instead of the usual one month. MMD significantly reduces patient visits to the ART centres from 12-14 times a year to 4-6 times, reducing travel time and costs for the patients while reducing the patient load at the ART Centres. Implementation of the MMD helps to decongest ART centres by reducing the average daily OPD significantly. Its implementation can ensure that healthcare workers have more time at their disposal to focus on new patients and on those who may require additional care such as children, adolescents, pregnant women, and patients with opportunistic infections/ coinfections or comorbidities. However, children, adolescents, pregnant women are not necessarily excluded from MMD, if stable.

4.3.2 Link ART centres (Decentralised ART service delivery models): ART is provided through decentralized sites set up near the patient's residence. These sites could be sub-district hospitals/ rural hospitals, community health centres, primary health centres, opioid substitution therapy centres, prisons, care and support centres, targeted intervention sites, other sites at NGOs/ CBOs/ CSOs.

i. **Decentralised ARV delivery through public health facilities (Link ART Centres at Sub-district/ Rural Hospitals Community Health Centres / Primary Health Centres / Urban Health Centres):** Link ART centres in the public health facilities are set up to make ART accessible near the patient's residence through the widespread network of public health care infrastructure across the country. These sites provide convergent, decentralized ART dispensation and comprehensive care to stable PLHIV while decongesting the crowded ART centres and integrating HIV care into general health systems. This model enables PLHIV to save transportation cost, loss of daily wage, and waiting time in hospitals to access ARV medication and help in reducing the burden of travel to far away ART centres. Through this model, PLHIV can receive ARV closer to their residence which helps improving their adherence and retention in care.

ii. **Decentralised ART refills for key populations (LAC at TI-NGO, OST centres):** To improve access to HIV treatment and retention in care amongst key populations, LAC are set up at TI NGO sites or at OST sites. ART refills through TI NGO helps to alleviate specific challenges faced by key populations to access to ART services, such fear of stigma and discrimination, health system barrier. These models provide access to ART to KP-PLHIV in a friendly community setting with which key populations are familiar as well as advantage of flexi-timing.

iii. **Community based ART refill (LAC at care and support centres / community based organizations /non-governmental organization):** These sites also help to improve retention by making ART available to PLHIV within the community setting, therefore providing the advantage of flexi timings, drug refill on holidays, fast track refills. This model helps to lessen the issues around stigma and discrimination by involving community, while shifting the responsibility of retention and management to community with the core support of the healthcare system.

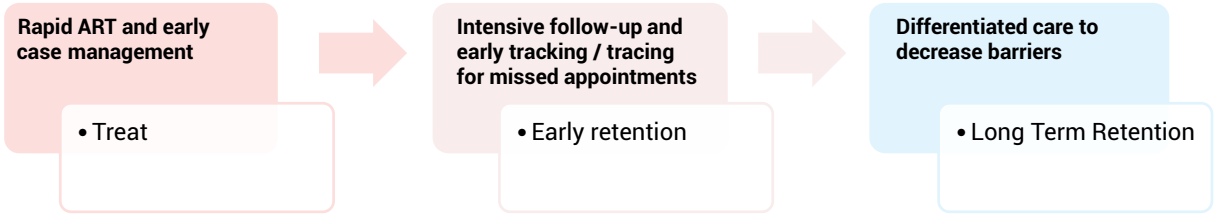
iv. **ART delivery in prisons (LAC in prisons and other closed setting)** PLHIV in prison and other closed settings face challenges in accessing ART due to multiple reasons. To overcome the challenges experienced by patients as well as prison staff, LAC are set up in prisons and closed setting so that uninterrupted ARV refills may be offered.

4.3.3 Community ART refill groups (CARGs): PLHIV receive their ART refills in a group. These groups can be managed and facilitated by PLHIV themselves/ PLHIV networks/ CSC/ CBO/ TI NGO /LWS/providers and are formally registered at ART centres. Generally, community ART refill groups meet outside of health care facilities. Please refer to Section 4.4.3.3 for details.

4.4 Standard Operating Procedures for Patient Centric Differentiated Care Packages

The framework below details patient centric strategies for a package of services anchored on the life cycle of PLHIV and the patient centric strategies to augment retention. Patient centric differentiated service packages based on their need, clinical status, and duration of ART would also provide an opportunity to the ART centre staff to cater to the prioritized requirements of specific patient groups.

Figure 8. Framework for patient centric differentiated care



Considering the evolving needs of PLHIV during various stages of treatment, packages of services for the following three groups of PLHIV:

1. **Package A:** PLHIV newly registered at ART centre, until 6 months after ART initiation
   Package A+: PLHIV with advanced HIV disease
2. **Package B:** PLHIV who are virally suppressed/stable
3. **Package C:** PLHIV who are virally unsuppressed/unstable

Figure 9. Flow diagram for patient centric service across treatment cascade

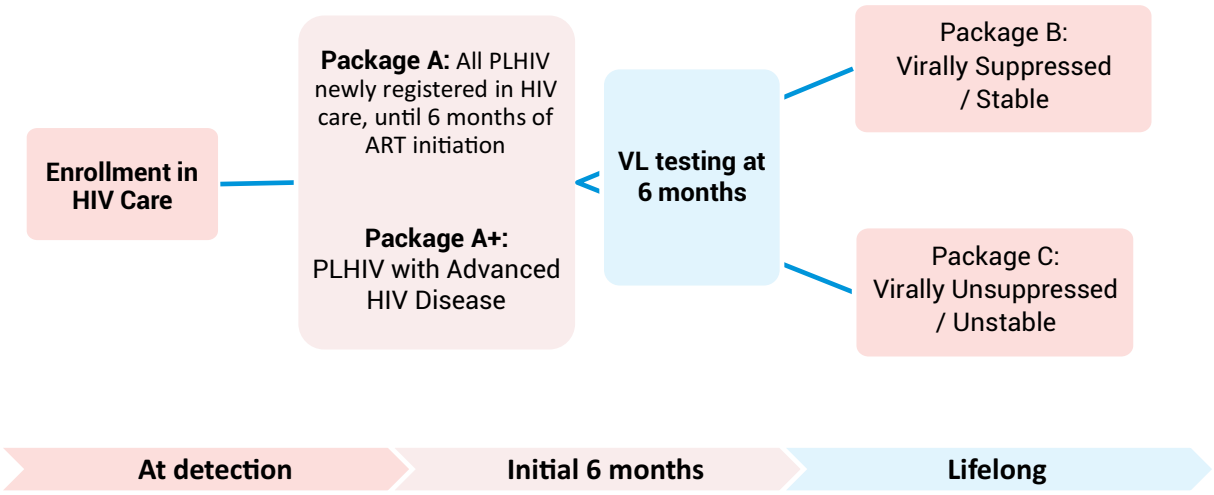


Table 5. Patient centric differentiated packages

Package of services for initiation and short-term retention		Package for long-term retention	
Newly registered PLHIV		PLHIV on ART > 6 months	
Package A	**Package A+**	**Package B**	**Package C**
• Preparedness counselling - Address verifications - Identification of care giver • Screening for TB and other OI (advanced HIV disease) • Rapid ART • TB preventive treatment • CPT (if eligible as per guidelines) • Case management: Intensive follow up (6 months) with tracking and tracing • Viral load testing (at 6 months) and utilization • Index testing referrals • Patient centric packages particularly for special populations - KP, adolescents, children, pregnant woman	Package A + Advanced disease management + Enhanced adherence counselling	• Differentiated service delivery - Multi month ART - Decentralised ART refill (LAC, co-located ART OST site, TI sites, CSC, Community ART refill groups) • Routine viral load testing	• Viral load testing and utilization (Enhanced Adherence Counselling, e-referral for timely switch) • Patient centric packages particularly for special populations -KP, adolescents, children, pregnant woman • Case management approach for focused and individualized care for PLHIV such as, monthly phone check-ins/ reminders, peer support, home visits, particularly for PLHIV who return to care after being missed/LFU • Tracking and tracing for missed appointments • Advanced disease management

For PLHIV who are already on ART:
package A, if < 6 months on ART; package B or C, if >6 months on ART

As shown in Figure 9, package of services is tailored as per the needs of PLHIV as categorized below:

4.4.1 Package A (services for PLHIV newly registered in HIV care, until 6 months after ART initiation)

Programme data shows that most of the Lost to follow up (LFU) and deaths among PLHIV occur during the first six-months after ART initiation. This is most commonly due to poor understanding by the PLHIV regarding ART, adverse effects of ART medication, opportunistic infections and delay in ART initiation. Effective ART preparedness counselling and proactive follow-up of the PLHIV in the initial six months may lead to improved engagement and retention of the patients in ART care.

Package of services for new PLHIV (less than 6 months on ART) includes:

- Preparedness counselling for all with a specialized focus on identifying individuals who are likely to become LFU (e.g. people with substance abuse, migrants, adolescents, KPs, residing in far away or hard to reach areas)
- Address verifications
- Identification of care giver
- Symptom screening for TB and other OI (advanced HIV disease)
- Rapid ART initiation
- TB preventive treatment
- Case management: Intensive follow up (6 months) with tracking and tracing
- CPT (if eligible as per guidelines)
- Intensive follow-up for 6 months to ensure retention
- Viral load testing and utilization for those PLHIV on ART for six months

White cards of PLHIV under "Package A" will be tagged with yellow colour stickers

For the first 6 months after ART initiation, all PLHIV will be closely tracked for their pill pick up through telephonic contact (probably in the middle of the month) at least twice in a month for initial 3 months and then once a month until they complete 6 months on ART. In case patients do not turn up, timely measures for tracking and retrieval should be taken. Refer to Section 2 for detailed SOPs on ART initiation and Section 3 for monitoring.

Package A+ (services for PLHIV with advanced HIV disease)

- In addition to above package, PLHIV with advanced HIV disease will get package for ADM (package A+). Please refer to Section 2.6 for details on ADM package.
- PLHIV with higher potential to become LFU (such as KP, migrants, adolescents etc. may also be considered for package A+.

For PLHIV under package A+, please mention A+ on yellow sticker

4.4.2 Triaging of PLHIV to package B or C

Viral load testing should be done at 6 months, 12 months of completion of ART. Depending on the Viral Load result and other criteria, patient should be categorized either as stable or unstable.

Nurse will assess the PLHIV who have completed 6 months. PLHIV/CLHIV who fulfil the criteria (as given under definition of 'stable' in Section 3.1.4) will be labelled as "stable" in green book and white card (Section 13) and should be triaged to package-B. PLHIV who do not fulfil any of the above criteria will be labelled as "unstable" in the green book. Unstable patients should be triaged to package-C. Stable and unstable status are dynamic and should be assessed during every visit by the patient.

Note: PLHIV on TPT who have completed 3 months on TPT may also be provided benefits of service delivery models for stable PLHIV, if fulfilling above criteria

4.4.3 Package B (services for stable PLHIV)

PLHIV who are stable do not require frequent clinical care. Since ART is a lifelong treatment, it is critical to consider the patient convenience by minimizing the burden of unnecessary travel and financial cost thereof. This would help in maintaining retention on ART and viral suppression and improving health outcomes in long term while reducing the burden on the health care systems as well. Therefore, the services for **stable** PLHIV include:

- PLHIV who are stable should be considered for Differentiated service delivery models (DSDM) like multi-month dispensation (MMD) for 3 months, Link ART centres, community-based refill groups.
- For all patients on first-line ART, routine viral load testing should be done at 6 months and 12 months after ART initiation and thereafter annually.
- White cards of PLHIV under package C should be tagged with green removable sticker.

4.4.3.1 Multi-month drug dispensation (MMD): Under this model, stable PLHIV get ARVs for three months at a time and are required to come to ART centres once in 3 months.

Standard operating procedures for implementing MMD:

(a.) Preparedness for initiating stable PLHIV on MMD:

1. PLHIV should be provided adequate counselling regarding multi month dispensation (benefits, frequency of visits, dosages, storage of drugs) and their willingness should be assessed.
2. Counsellor should document detailed counselling notes in green book.
3. Medical officer should ascertain the eligibility for MMD by assessing the PLHIV for the stable criteria.
4. White cards PLHIV who are initiated on MMD should be tagged/marked (e.g.with **green removable sticker**).
5. PLHIV who are initiated on MMD should be provided adherence counselling and proper guidance on due date. PLHIV should be advised to come to ART centre before the due date in case they are not able to follow the scheduled date due to any unforeseen reason.
6. PLHIV should also report to ART centre earlier if they develop any new symptoms. Contact details of ART centre should be provided to them for any telephonic consultation in such scenario.

(b.) Follow up:

1. Patient prescribed MMD should be proactively followed up and monitored for adherence and on-time visits. ART centre counsellors/care coordinator may remind them regarding their scheduled visit a week before the due date.
2. Patients during his/her follow up visit at ART centre shall follow the routine patient flow.
3. When a patient visits ART centre at 3 months, nurse/counsellor should assess the PLHIV for the following parameter and record information in green book:
    - Any major OI / concurrent illness that require further work up/regular monitoring/ follow up
    - 4 symptoms for TB
    - Any adverse drug effects that require regular monitoring
4. Counsellor assesses three-month adherence, fills the relevant sections of white card. PLHIV with adherence < 95 % should be counselled accordingly to address the issues.
5. When patient on MMD visits medical officer, s/he ensures the following:
    - No major OIs/concurrent illness that needs work up
    - No adverse effects that require regular follow up
    - Verify that adherence is more than 95% in last two dispensation cycles
    - Patients understand concept of lifelong therapy
    - Reconfirm willingness

If due, VL and/or CD4 testing should be done on the day of visit to ART centre by PLHIV (in line with the VL and CD4 testing schedule under monitoring guidelines)

- **PLHIV who fulfil the criteria for "stable" patients, should be continued on MMD.** SMO/MO prescribes ART for three months (90 days) and suggests next due date in such a way so that patient has at least two days drugs left with him at the due date. **Medical officer to mention this specifically in the white card in section 13, column number 13 as name of ART regimen–MMD e.g. TLD–3MD.**
- In case the patient does not meet the criteria, discontinue MMD, and the patient should be moved to package C.
- Good adherence is critical for achieving viral suppression. PLHIV with adherence <95% should be assessed and counselled accordingly to address the issues. Decision to continue/discontinue on MMD may be taken on case to case basis, while considering the reasons for non-adherence However, if a PLHIV has less than 95% adherence for 2 consecutive cycles after adequate counselling, they may be given one-month dispensation with adequate step up counselling.
- PLHIV having any of the 4 symptoms for TB and being worked up for TB should be given one-month dispensation and called back to ART centre when investigation reports are available.
- PLHIV who have undergone VL testing during the quarterly visit should be provided MMD. When VL test report is available,
    - Reports of PLHIV with suppressed VL should be provided to counsellor responsible for package B for attaching them with white card.
    - In case, PLHIV is unsuppressed, report should be provided to counsellor of package C for further follow up. S/he should be called back to ART centre for step up counselling within 2 days of availability of VL test result. Alternatively, 3 sessions of step-up counselling may be done telephonically with proper documentation in the **step-up counselling form** (Refer to Section 4.4.4.1)

7. The pharmacist dispenses ARV drugs for three months and records this in dispensing register and IMS.
8. Information on the **white card of MMD PLHIV is to be entered in master line list/IMS by data managers.** The column of date of visit, next visit and regimen shall be filled appropriately and updated regularly. The proper due date shall be noted in the routine due list of the centre.
9. **For reporting in MPR, PLHIV who are on MMD and not due for ART pill pick up in the reporting month will be reported as "Alive and on ART"**

10. If patients on MMD do not turn up for drug pick up, same existing guidelines of tracking shall be followed up (refer to Section 3.5.2 for details):
    - Call should be made within 48 hours of the missed appointment
    - List shall be shared with CSC for home visits by the end of the week
    - Labelling of MIS/LFU shall be same as per existing guidelines

4.4.3.2 Decentralized ARV delivery models (LAC): Stable PLHIV should also be considered for decentralized ART delivery through Link ART Centres in peripheral health system and community. Please refer to Section 5 on LAC/LAC plus for detailed SOPs for decentralized ART delivery.

4.4.3.3 Community ART refill groups (CARG): Under this model, PLHIV receive their ART refills in a group. These groups can be formed by any group of people including from the same geographical area or a specific population of patients e.g. adolescents only or family units or community groups/networks or members of a specific key population. These groups can be managed and facilitated by PLHIV themselves/ community members/peers/PLHIV networks/ CSC/CBO/TI NGO/LWS/providers. Following are the SOPs for **community ART refill groups (CARG)** formation and functioning:

- These can be formed by community itself based on common need for care or geography or typology. ART counsellor/other providers can also identify and support in formation of these groups and orient the group members on the standard operating procedure of CARG and reporting requirements. These groups could be facilitated by PLHIV networks/CSC/CBO/TI NGO /LWS/providers.
- Ideally, a group may have 10-30 members, however number of members may vary based on local context and may be smaller in rural and difficult areas.
- These groups are formally registered at ART centre, along with details of focal person and all group members.
- Patients should be willing to be part of CARG.
- All the members should be willing to disclose their status to each other and should be fulfilling the criteria for stable PLHIV. However, on a case to case basis, non-adherent PLHIV may be considered. Please refer to Section 4.4.3.
- The group to identify a focal person who will function as a link between the ART centre and the CARG. The group members can take turns to be the focal person. However, other members of the group should not be charged.
- One member from the group (by rotation) or a CARG representative collects ARVs for the whole group from the ART Centre, upon providing on adherence, 4 symptoms for TB or any other symptom.
- Counsellor shall follow-up CARG at ART centre visit for adherence, status of CARG members and any action required for any of the CARG members. Counsellor shall also update adherence and other relevant details of the members in their original white card and other records during each visit of the CARG representative.
- It is ensured that each member of the group visits ART centre, at least once in six months for clinical consultation and necessary investigations.
- ART centre should call the PLHIV to ART centres if they are due for their clinical consultation/ VL testing/SACEP referral/switch.

Responsibilities of the CARG focal person: While the focal person will be responsible for the overall functioning of the group, it is not necessary that s/he should accompany the group representatives during the ART visit. In general, the focal person will have the following responsibilities:

a) Ensure timely pick up of ART from the centre and refill for all members of the group

b) Monitor adherence of the members and document the same in relevant tools/registers

c) Provide peer counselling on adherence to ART, proper nutrition and positive living to the members

d) Verbally screen members of the group for TB symptoms (4S) and refer them to the ART centre if found symptomatic

e) Refer members back to the ART centre for symptoms suggestive of OIs, adverse-effects; and those requiring prenatal and antenatal care

f) Ensure timely visit of the members to the nodal ART centre for routine clinical and laboratory assessment, including viral load testing, as prescribed by the ART centre

g) Maintain robust coordination with the ART centre for effective and smooth functioning of the group

Responsibilities of CARG Members

a) Maintain good adherence to ART and report it to the focal person

b) Attend the group meetings as scheduled by the focal person

c) Visit the ART centre representing the group as per schedule and undergo clinical and laboratory examinations as prescribed by the ART centre

d) In case of TB symptoms, OIs, ART adverse effects or any serious ailments, inform the focal person and schedule a visit to ART centre at the earliest.

4.4.4 Package C (services for retention in care for unstable PLHIV)

This group includes PLHIV who do not fulfil the stable patient criteria after being on ART for 6 months. These include **PLHIV who are virally unsuppressed; having an OI/ current illness; or return to care after being missed and LFU.** Unsuppressed viral load in a PLHIV indicates:

- patient is not taking ART properly/ non-adherence; or
- patient has developed treatment failure

For PLHIV who are unstable, package of care includes:

i. Management of PLHIV with unsuppressed viral load
   - Step up counselling and repeat VL after 3 months
   - e-referral to SACEP for review for second/third line

ii. Case management / individualized approach

iii. Tracking and tracing of PLHIV with missed appointments to improve adherence

iv. Advanced disease management

White cards of PLHIV under package C should be appropriately tagged/marked (e.g. with red removable sticker) for optimal follow up of PLHIV.

4.4.4.1 Management of PLHIV with unsuppressed viral load

Step-up adherence counselling and e-referral to SACEP for review for second/third line: PLHIV with viral load ≥1000 copies/ml should undergo stepwise adherence counselling for three months*.

- When VL test report is available, line list of PLHIV with unsuppressed VL should be generated on daily basis from IMS (Annexure 5).
- The list should be shared with counsellor delivering services under packages C to telephonically follow up PLHIV with unsuppressed VL and call them back to ART centre.
- Counsellor should provide intensive support to improve treatment adherence.
- A minimum of three sessions (15 days or 1 month as deemed fit by the counsellor at ART centre) are recommended for step-up adherence counselling but additional sessions should be conducted as needed. Figure 10 describes the detailed process for step up counselling.
- It is preferred that all counselling sessions are taken by the same counsellor (so that s/he acts as case manager) to ensure consistency, continuity, and proper documentation of issue resolution.
- These sessions should be conducted when the patient visits the ART centre to collect his/her medication.
- Counsellors should use the **ready reckoner** (Figure 10) **and step-up counselling form** (Annexure 6) to facilitate the process.
- In case PLHIV is not able to come to ART centre and is on MMD, three sessions of step up counselling may be done telephonically with proper documentation in step up counselling form.
- During step up counselling, HIV testing of spouse/partner and children should facilitated/ ensured
- Repeat viral load testing (along with other lab investigations) must be done once treatment adherence is >95% for three consecutive months. Patient should be simultaneously informed that in case VL is

not suppressed, e-referral will be done to SACEP and he would be called back to ART centre for switch (based on SACEP recommendation)

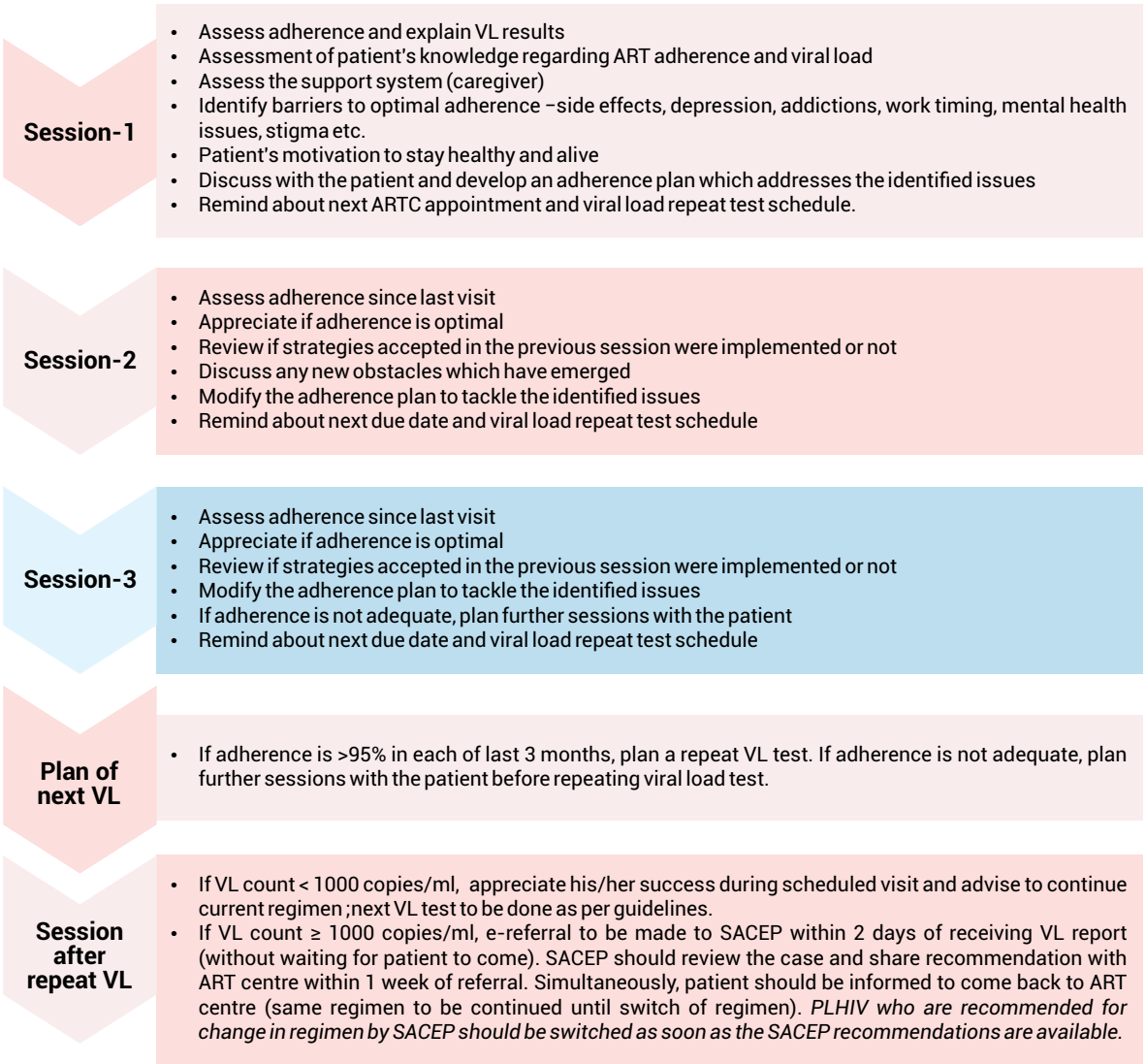
- **If VL count<1000 copies/ml, categorize PLHIV as 'stable' (package B), appreciate his/her success (during scheduled visit) and advise to continue current regimen.**
- **If VL count≥1000 copies/ml, e-referral to be made to SACEP within 2 days of receiving VL report (without waiting for patient to come). SACEP should review the case and share recommendation with ART centre within 1 week of referral. Simultaneously, patient should be informed to come back to ART centre for regimen switch as recommended by SACEP (same regimen to be continued until switch of regimen).**

- Though all efforts should be made to get the appropriate baseline laboratory investigations done for switch during step up counselling period, non-availability of these lab investigations/results shouldn't delay the referral.
- PLHIV who are recommended for change in regimen by SACEP should be switched to new regimen as soon as the SACEP recommendations are available.

**In case of PLHIV with high viral load, declining CD4 counts and poor clinical conditions, ART MO may refer the patient to SACEP, even based on single viral load report, for further management. If patient is HIV 2 positive, decision of referral to SACEP is taken based on immunological failure criteria*

Please refer to Section 6 on 'Provision of second and third line ART' for more details on SACEP referral process.

Figure 10. Detailed process of step-up counselling



4.4.4.2 Case management / individualized approach

- Case management, monthly phone check-in by the counsellors, SMS reminder or home visits by peer counsellors/ORWs to make sure they are adhering to their medication, etc.
- Peer counselling support to those PLHIV struggling to cope with HIV-related issues such as disclosure, stigma, gender-based violence (GBV) or intimate partner violence (IPV), depression, and substance abuse are important interventions to improve retention with PLHIV struggling with these particular issues.
- PLHIV who return to care after being missed or LFU should be provided friendly and welcoming environment; appropriate counselling and support to address the barrier to adherence.

4.4.4.3 Differentiated care for unstable PLHIV:

PLHIV with poor adherence to ART *(esp. if poor adherence is mainly due to barriers* that make routine clinic visits challenging such as *long distance travel to ART centre, financial reasons, non-availability of caregiver to accompany,* conflicting timing with work or school schedule etc.) **may be linked to LACs** in order to enhance adherence and retention **(on a case to case basis).** However, a rigorous follow-up mechanism of these PLHIV at LAC should be ensured. Community-based sites (such as CSC, TI, CBO, NGO etc.) may be preferred in such scenario. With flexibility and additional support, they may be able to remain in care and on treatment and may benefit the most from differentiated service delivery models.

4.4.4.4 Tracking and tracing for missed appointments to improve adherence

- Daily due list to be generated every day
- If PLHIV do not turn up in the next day, they need to be called up same day through telephone.
- Line list to track "on-ART" patients who have missed their appointments (MIS) should be prepared on a weekly basis and shared with the ORWs
- Conduct monthly ART-CSC coordination meetings to monitor tracking and tracing activity

Please refer to Section 3.5.2 for details.

4.4.4.5 Advanced disease management:

Please refer to Section 2.6 for details on ADM package.

4.4.4.6 Implementation of patient centric package of services:

To improve retention among PLHIV, the staff at the ART centre will require a functional change to have a differential approach to provide quality care. Based on the HR available and patient load, ART centre staff should be designated set of roles and responsibility to deliver a specific package. Examples of patient flowcharts that can be implemented in the ART centres depending on the HR norms/patient load are given as Annexure 7). The staff may rotate from package to another every four months.

4.5 Ensuring Uninterrupted Access to ART Services in Difficult Situation

Under difficult situation such as local calamity/epidemic (e.g. COVID-19, earthquake, floods, cyclones etc), having contingency plans to **ensure access to uninterrupted ART services to all PLHIV is very critical.**

4.5.1 Development Contingency Action Plan unforeseen/ difficult situation restrictive scenarios such as local calamity/epidemic (such as COVID-19, earthquake, floods, cyclones etc.)

- All states should to develop contingency plan detailing local strategies and tailor-made solutions for all PLHIV availing ART services and for staff engaged in service delivery. These action plans should be based on local context, challenges and available resources, and with due approval from respective PD, SACS, and with intimation to NACO.
- Local action plans may be developed in consultation with ART centres and community networks, to ensure that PLHIV receive uninterrupted ART supply without having to travel to ART centres every month
- SACS should involve local **DAPCUs** to implement these contingency and coordinate with various stakeholders (all NACP facilities, local authorities, public health facilities, CSC, NGO, CBOs, community members etc) to ensure decentralized drug refill/ home deliveries.

4.5.2 Ensuring uninterrupted ART service provision:

- SACS should include 'ART services' under essential services under any contingency situation. It was All steps should be taken so as not to deprive any PLHIV of ART.
- Under such situations, all PLHIV (irrespective of stable/unstable criteria) may be provided MMD/ decentralized ARV refill/ home delivery with prior approval of SACS /NACO, as a contingency measure, as done in COVID -19 times. Provision for laboratory services through decentralised specimen collection (VL and CD testing) and establishing linkages with nearest lab facility for other routine investigations and OI diagnosis
- **Multi-month dispensation (MMD):** As a contingency measure, **Multi-month dispensation (for 3 months)** may be given to all patients on 1st line, 2nd line and 3rd line ART, along with TPT/CPT prophylaxis. These MMD guidelines may be followed at all ART centres, and LACs.
- **Decentralised ARV drug refill:** For drug refill closer to the community, states should explore possibility of utilizing the public health facilities (CHC/PHC) within the larger health system. Within the programme also, dispensation may be decentralized to LAC/ICTC/CSC/OST centres/other NACP facilities etc.
- **Community dispensation:** Strategies like community refill (through care and support centres, TI NGO, home delivery through ORW, volunteers, PLHIV networks) and family refill etc. may be followed in such scenario.
- ART centres should prepare the line-list of patients due for ART medicine collection till the time situation is expected to prevail, and explore all possible ways of drug dispensation, online counselling, telemedicine guidance, IEC through social media apps, etc.
- Even if a patient is registered at one ART and reaches out to another facility anywhere in country in such scenarios, he/she shall be provided with medicines and patient would be labelled as **"In transit"** by the ART centre dispensing ARV drugs. Therefore, all ART centres/CoE to ensure uninterrupted ART service provision for patients stuck in other states/districts, so that they receive ARV drugs through nearest ART centres. For this, coordination between SACS /DAPCU and CSC teams is required on a daily basis.
- Travel allowance for these activities in such scenario may be provided from existing funds with approval of PD, SACS.

4.5.3 Supply chain management

- For drug transport, government vehicles under NHM/Municipality/DH and ambulances may be utilized by SACS after due approvals, for inter-district/intra-district transport of ARV drugs/other commodities to ART centres. Also, mobile vans may be utilised for dispensing ARV drugs to the peripheral health facilities in rural/difficult to reach areas.
- In case of low stock, SACS should coordinate with NACO for additional supplies or relocations. In this regard, NACO may also follow up with procurement agent regarding supply of ARV drugs in quarantine at various regional warehouses and expedite the procurement process.

4.5.4 Data recording and reporting for ARV dispensation to PLHIV from other ART centres

- All ART centres to ensure IMS entries of ARV drugs refilled through decentralized Community-dispensation methods. Information from decentralized or community sites should reach back ART centres at the earliest. A common standard format should be prepared & shared with all ART centres with guidance for collecting data from decentralised sites
- The information regarding the dispensation to PLHIV from other ART centres can be shared with parent ART through email. In IMS, dispensing ART centres will make data entry under "transit patients"; parent ART centre to do routine entry as usual after getting intimation from dispensing ART centre.

4.5.5 Trainings and mentoring

- Staff from all ART centres and decentralized sites should be trained and provided continuous mentoring using virtual platforms.

CHAPTER 5

Link ART Centres and Link ART Centres Plus

The National AIDS Control Programme has been in the forefront in providing patient centric care. The programme rolled out differentiated service delivery model for PLHIV in 2008, well ahead of WHO recommendations in 2016. The aim of this model was to make the treatment services easily accessible to PLHIV and promote adherence by addressing the barriers associated with inconvenience due to frequent visits, long distance travel and cost for the travel. These centres are linked to a nodal ART centre and function as its outreach units. The evaluation of the scheme in a year after the roll out of the model, provided clear evidence on benefits of this patient friendly initiative and over time, this has been expanded to 1264 centres, providing services to 1,16,000 PLHIV to support drug adherence and retention in care.

5.1 Model of Link ART Centres (LAC) and Link ART Centres plus (LAC plus)

5.1.1 Model of LAC

Initially, ART services were only provided through ART centres located mainly in medical colleges, tertiary hospitals and select district hospitals in high prevalence states. The field observation and results from operational research studies, revealed that the distance from patient's residence to ART Centres, geographical barriers and economic consequences, thereof, are the main constraints in accessing ART services which affect the adherence to treatment. Therefore, NACO rolled out 'Link ART centres'-a differentiated service delivery model for stable PLHIV in 2008. The aim of LAC is to provide patient friendly services and minimize travel needs, waiting hours and costs to patients. The main functions of LACs are monitoring PLHIV on ART, refilling drugs for the patients on ART, treatment of minor OIs, identification and management of adverse effects and reinforce adherence on every visit.

Link ART Centres (LAC) were initially set up at ICTCs in the district /sub-district level hospitals/community health centres nearer to the patient's residence. Moving ahead, the scheme is being expanded to include Opioid Substitution Therapy (OST) centres, prisons, care and support centres (CSC), targeted intervention (TI) NGO and other NGO/CBO/CSO.

5.1.2 Model of LAC plus

LACs were initially established for monitoring PLHIV on ART, drug distribution to patients on ART, treatment of minor OIs, identification and management of adverse effect and reinforce adherence on every visit. Further, it has been observed that there was significant linkage loss between ICTC and ART services. The study commissioned by NACO reflected that the reasons for this gaps in linkage included: PLHIV being asymptomatic at the time of detection, long distance travelled to reach the ART centre, financial issues, need for multiple visits for baseline investigations. Also, nearly 20% patients reach ART centres at a very late stage (CD4 count <100), when the risk of mortality is nearly 2-3 times higher. Therefore, the scope and functions of Link ART centre was expanded to include pre-ART care in 2011. Select Link ART centres were upgraded to "LAC plus" and pre-ART management (including basic investigations, CD4 testing, assess eligibility for ART and follow up the patient in pre-ART care) was included in the scope of work. The patients are followed up at LAC plus till they become eligible for ART or referred to ART centre for any other reason.

However, now with 'treat all' policy, all PLHIV need to be initiated on ART. Therefore, LAC plus scheme is being

revised to expand the scope to include ART initiation. LAC Plus centres shall also be authorized to initiate ART after written approval from NACO/SACS. This shall help in integrating HIV care into general health system; making ART more accessible and convenient to PLHIV; bridging the gap between HIV testing and treatment services. The detailed SOPs of LAC Plus centres are given in Section 5.6.2.

5.2 Objectives of LAC and LAC plus

- To increase the access to ART for the PLHIV
- To improve the drug adherence and retention of PLHIV on ART
- To bridge the gap between testing and treatment services for HIV
- To integrate HIV care, support and treatment services with the general health systems
- To increase involvement of community in retention of PLHIV

5.3 Functions of LAC and LAC plus

5.3.1 Functions of Link ART centres

The main functions of Link ART centres are indicated below:

Drug refill: LAC shall be responsible for ARV drugs refill to stable patients on ART linked out from nodal ART centre following established procedure. LAC shall not initiate/modify ART for any patient at any point of time.

Monitoring of PLHIV on ART: LAC shall monitor the linked outpatients on ART in terms of drug adherence, adverse effects of drugs and opportunistic infections. LAC shall also be responsible for patient follow up to maintain optimum drug adherence, prevent and trace MIS and LFU cases. Referral to the ART centre shall be required in case of major OI, serious side effect of drugs etc.

OI prophylaxis and treatment: Depending upon the capacity including diagnostic facilities and drugs, LAC shall identify, treat OIs and provide in-patient care whenever required. However, after stabilization/treatment, patient should be sent back to ART centre for evaluation of possible treatment failure. LAC shall also continue CPT and TPT as prescribed by nodal ART centre. Drugs for prophylaxis and treatment of common OIs like cotrimoxazole, metronidazole etc. shall be provided through the health facility. LAC in community setting which do not have facilities to manage OIs will refer the PLHIV to nodal ART centre/nearest health facility at the earliest.

Screening of PLHIV for TB symptoms: All PLHIV shall be screened for TB during every visit and all patients with symptoms of TB should be referred to the ART centre or NTEP facility whichever is nearest for diagnosis and if found infected with TB, should be sent back to nodal ART centre for appropriate management. HIV-TB line list should be maintained.

Tracing MIS and LFU: Daily due list of PLHIV on ART shall be maintained by LAC. The MIS/LFU cases shall be traced by counsellor through phone and outreach. Concerned ICTC, Link Workers, CSC and other outreach workers should also be involved in tracing of MIS/LFU cases.

Psychosocial functions: LAC staff shall provide psychological support, counselling on adherence, nutritional and positive prevention to PLHIV accessing the Link ART centre. LAC staff shall also provide information about the various social welfare schemes available for PLHIV and facilitate access to available resources provided by the government agencies and NGO.

5.3.2 Functions of LAC plus

In addition to the functions mentioned above for LAC, the LAC plus shall also perform the following functions:

ART initiation: PLHIV detected HIV positive at ICTC may be referred to nearest LAC plus as per patient's convenience for registration in HIV care, baseline investigations, ART initiation. Baseline investigations, in line with the NACO guidelines, shall be done through mechanism available under general health systems; and CD4 testing through linkage. PLHIV who are symptomatic or have advanced HIV disease (AHD) condition (clinically unstable) should be considered for appropriate diagnosis and management/expert consultation/

referral to nodal ART centre. Depending on the capacity including diagnostic facilities and drugs, the LAC plus may provide treatment /in patient care as required. The PLHIV shall be referred to nodal centre for any other illness that cannot be managed adequately at LAC plus. PLHIV who are not initiated on ART shall be traced by nurse and LAC counsellor (ICTC counsellor) through phone and outreach. Concerned ICTC, link workers, CSC and other outreach workers shall also be involved in tracing of MIS/ LFU cases.

Table 6. Functions of LAC and LAC plus

Functions of LAC	Functions of LAC plus
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	In addition to functions of LAC, LAC plus will have the following functions: 1. Enrolment of PLHIV in HIV care and ART initiation in PLHIV who are clinically stable 2. Baseline investigations and CD4 testing (through linkage). 3. Referral of symptomatic (clinically unstable) PLHIV to nodal ART Centre for ART initiation.

LAC shall not initiate/modify ART in any patient at any point of time

***Note:** The LACs at community-based sites, other than hospital set-up, may not have doctor or paramedical staff. Such facilities shall refer PLHIV with any adverse effects, symptoms of OI or 4S positive to the nodal ART centre for consultation, diagnosis and management of the condition.*

5.4 Setting up of Link ART centres and Link ART plus centres

5.4.1 Setting up of Link ART Centre

Link ART centres shall be set up in a public health facility (preferably with an ICTC), OST centre, TI NGO, CSC, prison or any other NGO/CBO/CSO (after approval from NACO/SACS)

Eligibility criteria for site selection of Link ART centre in a health facility: Link ART centres shall be established based on one or more of the following criteria:

- Significant number of positive cases detected in ICTC (>100 PLHIV over last five years in the catchment area)
- ART centres where patient load is high
- Long distance from patient's residence to reach ART centre and longer time taken by public transport
- Districts which are not covered by ART services
- The above criteria may be relaxed in areas with difficult accessibility (difficult terrains and hard to reach areas such as hilly regions, desert areas, tribal regions etc.), closed setting, co-located OST or TI sites or other community-based site for flexible timings as per convenience of patients

Requirements for setting up LAC in health facility: The link ART centre should fulfil the following requirements:

Space for LAC: In addition to existing infrastructure of ICTC where LAC is being established, at least one additional room is required for the nurse/staff provided by the institution/organization, for record keeping and other LAC functions.

Staff at LAC: LAC shall utilize the existing human resources of the facility/ICTC and no other additional manpower shall be provided to the LAC.

1. **Doctor:** The health facility should identify 2-3 doctors (at least 2) in such a way that the patient can be attended and examined on all OPD working days. One of the doctors amongst them (preferably a physician) shall be the LAC in-charge and responsible for day-to-day activities and reporting to the nodal ART centre.
2. **Counsellor:** The ICTC counsellor shall bear the responsibility of ART counselling of PLHIV on ART. Counsellor from other NACP facilities (STI/ PPTCT etc.) may also be involved to share the responsibility.
3. **Staff nurse:** The facility should depute a nurse to assist doctor and coordinate with counsellor. Computer literate nurses should be given preference for deputation in the LAC.
4. **Pharmacist:** One of the pharmacists in the health facility shall be identified and she /he shall be responsible for drug storage, dispensing and drug record keeping. Computer literate staff should be preferred.

All above staff shall be trained by NACO/SACS on structured LAC curriculum at identified training centres. LAC feasibility assessment should be done using the standard format (Annexure 8).

5.4.2 Steps in setting up Link ART centre*

Table 7. Steps in setting up link ART centre

Activities	Responsibilities
Identification of prospective site for LAC and submission of proposal during exercise for Annual Action Plan (AAP)	SACS
Administrative approval in AAP	NACO
Meeting between SACS/DAPCU, Civil Surgeon/ Medical Superintendent of Hospitals, and SAC/ DAPCU/RC/TE-CST for feasibility assessment, identify and sensitize the key staff at hospital. (Refer to checklist at Annexure 8)	Concerned SACS, In-charge of District/ Taluka Hospitals, medical officer and RC
Approval letter to set up LAC, subject to satisfactory feasibility report	SACS (with information to NACO)
Training of LAC Medical Officers at NACO designated training centres	CST officials of SACS, Regional Coordinator, TE-CST NACO
2 days hands-on orientation of whole LAC team (MO, counsellor, staff nurse, pharmacist, lab technician) at Nodal ART Centre	CST officials of SACS, Regional Coordinator, TE-CST Nodal ART centre in charge, LAC in-charge, DACO/DAPCU/ District Nodal Officers
Provision of recording and reporting tools and IMS	Concerned SACS
Operationalization of Link ART centres	CST officials of SACS, nodal ART centre in charge, LAC in charge

** For setting up LAC at community sites, eligibility criteria for site selection and HR requirement shall be relaxed after approval from SACS with intimation to NACO. LAC at community sites shall not have any additional financial implications to NACO/SACS and can be set up based on needs of PLHIV even outside the AAP after approval of SACS with intimation to NACO. All other steps for setting up LAC at community sites would be the same.*

5.4.3 Upgradation of LAC to LAC plus:

The LAC plus scheme is rolled out at existing Link ART centres (within the health systems) with a patient load of more than 70 PLHIV on ART (after prior approval of NACO) and these centres are provided with additional staff nurse to assist in carrying out functions of LAC/LAC plus. In these revised guidelines, the criteria for upgradation of LAC into LAC plus would remain the same, the scope of LAC plus is being expanded to include ART initiation and follow up (after approval of NACO/SACS). Only the LACs within the health systems will be upgraded to LAC plus. The scope of existing LAC plus to ART initiation shall be revised only after submission of feasibility report (Annexure 9) and written approval from NACO.

5.4.4 Additional staff at the LAC plus: A staff nurse shall be provided to LAC plus by NACP.

Staff Nurse: One contractual staff nurse to be recruited as per NACP norms. The staff nurse should be B.Sc. Nursing, with working knowledge and skills on computers, Microsoft Office software and internet. If not available, GNM may be appointed. The remuneration will be as per NACP norms. The recruitment of LAC plus staff nurse needs to be carried out by the administrative head of the concerned health facility. Please refer to Section 13 for more details on human resources.

For CD4 blood sample collection and transport, the existing laboratory technician at ICTC lab shall be utilized. All above staff shall be trained by NACO/SACS on structured LAC curriculum at identified training centres.

5.4.5 Steps in upgradation of LAC into LAC plus

Table 8: Steps in upgradation of link ART centre into LAC plus

Activities	Responsibilities
Identification of LAC with more than 70 PLHIV on ART	SACS
Approval by NACO during AAP	NACO/SACS
Feasibility visit to assess capacity for ART initiation in terms of HR, lab, willingness and space	CST officials of SACS, Regional Coordinator/ Technical Expert (CST), DACO/DAPCU/ District Nodal Officers
Appointment of Staff nurse	DAPCU/District Nodal officer for HIV-AIDS/ Concerned Health Facility
Training of staff nurse & lab technician	NACO/SACS/Regional Coordinator/ TE- CST
Orientation of whole LAC team (MO, Counsellor, staff nurse, pharmacist, LT) at nodal ART Centre	CST officials of SACS, Regional Coordinator/ Technical Expert (CST), Nodal ART centre in charge, LAC in charge, DACO/DAPCU/ District Nodal Officers
Provision of monitoring and evaluation tools	Concerned SACS
Operationalization of LAC plus	CST officials of SACS, Regional Coordinator/ Technical Expert (CST), Nodal ART centre in charge, LAC in charge, DACO/DAPCU/ District Nodal Officers

5.5 General Guidelines for LAC/LAC plus Functioning

5.5.1 Working days for LAC/LAC plus: At LAC/LAC plus in the health facilities PLHIV shall be examined in the General OPD on all the working days within the OPD timings. The LAC shall follow the same holidays as per the health facility. The timings/working days for LACs in community settings shall be decided, in consultation with community and SACS/DAPCU, based on other routine operations carried out at that community site, with the aim of providing flexi-timings to PLHIV. Efforts should be made to provide services on days and timings convenient to the PLHIV.

5.5.2 Computer and internet: The Link ART centre shall utilize the computer facility already available with the site -ICTC/OST/TI/CSC/NGO/CBO. The LAC should have a broadband internet connection. Funds provided under LAC grant may be used, if not available under ICTC.

5.5.3 Display of information: The information regarding LAC/LAC plus working hours, services available, emergency contact details, holidays should be displayed at LAC prominently along with details of nodal ART centre. LAC plus shall also display information about the days for sample collection for CD4 testing.

5.6 Standard Operating Procedures (SOP)

5.6.1 For PLHIV "on ART" at LAC/LAC plus

5.6.1.1 Referral of Patient from Nodal ART Centre to Link ART Centre

Eligibility criteria for "link out" of "on ART" PLHIV (adult and adolescents) from nodal ART centre to LAC/ LAC plus:

- PLHIV and CLHIV on any ART regimen and fulfilling the 'stable' criteria as per details given under Section 3.1.4 of these guidelines
- The patient is a resident of an area closer to the LAC/LAC and is willing to be linked out and collect their ARV drugs from the LAC/LAC Plus, once the above conditions are fulfilled.
- Definition of stable patient shall be applicable for patients on any ART regimen (1st, 2nd and 3rd line) after being on that line of regimen for at least 6 months.
- PLHIV on TPT who have completed 3 months on TPT could also linked out (after proper counselling on adherence and adverse effects), if fulfilling above criteria.

Note: LACs are encouraged to provide MMD to stable patient availing services at LAC

PLHIV with poor adherence to ART (esp. if poor adherence is mainly due to barriers that make routine clinic visits challenging such as long distance travel to ART centre, financial reasons, non-availability of caregiver to accompany, conflicting timing with work or school schedule etc.) **may be linked to LACs** in order to enhance adherence and retention **(on a case to case basis)**. However, a rigorous follow-up mechanism of these PLHIV at LAC should be ensured and monthly telephonic follow up by ART centre shall be required.

5.6.1.2 ART prescription: Once it has been decided that the patient is ready to be linked out to a Link ART centre as per Section 5.6.1.1, nodal ART centre shall

- counsel the PLHIV, provide all information about LAC (contact details, when to reach to LAC) and dispense one-month ART to PLHIV
- prescribe ART for 6 months to the PLHIV being linked out, who would be provided drug refills from LAC.

The Nodal ART centre shall report about the total patients linked out to Link ART centres in the monthly ART reporting format (MPR).

LAC shall not initiate/modify ART in any patient at any time

Only **patients from designated nodal ART Centre** shall be **'linked out'** to attached LAC/LAC plus. For example if LAC Ambala is a Link Centre for nodal ART centre Chandigarh, it shall cater to PLHIV originally registered with ART centre Chandigarh who are staying in and around Ambala district only and not to patients registered with any other ART centre in the nearby geography e.g. Jalandhar or Amritsar. In case a new ART centre/LAC is opened near the patient's residence, the patient shall have to be first sent back to the nodal ART centre and then transferred out/linked out to the new centre as per the linkage plan.

The patients at LAC/LAC plus shall remain the patients of nodal ART centre and shall not be shown as transferred out from the nodal ART centre. Instead, the term **"linked out"** should be used.

5.6.1.3 Documents for "link out" of "on ART" patients from nodal ART centre to LAC/LAC plus

Patient should be sent to the LAC/LAC plus with the following:

- Patient should be **linked out to LAC through IMS** (no need to maintain link out forms). Prompt will go in IMS to LAC whenever PLHIV is linked out.
- Original **Patient Booklet** (green booklet), with details of link out (address and contact details of LAC).
- One-month drugs.

White card to be maintained at both centres, marked as LAC copy and ART centre copy. The card to be updated based on information received from NAC/LAC/LAC Plus

5.6.1.4 Availability of ARV drugs at LAC/LAC plus: Ideally at least 3 months stock should be available for PLHIV at LAC/LAC Plus at any point of time. Calculation of quantity of ARV drugs*:

- **For LAC:** Number of linked out PLHIV (Alive and MIS) from nodal ART centre X 3 months + one month buffer stock
- **For LAC Plus:** In addition to above, LAC plus will also receive drugs for ART initiation in new PLHIV (Average no of PLHIV/ month X 3) + one month buffer stock

** PLHIV already on MMD or expected to be on MMD to be considered.*

5.6.1.5 Mechanism for drug transfer to LAC:

- Based on calculation at Section 5.6.1.4, ARV drugs should be supplied on a quarterly basis or earlier, if required
- Pharmacist at nodal ART centre to cross check with IMS and recommend for approval by SMO/MO in charge of ART centre

5.6.1.6 Transportation of drugs: Drugs may be transported to LAC through LAC staff or by health system staff/ vehicle or through a courier agency/SCM agency. The cost for transportation shall be borne under operational cost provided to the Nodal ART Centre or recurring grant of Rs. 20,000/- given to LAC/LAC plus (in public health systems only). The TA/DA for contractual staff involved in drug transfer shall be given as per NACO/SACS guidelines and to Government staff it shall be as per State Government rules.

5.6.1.7 Drug stock reporting by nodal ART centre: The Nodal ART Centre shall not deduct the total quantity of drugs transferred to Link ART centre in the monthly report sent to NACO. It should only deduct the drugs actually dispensed to the patient at the LAC/LAC plus during the month as reported in monthly reporting format from LAC/LAC plus to nodal centre.

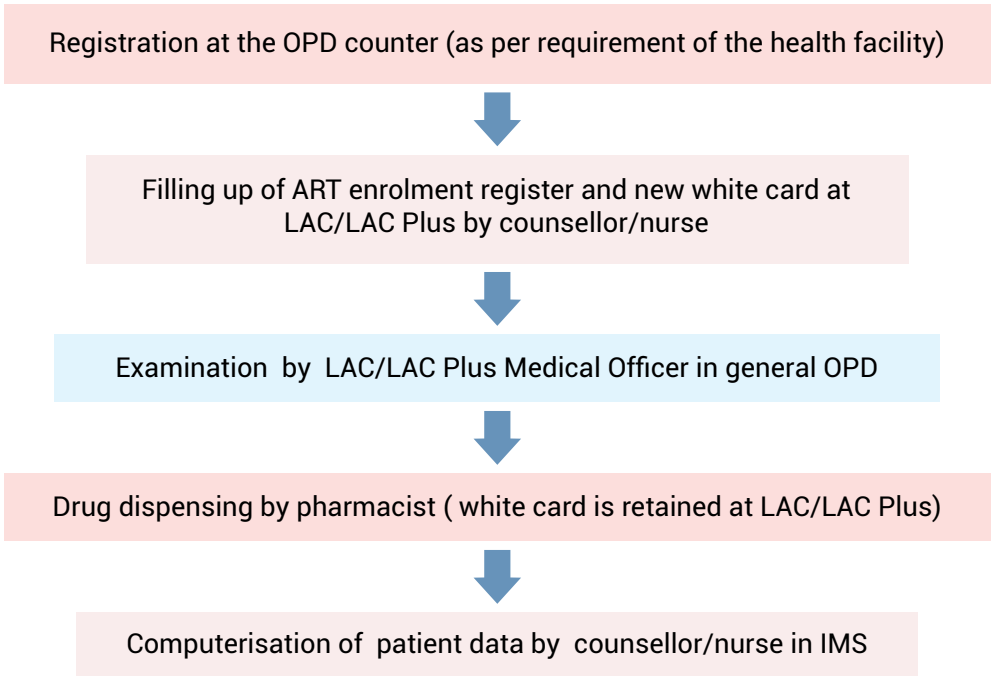
IMS entry: Pharmacist of NAC to report stock at IMS as soon as stock is given to LAC

- LAC staff update dispensation in IMS on daily basis
- LAC in charge should physically verify the stock of all ARV drugs every month, cross check with IMS and MPR and sign in stock register

5.6.1.8 Services at Link ART centres/LAC plus for "on ART" patient:

- Once the patient reaches LAC/LAC plus; he/she is enrolled in ART enrolment register (same as ART enrolment register at ART centres). The serial number of the ART enrolment register of LAC shall become the LAC registration number of the patient.
- A new patient treatment record (white card) shall be maintained at LAC. The LAC registration number needs to be mentioned on the white card prepared by LAC along with the ART registration number.
- This data should be computerized at the LAC/LAC plus by the counsellor/staff nurse in the IMS. In case there is any issue with maintenance of IMS, format 4B needs to be continued.
- On monthly visits to the LAC/LAC plus, PLHIV should be examined by medical officer of LAC for the following parameters (WAAO) and information recorded in the ART enrolment register, patient treatment record (white card) and patient booklet (green booklet):
- **W**eight of the patient
- **A**dherence
- **A**dverse Effects of ARV drugs and **O**I, if any
- Drug refill to be done every month to PLHIV at LAC. Multi-month refills may also be done for stable PLHIV on ART.

Figure 11. Flow of "on ART" PLHIV at LAC/LAC plus



5.6.1.9 Referral of "on ART" patient from LAC/LAC plus to nodal ART centre: The referral back is termed as "Linked in" to nodal ART centre. Patients shall be referred back to nodal ART centre in the following conditions:

i. Routinely once every six months – for repeat VL testing, CD4 count and comprehensive clinical review, as per guidelines. The patient should be sent at least 1-2 week before due ARV refill date so that there is enough time for carrying out VL testing/CD4 count and other necessary investigations and the patient does not fall short of his drugs.

The referral slip should be given at 5th month itself and explained accordingly.

ii. Referral before six months

- If TB or any major OI is diagnosed/suspected
- If there are any major adverse effects of ARV drugs
- Pregnancy (if required)
- Unstable/unsuppressed PLHIV who have completed step up counselling and have 95% adherence for 3 consecutive months
- For LAC outside the health facilities, PLHIV who are 4S positive or have any minor OI or adverse effects etc.

When the patient is referred back to nodal ART centre, he/ she should be given the following documents for follow up at nodal ART centre:

- Patient should be 'linked in' to nodal ART centre through IMS (no need to maintain link in forms). Prompt will go in IMS to ART centre whenever PLHIV is linked in.
- Original patient booklet (green book), with details of link in (address and contact details of ART centre)
- The following activities shall be done at nodal ART centre on a routine 6 monthly basis:
- Clinical review, 4S screening, VL testing and CD4 count (as per guidelines), other required investigations of the patient. Review/ modification of the drug regimen, if required.
- **Whenever the PLHIV visits the ART centre either for 6 monthly follow up or earlier, drug refill shall be done from ART centre** (for the month when patient is "linked in").
- **In case regimen is switched, patient may be relinked to LAC after 6 months of switch if s/he fulfils the criteria for stable PLHIV. PLHIV undergoing substitution may be linked as soon as they are considered stable.**

- Filling up of the ART copy of patient treatment record (white card) from the photocopy/ electronic copy of the Patient Treatment Record (white card) and Patient Booklet (green booklet).
- Refer back to LAC/LAC plus with next 3 months drugs to be transferred to LAC/LAC Plus through established mechanism of drug transport. In case patient is retained at nodal ART centre, due to any reason, the information of the same should be provided to the LAC/LAC plus immediately through IMS.

5.6.2 Standard operating procedure for ART initiation at LAC plus

5.6.2.1 Enrolment in HIV care and ART initiation at LAC plus:

- ICTC counsellor shall encourage all PLHIV detected at ICTC to get registered in HIV care at LAC plus. During post-test counselling at ICTC, the counsellor shall also do preparedness for treatment initiation and will facilitate their registration in HIV care at LAC/LAC plus.
- Any patient detected positive in the ICTC (within the Health facility/ICTC in periphery) shall be registered at the LAC plus in the HIV care register (same as used at ART centres) by giving serial number as LAC plus registration number.
- Staff nurse does the further preparedness counselling at LAC plus (refer to checklist at Annexure 1).
- Staff nurse shall document all the required information in the HIV care register, prepare patient treatment record (white card) and issue patient booklet (green booklet).
- LAC medical officer will examine the patient and do the detailed clinical screening as per algorithm (Figure 3 in Section 2).

- If PLHIV does not have any symptoms and signs and are found to be ready for ART initiation as per the algorithm, MO at LAC will initiate the ART and simultaneously request for the baseline investigations and CD4 count (as per guidelines).
- If the PLHIV has any signs/symptomatic as per the algorithm, s/he should be considered for appropriate diagnosis and management/expert consultation/referral to nodal ART centre (presumptive TB cases (4S+) shall be referred to NTEP for TB diagnosis). Depending upon the capacity including diagnostic facilities and drugs, the facility may provide treatment/in patient care as required. The PLHIV shall be referred to nodal centre for any other illness that cannot be managed adequately at LAC plus. Baseline investigations (other than CD4 testing which may not be available in the facility) should be done for these PLHIV so that their multiple visits to nodal ART centre for lab investigation may be avoided.
  - HIV care number shall be issued only by nodal ART centre telephonically and in IMS, after registering the PLHIV in HIV care register. One copy of white card (ART centre copy) shall be maintained by the nodal ART centre after issuing HIV care registration number for that patient. Patient tracing in case of MIS/LFU in preparedness phase shall also be done at LAC plus.

5.6.2.2 Baseline investigations

- Baseline investigations as per details in Section 3, shall be done through mechanism available under general health systems.
- Staff nurse shall refer patient for baseline investigations as recommended by MO.
- The blood sample for baseline CD4 testing for PLHIV registered at LAC plus shall be collected at LAC plus itself on a pre-fixed day and sent to nodal ART Centre.
- ICTC LT/staff nurse will draw the blood sample on same day (one prick sample collection for both basic investigations and baseline CD4 tests). Sample for CD4 test will be sent to nodal ART centre and other baseline investigations will be done within the health facility.

Baseline work up of all PLHIV for ART initiation and to rule out OI shall be done at LAC plus as per National Guidelines for HIV care and Treatment 2021. If the facilities are not available at LAC plus, the investigations may be done at nodal ART centre.

CD4 testing: Blood sample shall be collected at LAC plus once in a week (preferably in morning hours) on designated day which shall be decided after mutual consultation between LAC plus and the nodal ART centre. Sample transportation to nodal ART centre shall be done for baseline CD4 testing by lab technician of ICTC/ LAC plus as per CD4 sample transport guideline. For this, a sample of 5 ml blood need to be sent in an EDTA vacutainers (purple cap) using a sample transportation box. The lab technician shall be oriented on

proper sample collection and transport procedures. The CD4 reporting by the nodal ART centre shall be done preferably on the same day. Vacutainers are to be provided by nodal ART centre to their LAC plus. It shall be the responsibility of the MO in-charge of LAC plus to see that the CD4 report is handed over to the PLHIV with proper guidance and counselling. If the PLHIV is found to be eligible for ART, referral to the nodal ART centre must be ensured.

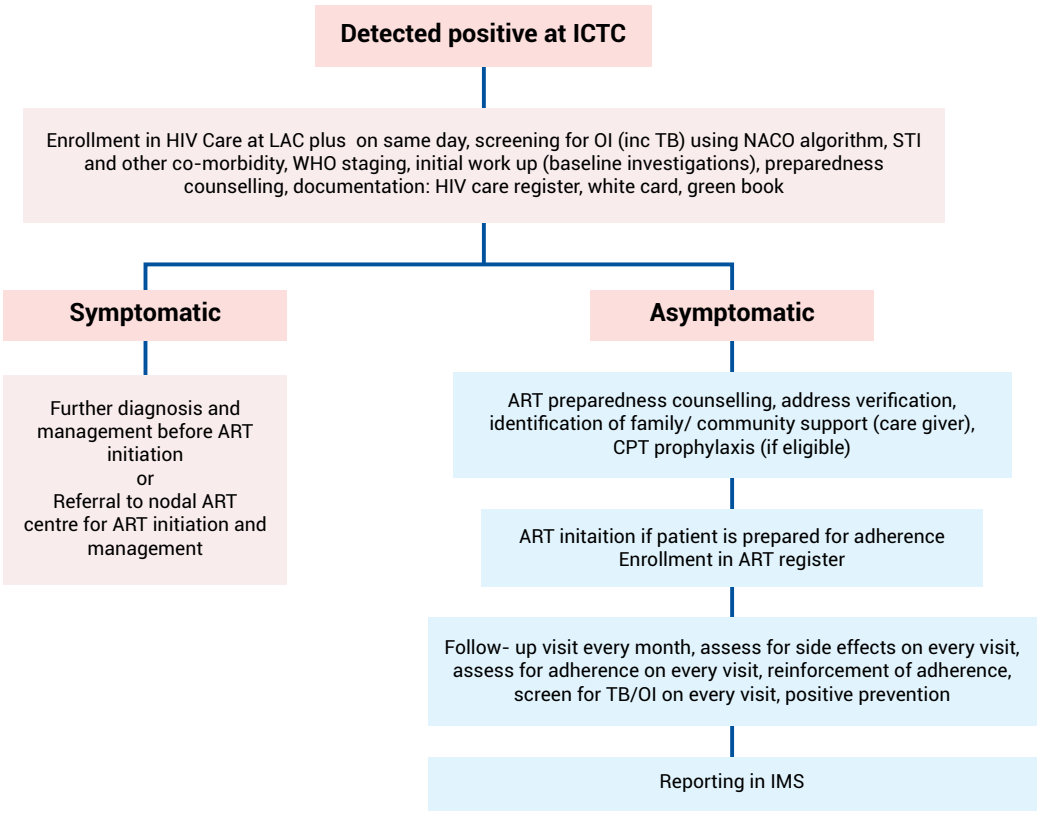
5.6.3 PLHIV who are initiated on ART at LAC Plus

- For PLHIV initiated at LAC plus, date of ART preparedness and the date of initiation will be recorded in the HIV care register and patient will be registered in ART enrolment register.
- When the baseline investigation reports are available, PLHIV whose reports are not normal should be called back to LAC Plus centre (as soon as possible, without waiting for one month to complete). If necessary, MO needs to make necessary adjustments in ART regimen for management of comorbidities (as per NACO guidelines).
- Information related to the registration and initiation of PLHIV in LAC shall be shared weekly with the nodal ART centre through IMS.
- Only the nodal ART Centre shall issue 'ART number' after enrolling the PLHIV in ART enrolment register. In case, ART is started by the LAC Plus, the information should be provided to the nodal ART Centre through email/telephonically/IMS and the on-ART number to be generated/shared by the ART centre based on such information on the same day of ART initiation.
- Patients initiated at LAC would be followed up on monthly basis at LAC and treatment/laboratory monitoring will be done as per NACO guidelines. The follow-up CD4 testing/VL testing for those on ART at LAC Plus, will be done at the nodal ART centre during regular 6 monthly visit. Feasibility of sample transportation from LAC plus may also be worked out.
- Patients would be referred (linked out) to nodal ART centre for the following reasons:
  - Presence of TB or any other OI, not manageable at LAC plus
  - CD4 and VL testing as per guidelines PLHIV
  - Management of treatment failure
  - Adverse events or complication
  - Patients with poor adherence and not manageable at LAC plus
  - The nodal ART centre should include all LAC plus patients (initiated on ART as well as 'on ART') as nodal centre patients for reporting in MPR

5.6.4 Referral of PLHIV to nodal ART centre for management and ART initiation

- PLHIV who cannot be initiated on ART at LAC plus shall be referred to nodal ART centre by adding details in IMS. In HIV care register under remarks column staff nurse will record the status as "referred to nodal ART centre".
- When the patient is referred to nodal ART centre for management/ART initiation, he/ she should be given the following documents for follow up at nodal ART centre:
  - Patient should be 'linked in' to nodal ART centre through IMS (no need to maintain link in forms). Prompt will go in IMS to ART centre whenever PLHIV is linked in.
  - Original patient booklet (green book), with reason for link in (along with address and contact details of ART centre)

Figure 12. Algorithm for registration and ART initiation at LAC plus



5.7 Recording and reporting tools for LAC/LAC plus:

Recording and reporting tools for LAC/LAC plus will be supplied by SACS.

5.7.1 Recording and reporting tools to be maintained at LAC:

- **ART enrolment register** (same as ART enrolment register of ART centre) To be filled by counsellor/staff nurse
- **Patient treatment record (white card):** To be updated during every visit
  - o Section 1 to 3 and 10: are to be completed by counsellor/staff nurse
  - o Section 4 to 13: are to be completed by LAC medical officer
- **Patient booklet (green booklet):** To be filled by staff nurse, counsellor and doctor during every visit
- **LAC drug stock register:** To be auto generated from IMS by pharmacist/Nurse.
- **LAC drug dispensing register:** To be auto generated from IMS by pharmacist/nurse.

White card is to be maintained at both centres, marked as LAC copy and ART centre copy.

5.7.2 Recording and reporting tools to be maintained at LAC plus

In addition to recording and reporting tools maintained by LAC, the following tools will be maintained for PLHIV registered in HIV care at LAC plus:

1. ***HIV care register*** for LAC plus (same as HIV care register of ART centre): To be filled by staff urse.
2. ***CD4 lab (sample transport) register:*** To be maintained by ICTC lab technician
3. ***HIV-TB register and line list:*** To be generated from IMS

5.7.3 IMS: IMS login shall be created for each LAC and LAC plus for entry of PLHIV details to monitor drug dispensation and to generate other reports. Nodal ART centre staff shall conduct an orientation for LAC staff on IMS and will assist in supportive supervision for the same. Regular drug dispensation/refilling entries shall be done by pharmacist, staff nurse or counsellor (depending on site of LAC e.g. LAC, TI NGO, CSC etc). Due to

unavoidable circumstances if IMS entry is not possible at LAC/LAC plus then form 4B for LAC and form 4C for LAC plus need to be continued as were used previously.

Data between nodal ART centre and LAC/LAC plus to be exchanged/ shared via IMS. Therefore, both nodal ART centre and LAC/LAC plus should ensure real-time entry in IMS whenever PLHIV visits them.

5.7.4 LAC monthly reports: Monthly progress report of LAC/LAC plus (Annexure 10) will be auto generated in IMS which will be accessible to nodal ART centre also. **LAC /LAC plus should download the MPR and maintain hard copy/ soft copy for their use.**

No LINK ART CENTRE/LAC PLUS report shall be sent to NACO unless specifically asked for.

5.8 Roles and Responsibilities of Staff at the LAC/LAC Plus

5.8.1 Responsibilities of LAC in-charge

- Overall responsibility for the smooth functioning of the Link ART centre.
- All administrative matters relating to the centre as per guidelines.
- Ensure adherence to the highest standards of quality.
- Ensure that PLHIV are not discriminated in the hospital.
- Train and involve other medical officers from the health facility.
- Review and monitor the functioning of the LAC every week and ensure submission of reports as required.
- Ensure timely receipt of drugs from the nodal ART centre by coordinating with Nodal Officer/SMO of the nodal ART centre.
- Ensure all patients enrolled at LAC are being sent regularly for the 6-monthly follow-up examination and CD4/viral load testing as per guidelines at nodal ART centre
- Coordinate and develop referral system and linkages with nodal ART centre, NGOs, and positive network groups etc.
- Supervise the administrative and medical functions of the LAC on a day-to-day basis and provide leadership to the staff to work as a cohesive team and deliver the services effectively.
- Complete and/or supervise the recording of information in the various recording and reporting tools used by LAC, including entry of data in IMS and report sent on monthly basis
- Attend meetings at nodal ART centre/SACS as required from time to time. Coordinate with DAPCU officers.

Additional responsibilities under LAC plus:

- Ensure provision of HIV care, baseline investigations and CD4 testing of PLHIV enrolled at LAC plus
- ART Initiation
- Referral of PLHIV to nodal ART centre for ART initiation (if ART initiation is not feasible at LAC plus)/ treatment of OI (if required)

5.8.2 Medical Officer (including LAC I/C)

- Prescription of ARV/OI drugs
- Monitor the patients enrolled at LAC/LAC plus for ART/Pre-ART care
- Ensure for the 6-monthly follow up of all PLHIV enrolled at LAC/LAC Plus at odal ART centre for clinical evaluation, CD4/viral load testing
- Monitor the patients on ART and identify the symptoms suggestive of OI, adverse effects of ART / OI medication, pregnancy and ANC care etc
- Inform the SMO of the nodal ART centre whenever the patient is referred to the nodal ART centre by email and telephone/post and also if the patient does not return on the due date after being referred to nodal ART centre for six monthly evaluation/for management of OIs and adverse effects of drugs
- Supervise the staff at the centre; ensure that record keeping, and reporting are carried out properly and on time and see that all the guidelines for running and maintaining the Link ART centre are abided by
- To facilitate linkages between other service providers

- Refer the cases to the nodal ART centre for further expert opinion/intervention including admission and inpatient care, if required
- Ensure drug adherence and counsel the patient towards safe sex, condom usage, proper nutrition and positive living
- Monitor the consumption and availability of ARVs, other medicines and to alert the nodal ART centre in case of impending shortage well in advance to enable adequate replenishment without disruption of ART care and support to PLHIV

Additional responsibilities under LAC plus Scheme

- Get the basic investigations and CD4 testing done
- Examine the patient and do the detailed clinical screening as per algorithm (Figure 3 in Section 2)
- Initiate the ART and simultaneously request for the baseline investigations and CD4 count
- Consider appropriate diagnosis and management /expert consultation/referral to nodal ART centre for PLHIV with any signs/symptomatic.
- Ensure completion of entries in IMS

5.8.3 Nurse

The facility should depute a nurse to assist the doctor and the counsellor. Computer literate nurses should be given preference for deputation to the LAC.

- Assist LAC In-charge in administrative and clinical work
- Maintain all recording and reporting tools as per guidelines
- Preparation of Monthly report under supervision of medical officer
- Communication with nodal ART centre on link in and link outpatients
- Patient counselling on treatment, adherence, positive prevention and nutrition
- 4 symptom screening for TB
- Drug dispensing in absence of pharmacist

Additional responsibilities under LAC plus (one dedicated staff nurse will be posted under NACP at LAC plus)

- Registration of PLHIV in HIV care and ensure their baseline investigation
- Ensure ART initiation or appropriate referral
- Blood sample collection and transportation in absence of lab technician
- Activities pertaining to prevention and mangement HIV TB coinfection, including maintenance of HIV-TB tools
- Data management and reporting

5.8.4 Counsellor

The ICTC counsellor shall bear the responsibility of ART counselling of PLHIV on ART at LAC/LAC plus. S/he also should be computer literate with working knowledge of MS Word, MS Excel and usage of internet and electronic mail (e-mail). The counsellor plays a very important role as a member of the team and his/her responsibilities are crucial for the success of the programme and improved outcomes of the patients. The counsellor deals with the following:

- Address issues related to ARV treatment and adverse effects.
- Adherence counselling and monitoring, identification of barriers to adherence and suggestions (remedies) to remove these barriers.
- Provide emotional, social, and psychological support to patients and/or direct the patient to the concerned person or organization
- Repeatedly stress on positive living, and positive prevention
- Address issues of stigma and discrimination and rights of PLHIV
- Patient tracing of MIS/ LFU cases

- Maintain LAC tools and computerization of patient data as per guidelines

Additional responsibilities under LAC plus

- Preparedness counselling and treatment education
- 4S screening of patients before ART initiation
- Patient tracing in case of MIS/LFU in preparedness phase
- Record keeping as per guideline

5.8.5 Pharmacist: The existing pharmacist of health facility shall be in charge of drug storage, refill and drug record keeping. Computer literate staff should be preferred. The pharmacist/nurse (as per the availability) should perform the following tasks:

- ARV drug refill
- Maintain the drug stock register and drug dispensing register
- Ensure that the centre has stock of ARV drugs for each patient, which shall last till the next visit of the patients
- Inform the LAC in-charge if there is a problem with the drug stock (e.g. expiry, delay in release of drugs from nodal ART centre, improper package/damage) of the patients
- Advise the patients and family about importance of adherence during each visit
- Advise the patients on possible drug adverse effects and reporting of the same

It shall be preferred that pharmacist carries out these activities. In case the pharmacist is not available, the health facility/hospital should depute a nurse to carry out these duties.

5.8.6 Lab technician: The existing lab technician in the ICTC/health facility shall be involved.

- Sample collection for CD4 testing. If required, blood sample collection for baseline investigation shall also be done and sent to main testing lab at health facility
- Sample transport to CD4 lab facility in the ART centre shall be the responsibility of ICTC lab technician, in case of ICTC LT is not available due to any unavoidable reason, the alternative arrangement for the blood sample collection and transportation is to be done by the LAC in-charge
- Maintain CD4 record

For LAC in community setting, appropriate staff should be identified to carry out the relevant roles and responsibilities described above (particularly under counsellor, nurse and pharmacist)

5.9 Capacity Building of LAC/LAC plus

5.9.1 Trainings for LAC/LAC plus

The following trainings shall be conducted for staff of Link ART Centres

Table 9. Capacity building at LAC/LAC plus

Training	Responsibility	Venue	Duration	Participants	Training Curriculum
LAC medical officer	NACO/SACS	CoE/NACO designated training centres	2 days	LAC in charge and LAC medical officers	As per approved curriculum
LAC counsellors training	NACO/SACS	NACO designated training centres for counsellor training	3-5 days	LAC (ICTC) counsellor	As per approved curriculum
Hands on orientation of LAC team*	SACS nodal ART centre	Nodal ART centre	2 days	LAC in charge, LAC MO. counsellor, nurse, lab technician, pharmacist,	Annexure 11

5.9.2 Additional trainings for LAC plus

Table 10. Additional trainings for LAC plus

Training	Responsibility	Venue	Duration	Participants	Training Curriculum
LAC plus nurse	NACO/SACS	NACO designated training centres for nurses training	5 days	LAC Nurse	As per approved curriculum
Hands on orientation of LAC plus team*	SACS/nodal ART centre	Nodal ART centre	2-5 days	LAC in charge, LAC MO. counsellor, nurse, lab technician, pharmacist,	Annexure 11

**First hands on orientation of LAC team shall be done at nodal ART centre and coordinated by SAC/DAPCU; however, rest of the training programmes can be facilitated by SACS officials/nodal ART centre officials.*

Overall responsibility of coordinating all trainings for LAC staff shall lie with concerned SACS. LAC MO training shall be facilitated by NACO. If the staff at a functioning LAC is replaced/transferred; s/he should be trained during the training programmes organized for new LACs.

5.10 Role of Health Facility, SACS, DAPCU and Nodal ART Centre

5.10.1 Role of health facility: LAC/LAC plus are being established at existing health facilities with the aim of convergence of HIV care with general health systems as integral part of the health care facilities. The health facilities should take ownership of the Link ART centres. The health care staff at these sites should be directed to be fully involved in the functioning of LAC/LAC plus. The health facility should facilitate the availability of investigations required for baseline workup of the patients to initiate ART and to monitor patients on ART where LAC/LAC plus centres are located. The health facility should facilitate the availability of the drugs for prophylaxis and treatment of OIs at LAC/LAC plus. Also, these drugs for OIs particularly Cotrimoxazole should be given for a longer duration as per requirement to minimise unnecessary travel needs for patients as ARV drugs are given for a month. The LAC in-charge should participate in the meetings conducted at district level by CMO/DHO to review the functioning of health care facilities and issues related to HIV care should also be discussed during such meetings.

5.10.2 Role of SACS: SACS shall be responsible for liasoning with health systems/NHM for better functioning of LAC. CST officials at SACS will also be responsible facilitate trainings of the staff at LAC as per guidelines. SACS is supposed to provide supportive supervision to LAC and LAC plus (Annexure 12). SACS is also supposed to look into the coordination issues between nodal ART centres and LAC/LAC Plus.

5.10.3 Role of DAPCU: In the districts where DAPCU exists, DAPCU should support for feasibility assessment, setting up of LAC/LAC plus, coordination between stakeholders, training of LAC/LAC staff. DAPCU should provide supportive supervision to LAC/LAC plus. LAC/LAC plus functioning should be part of the District AIDS Prevention Control Committee meetings which are headed by District collector. DAPCU should also facilitate coordination and linkages of LAC with health systems (NHM) as well as NACP components in the districts. The outreach activity for LAC/LAC plus should also be coordinated by DAPCU. In the districts where DAPCU do not exist, District Nodal Officer for HIV/AIDS should facilitate the functioning of LAC.

5.10.4 Role of nodal ART centre: The patients linked out at LAC/LAC plus will continue to be the patients of Nodal ART centre. Mentoring and Monitoring of LAC is the responsibility of Nodal ART centre. LAC staff shall be provided hands on training before operationalization of LAC at Nodal ART centre.

Further follow up, reinforcement of training mentoring and monitoring is to be done by nodal ART centre. There should be smooth coordination and regular communication between nodal ART centre and LAC/LAC

plus. Nodal ART centres should guide the LAC in technical and operational issues. The staff of nodal centre is expected to make periodic visits to LACs to facilitate and supervise the functioning of LAC/LAC plus.

5.11 Financial Guidelines for LAC in Health Facility

5.11.1 Financial assistance: The funds provided to the LAC are as below:

Table 11. Financial assistance for LAC/LAC plus

a) One-time grant for furnishing of centre	**Rs. 15,000/-**
b) Recurring grant: 1. Internet connection @ Rs. 650/- p.m. x 12 2. Cost of stationery, records and contingency (including phone) 3. Cost of travel and drug transfer 4. Remuneration of nurse (For LAC plus only)	 Rs. 7,800/- p.a. Rs. 10,000/- p.a. Rs. 20,000/- p.a. Rs. 96,000/- p.a.
Total recurring grant: **Link ART centre (LAC) LAC plus*** ***LAC plus get additional support for staff nurse.**	 **Rs. 37,800/ p.a.**

Cost of training of staff shall be borne from GIA to SACS for training

The Link ART centre shall utilize the computers facility already available with the site. The LAC shall get a broad band internet and phone connection from the funds provided as per the LAC approved financial support.

LAC at community sites shall not have any additional financial implications to NACO/SACS and can be set up based on needs of PLHIV even outside the AAP after approval of NACO/SACS.

Bank account for LAC: A separate bank account shall be opened by LAC for maintenance of fund. The two signatories of the account shall be the Medical Superintendent/administrative head of health facility and LAC in-charge.

CHAPTER 6

PROVISION OF SECOND LINE AND THIRD LINE ART

Patients with suspected ARV treatment failure, severe adverse effects and complicated clinical cases are referred for review by a panel of experts called State AIDS Clinical Expert Panel (SACEP) at Centre of Excellence /ART plus centres for further evaluation and timely switch/substitution to appropriate ART.

6.1 State AIDS Clinical Expert Panel (SACEP)

6.1.1 Constitution of SACEP

SACEP at Centre of Excellence (CoE): The Programme Director of the CoE shall propose a group of experts/ faculty from the institution faculty and share the list of these experts with SACS and NACO annually, or earlier if required.

1 Programme Director of CoE and /or Deputy Programme Director

2 Nodal Officer of the ART centre

3 One/two additional faculty preferably from the department of medicine or allied department

4 External ART expert (if necessary, from other government or private institution)

5 Regional Coordinator/Technical Expert CST/Joint Director (CST)/Consultant (CST) at SACS

6 One paediatrician from the institution shall attend if there are children among the list of referrals

The SMO and MO from ART centre of the CoE should attend SACEP meeting by rotation. SACEP coordinator, research officer (clinical and non-clinical), nutritionist and the data analyst should also attend SACEP meeting at CoE.

SACEP at ART plus centre: The Nodal Officer of the ART plus centre shall propose a group of experts/faculty from the Institution and share the list of experts with SACS and NACO annually.

The SACEP at ART plus centre consists of

1. Nodal Officer of the ART plus centre
2. One/two additional faculty preferably from the department of medicine or allied departments
3. External ART expert (if necessary, from other government or private institution)
4. Designated representative from SACS/DAPCU/Regional Coordinator/TE CST
5. One paediatrician from the institution shall attend if there are children among the list of referrals.

The SMO and MO from ART centre should attend SACEP meeting by rotation. Counsellors on rotation will take the role of SACEP Coordinator. Staff Nurse and the Data Manager should also attend SACEP meeting.

6.1.2 SACEP schedule: SACEP meets weekly at the Centre of Excellence (CoE) or paediatric CoE (pCoE) or ART plus centre to review all cases referred in that week and backlog if any

- It meets on next working day in case the designated SACEP day happens to be a holiday
- In case of high backlog, SACEP may meet more than once in a week

6.1.3 Functions of SACEP

- Review and decide on eligibility for switch to appropriate ART regimen all cases referred by the attached ART centres. Prescribe ART regimen, if the switch is decided.

- Review and decide on substitution to appropriate alternative ART if necessary, to all cases referred by the attached ART centres. Prescribe ART regimen, if the substitution is decided.
- This is to ensure that there is no delay in review /and processing of referred cases.
- Mentoring referring ART centres and ensuring high quality case management of PLHIV by providing necessary guidance.
- Ensure correct and complete documentation, registration and monitoring progress of all patients referred for SACEP review.
- Identify operational issues of the attached ART centres and give appropriate feedback to the referring ART centres (responsibility will primarily be on the Regional Coordinator/Technical Expert CST, other CST officials of SACS and DAPCU (in case of ART plus centres).
- Share the result over email and phone within one week of receiving e-referral from ART centre.
- SACEP should refer to National Guidelines for HIV care and Treatment 2021 and/or office memoranda to decide the regimen for switch and/or substitution.

6.1.4 Jurisdiction of CoE/ART plus centre

SACS should develop a linkage plan for all ART centres in the state by mapping the functional SACEPs at CoE and ART plus centres. SACS should make linkage plan by carefully looking at patient's convenience to travel to SACEP centre if required and should try to equally distribute the caseload on all SACEPs of the state. In case SACEP in not able to handle the increasing caseload, new ART plus centres should be proposed by SACS to NACO. **Each CoE or ART plus centre will have defined ART centres attached to it and patients from these centres only shall be reviewed by the designated CoE or ART plus centre.**

6.2 SOPs for SACEP Review

6.2.1 Mechanism for referral and review of PLHIV by SACEP

E-referral to SACEP : Patient treatment details (ART history, viral load test results, latest and serial CD4 test results, treatment adherence details, other relevant clinical details in RRF form-Referral and Reply) are shared by the referring ART centre to the CoE or ART Plus centre. The SACEP review would be conducted in absence of the patient. Recommendation of the SACEP should be shared with the referring ART centre over an email.

Note: *In certain situations, SACEP may want to review the PLHIV in person. Patients visit the centres on the designated SACEP days for the clinical consultation. Preferably, in person review should be done for PLHIV belonging to the same COE/ART plus where SACEP is being conducted.*

Tele SACEP : After following the e-referral procedures described above, ART centre and the ART plus/CoE would be virtually connected over video/ tele conferencing. ART centre presents the cases to the SACEP in presence/absence of the patients and SACEP gives recommendations for further course of action. This helps in reducing turnaround time for SACEP review and need for multiple communications between ART centres and SACEP, while providing opportunity for mentoring and capacity building of referring ART centres through immediate feedback on patient care by SACEP. Patients requiring in-person consultation can also be reviewed through tele-SACEP avoiding the need for travel. Considering the benefits, all CoE and ART plus centres are encouraged to conduct tele-SACEP.

6.2.2 When should a patient be referred to SACEP?

- Patients with suspected ARV treatment failure (as per the definition below)
- Patients with suspected moderate to severe ARV adverse effects to decide for substitution of one/ more ART drugs of different class
- SACEP referrals shall also cover PLHIV with drug related complications or management of severe OIs, that cannot be managed at ART centres
- Patients from private sector on a regimen other than preferred regimen under NACP can be referred to SACEP after enrolment under care at the ART centre, for opinion about most suitable regimen under the programme for them

- **Decision for initiation of third line ART shall be taken by the SACEP at CoE or select ART plus centres after e-review. SACS in consultation with CoE and after approval from NACO may authorise SACEP of select ART plus centres (based on their functioning/capacity) to prescribe third line ART**

Note: *After the SACEP has reviewed the patient and prescribed 3rd line ART, initiation and follow up dispensations would be done by parent ART centres (as done for second line ART). Henceforth transfer out for initiation of third line ART is not required.*

Determining ARV treatment failure

Table 12. Interpretation of viral load test results

Viral load test result	Interpretation	Action	Advise next viral load test
< 1000 copies/ml or TND	Virally suppressed	Continue same ART regimen	As per guidelines
≥ 1000 copies/ml	Virally unsuppressed	Enhanced adherence counselling for three months*	Repeat viral load test when treatment adherence is more than 95% for three consecutive months. - If VL <1000 copies/ml or TND, then continue same ART regimen - If VL ≥1000 copies/ml, then refer to SACEP

**In exceptional cases of PLHIV with high viral load and poor clinical conditions, ART MO may refer the patient to SACEP for further management even on the basis of a single viral load report.*

***In patients with HIV 2, decision of ART failure is taken based on immunological failure criteria*

6.2.3 Steps for referral to SACEP : Steps for referral to SACEP are described in table below.

Table 13. Steps for referral to SACEP

Step 1	For PLHIV requiring referral to SACEP, ART centre shall share details of patient with CoE/ART plus centre by filling up the Request and Reply Format (RRF) for e-referral to SACEP. The details in referral to include: • Complete ART history • WHO clinical stage • Treatment adherence details (at least last 6 months) • Serial CD4 counts • Serial viral load test results • Latest investigation results, as indicated (CBC, biochemical parameters etc.) • Other treatment details of the patient • Photo of visible signs of ARV adverse effects/clinical conditions in PLHIV (if available for review) • Other clinical records (e.g. discharge summary, or any other relevant hospital records)
Step 2	SACEP coordinator of CoE/data manager at ART plus centre shall download the patient information and prepare SACEP meeting format for review during the SACEP meeting. *In case tele- consultation is conducted, referring ART centre should be informed in advance about the date of SACEP to call the patient.*
Step 3	SACEP will review the documents (in absence of the patient) and make recommendations in the SACEP meeting format
Step 4	SACEP coordinator of CoE/data manager (at ART plus centres) shall share the recommendation of the SACEP with the referring ART centre in RRF
Step 5	Referring ART centre should confirm the action taken to SACEP by filling up RRF

6.3 National AIDS Clinical Expert Panel (NACEP)

National AIDS Clinical Expert Panel (NACEP) is a mechanism to respond to the queries raised by SACEP of CoE and ART plus centres. The functioning of NACEP is coordinated by NACO. This panel has representatives from ART Technical Resource Group (TRG) of NACO, institutions or independent experts deemed most appropriate for the query under consideration. Hence, the composition of the NACEP is dynamic and its composition will vary depending on the type of technical query. This is to ensure that most appropriate response and guidance is provided for the query by the variety of experts and expertise on various areas under treatment and care for HIV. Most of NACEP work is done through e-consultations.

6.4 SACEP Recording and Reporting

Table 14. SACEP referral, recording and reporting tools

	Tool	Description	Instructions
1	SACEP Referral and Reply Form (RRF)	Referral format to be auto generated and filled in IMS (to be used for referring patients for SACEP review) (Annexure 13)	To be generated in the IMS at ART centre when referring the patient by ensuring all appropriate details needed for SACEP review are updated The reply portion to be sent back to referring centre by SACEP after the evaluation of the patient (in IMS only). The referring ART centre will then inform to the CoE/pCoE/ART plus centre on the action taken on the SACEP's recommendations Hard copy of complete form to be maintained with white card at referring ART centres.
2	Referral summary line list (revised)	Referral Summary (second line/ third line) List of patients referred to SACEP for review during the FY along with recommendations of SACEP and action taken by referring ART centre (Annexure 5)	To be maintained at all ART centres in one continuous excel sheet (soft copy only). This may be generated automatically from IMS
3	SACEP register (revised)	List of all patients referred to SACEP for review along with recommendations of SACEP and action taken by referring ART centre (Annexure 5)	To be maintained at all SACEP of ART plus/ CoE/pCoE ART centres. This may be generated automatically from IMS (soft copy only)
4	SACEP meeting format	SACEP Meeting format (second line) This format should be prepared before every SACEP meeting for all patients (children and adults) to be reviewed in that particular meeting for suspected treatment failure	To be prepared from SACEP register in IMS before every SACEP meeting, given to all members during the meeting and maintained at all centres (in file ring binder and soft copy) Recommendation to be entered back in IMS

Note: *Print out of soft copies to be kept at CoE/pCoE/ART plus centres in separate ring binder files year-wise.*

CHAPTER 7

ART SERVICES FOR SPECIAL POPULATIONS

7.1 Key Populations

In the context of the concentrated HIV epidemic in India, the key population (KP) are disproportionately affected by HIV. KPs include Female Sex Workers (FSW), Men who have Sex with Men (MSM), Transgender/ Hijra (TG/H) and People Who Inject Drugs (PWID). It is essential to focus on client-centred prevention-to-care continuum needs of the KP in order to increase access to services in a stigma-free environment, improve the quality of life and to attain epidemic control. For KP PLHIV who belong to the KP groups (KP PLHIV), the NACP is committed to provide quality services at the ART centres in stigma and discrimination free environment and to prevent lost-to-follow-up.

This chapter describes the areas that need special attention for provision of care to KP PLHIV, in addition to the routine services offered to the PLHIV.

7.1.1 Differentiated care for KP PLHIV for retention in care:

Key populations (KPs) are disproportionately affected by HIV and often have low access to treatment services. Differentiated approaches are critical to enhance access to treatment and retention for KP PLHIV, who are often stigmatized. By catering to the specific needs of each KP individual, differentiated approaches would increase service acceptability, coverage, quality of care and retention in PLHIV, thus improving quality of life of KP PLHIV as well as prevention of transmission.

7.1.1.1 Linkage of KP PLHIV with ART:

In line with the NACO strategy document on 'Revamped and Revised Elements of Targeted Intervention for HIV Prevention and Care Continuum among Core Population' (http://naco.gov.in/) peer navigation should be encouraged for all the KP PLHIV from TI NGOs/other facilities to ART centre.

7.1.1.2 Referral of newly diagnosed KP PLHIV from ICTC/TI/non-TI NGO to ART centre:

The KP who is diagnosed HIV positive may be referred directly from ICTC or through TI NGO or other partner NGO (non-TI) ensuring proper referral slip. Accompanied referral is preferred to minimize the linkage loss to ART centre.

7.1.1.3 Registration at ART centre:

The ART counsellor needs to build rapport with KP PLHIV and may leverage the support of NGO outreach worker/peer educator during the initial phase of counselling. The counselling and elicitation of information to fill the ART registers/white card should be conducted in a room with audio-visual privacy, ensuring confidentiality for registration of new clients. The following steps shall be ensured by the counsellor:

- Collect the correct address and phone number and an alternate phone number of care giver/relatives etc. of all the KP PLHIV, recognizing that clients may not wish to give current address. Ensure an address is there for someone whom the KP PLHIV trusts
- Collect the details/contact information of the caregiver
- All contact details of the TI/NGO from where the KP PLHIV was referred should be taken for future follow-ups (the phone number of the ORW/PE of the TI-NGO partner, in particular) and documented in white card
- Written consent must be taken after proper explanation to the client before initiating ART, as is done for other PLHIV.

7.1.1.4 ART initiation:

Timely initiation of ART should be done in all KP PLHIV as per the details given in Section 2 and in accordance with National Guidelines for HIV care and Treatment 2021, along with OI drugs/cotrimoxazole/TPT as relevant. Rapid/same day ART may be offered if there are no contraindications. Please refer to Section 2 for more details.

- Rapid ART initiation should be offered to KP PLHIV after preparedness counselling and readiness assessment if there is no clinical contraindication (in line with the existing guidelines, after screening of OI/TB). Individualized adherence support should be provided.
- Counsellor at the TI-NGO (who is trained on ART/adherence counselling/preparedness counselling) may provide preparedness and adherence counselling, to fast-track ART initiation.

7.1.1.5 Treatment retention, prevention and tracking of lost to follow-up of KP PLHIV:

- ART staff should be sensitive to the needs of KP PLHIV and provide services customized to the needs of the respective typology of the KP PLHIV. Since KP may have overlapping risk, it also may be important to ensure that counsellors and staff are giving generalized messages as well.
- KP PLHIV should be counselled on the need for adherence, regular follow up and continuing to access prevention services.
- The ART centre counsellors should spend uninterrupted and quality time with the KP PLHIV to identify life challenges which may impact the adherence and arrive at individualized solutions in consultation with the patient. In addition to the general adherence barriers to retention faced by the PLHIV, the KP PLHIV face additional barriers that relate to their profession, socio-economic and cultural context. The KP PLHIV may require regular support and monitoring of adherence.
- KP PLHIV should be counselled on positive living, measures to prevent further transmission of infection using U=U messages, harm reduction services, opioid substitution therapy (OST) services and on importance of regular medical check-ups.
- KP PLHIV should also be counselled on importance of their partner/spouse/children testing for HIV and mobilized.
- On each visit, contact details of the patient and the treatment supporters should be updated, and record the same in white card/ART records.
- TI-NGO ORW may provide need-based accompanied referral (to prevent linkage loss/ on ART LFU)
- The TI-NGO should also support ART centre in adherence counselling/ step-up counselling of KP PLHIV and referral to SACEP. Please refer to Section 6 for more details.
- The differentiated care models such as multi-month dispensation, linkage to community-based ART dispensation (such as LAC co-located with TI or OST centre, CSC, Community-led ART Refill Groups (CARG), should be optimally considered for KP PLHIV. Please refer to Section 4 for more details.
- Wherever feasible, LAC may be established in community-based settings for the linkage of the KP PLHIV. In consultation with TI /NGO partners, flexi-timing may be followed at these sites. Please refer to Section 5 for detailed SOPs.

7.1.1.6 Tracking the lost to follow up (LFU) KP-PLHIV: Data manager shall share the list of all KPs who are "MIS", "LFU" or "Eligible but not initiated" with the ART counsellors. The ART Counsellor shall telephonically reach out to patients in this list and record the outcomes of the phone call. If the KP PLHIV could not be reached over phone, the list will be shared with the CSC/TI NGO/LWS outreach staff for further follow up either through phone or physical outreach. Sharing of list must be done on a weekly basis electronically. The CSC/TI-NGO shall give a feedback after making efforts to reach out to the clients. These feedbacks should be discussed during the monthly DAPCU meetings.

7.1.2 Collaboration between stakeholders

a. In coordination with ART centre, the ORWs of CSC/TI/NGO partners/OST/ other stakeholders should track the LFU KP PLHIV and link them to ART; support in ART adherence, retention and mobilization of all eligible KP PLHIV for viral load testing.

b. During the DAPCU monthly meetings, which involves ART centres and other stakeholders (TI NGO, NGO partners of non-TI interventions, CSCs, OST centre, ICTC, NTEP and other key partners), to discuss, monitor and take actions on linkage of all KP PLHIV to ART centre (including those newly detected during

the reporting period), monthly ART registrations, tracking of MIS and LFU cases, mobilization for VL testing and SACEP referrals etc.

7.1.3 Facilitators for the delivery of KP-friendly services at the ART centres

a. **Sensitization of TI-NGOs** on the ART initiation, treatment adherence, retention, LFU tracking and viral load testing processes. The NGOs shall provide need-based accompanied referral of KP PLHIV to ART centre e.g. on registration of a KP PLHIV at ART centre and a KP PLHIV tracked after becoming LFU. ART centre staff (MO or counsellor) can take sessions in monthly meetings of TI NGOs for sensitization of KPs and the staffs of the TI/NGO partner which may be coordinated by DAPCU.

b. **Sensitization of all ART centre staff** on topics like – gender, sexuality, types of KP, special counselling skills for KP, identification of KP, disclosure etc. Virtual platforms and other modalities of training/orientation can be used to hold sessions on these topics for all ART centre staff

c. **IEC material** specific to issues of KPs should be displayed in the ART centre. Contact details (directory) of organizations /support systems, relevant to the KP, need to be available at the ART centre counsellor, which may also be displayed in the ART premises.

d. **Prevention services:** The counsellor shall reinforce comprehensive prevention strategies and prevention education /counselling delivered by the TI/NGOs, including condom promotion, condom demo and distribution (condom box at appropriate places in the ART/hospital premise) and safe injection practices

7.1.4 Metrics: As per the Revamped TI strategy guidelines, the following indicators are to be reported by the TI NGOs to NACO/SACS on monthly basis, and hence the ART centre should facilitate and provide relevant information to the TI NGOs for reporting, in coordination with DAPCU.

- Number of KP PLHIV navigated to ART centre out of total positive cases registered at TI/partner NGO (non-TI cases)
- Number of KP PLHIV initiated on ART
- Number of KP PLHIV retained on ART (after 12 and 24 months of ART)
- Number of eligible KP PLHIV on ART navigated for VL testing
- Number of navigated eligible KP PLHIV tested for VL

7.2. Vulnerable Populations

7.2.1 PLHIV in prisons and other closed settings

ART initiation for the newly detected cases as well as ART refill for PLHIV in prisons is challenging due to various operational issues, including limited availability of security personnel and vehicles at the prison to take PLHIV to ART centres. To address this gap in HIV care for PLHIV in prisons, National AIDS Control Programme (NACP) recommends setting up of Link ART centres (LAC) in prisons (refer to Section 5)

Steps to be taken to provide services to these patients are detailed below. *These are applicable for undertrials as well, as it is difficult to determine the exact duration of his/her stay in the prison. The objective is to ensure the provision of ART to the undertrials as well as convicts regardless of the term they serve in the prison*

7.2.1.1 Not on ART

a. MO of the prison hospital/ designated MO for the prison should be trained for ART initiation using rapid ART algorithm and concurrent sample collection for baseline investigations

b. In case, the above is not possible SACS may work with prison authorities for intervention to ensure ART initiation in PLHIV in prisons

7.2.1.2 Already on ART

a. Efforts should be made to have LAC at prisons and other closed settings, wherever feasible. Prison staff should be trained on SOPs for LAC. The patient shall be managed at the prison clinic/LAC as per the operational guidelines for Link ART centres.

b. If the patient is registered in any ART centre other than the nodal ART centre of the prison LAC, the patient will be transferred from his/her parent ART centre to the nodal ART centre and, in turn, transferred out to the prison LAC.

c. In case setting up of LAC is not feasible, ART refill group comprising all positive persons may be formed and an authorized staff (such as prison staff/ICTC staff/CSC staff) may collect ARV drugs for PLHIV and provide them to patients at prison. Refer to SOP for community ART refill groups (CARG) in Section 4.4.3.3.

d. Prison inmates should be prioritized for MMD, if fulfilling the criteria.

6-monthly follow-up: If there is no MO available at the prison, every patient will be sent to the nodal ART centre once in 6 months for clinical and laboratory monitoring and before 6 months in case of any other medical need.

Post-release linkage plan

ART centre should work with prison staff on post release plan for all PLHIV in prison-date of release, probable destination after release from prison with contact details. Accordingly, PLHIV at the prison should be guided to reach nearest the ART centre after release from prison.

Upon completion of the patient's term in prison, the nodal ART centre should be intimated, and the patient should be transferred out to an ART centre preferred by the patient. The prison staff has the responsibility to ensure that the patient is successfully transferred out and reached the ART centre where s/he was referred to.

7.2.2 Migrants and mobile population

'Migration' is the spatial mobility of people from one geographical area (place of origin / source) to another (place of destination), with the intention of settling temporarily or permanently or semi-permanently. Migrants are a critical group because of their 'mobility'. Unlike the general population, there are challenges in accessing healthcare services and quality HIV prevention, care and treatment services for migrant population.

At the ART centres, the following steps should be taken to ensure that migrants and mobile popultions (including truckers) are provided with continuous and quality care, support and treatment services:

a. Identification of PLHIV with potential for migration (at the time of registration and follow up): Experience from the ground has shown that assessment has helped to target migrants. During the first visit to the ART centre, the counsellor must try and identify the PLHIV with potential for migration.

b. Documentation of complete contact details: In addition to current contact details, address and phone number of the permanent residence/source/destination site must be taken for all clients. This will help track the client even if he/she chooses to migrate to a new location in future. Details of the caregiver must also be noted accurately.

c. Focussed counselling: The PLHIV identified above must undergo a focused counselling, where the counsellor shall

- provide details about the options of multi month dispensation and transfer-out mechanism which the client may use if s/he intends to move from the current location.
- Emphasise that s/he should inform the ART centre where they plan to travel so that mmd / transfer out may be done
- Inform that in case s/he goes randomly, s/he client may go to the nearest ART centre with the green book and get "transferred-in" and can continue to get his ART medication.

d. Follow up visits: During follow up visits, counsellor must actively enquire about the travel plans of such PLHIV. If necessary, mmd or transfer out can be done.

e. Weekly telephonic follow-up: For migrants who chose to get transferred-out, the counsellor must take a weekly telephonic follow-up to track the client till s/he reaches the destination ART centre.

f. In case a PLHIV, registered at one ART centre, reaches another ART centre for ART refill while travelling or during some restrictive situation, s/he shall be provided ART refill as a stop gap/ temporary arrangement to continue ART and patient would be labelled as **"in transit"** by the ART centre dispensing ARV drugs.

7.3 Management of HIV Positive Pregnant Women

India accounts for about 29.7 million pregnancies annually. Antenatal clinic check-up (ANC) is one of the first steps in ensuring good health of the mother and child and necessary steps are being taken by the Government

to increase ANC service utilization and institutional delivery. Interventions to improve the screening and treatment coverage of pregnant women for both HIV and syphilis could reduce incidence of stillbirth and perinatal deaths, thereby facilitating advancement to the SDG goal. To reach the targets of MTCT elimination for HIV and Syphilis, an accelerated response with focused tracking and uptake of Syphilis and HIV related services are required at both State/UTs and district level. Addressing gaps in programming, linkage and implementation is the main key for elimination of mother to child transmission.

7.3.1 Guidance regarding management of HIV positive pregnant women

It should be ensured that all positive pregnant women should get life long ART, irrespective of CD4 count or clinical stage (in line with the 'Treat All' policy).

Therefore, all pregnant women found to be HIV positive at ICTC should be immediately referred to the nearest ART centre/LAC plus centre for registration and ART initiation. This will also allow for clinical staging, detection and management of opportunistic infections. **ICTC counsellors should give highest priority to this and counsel, motivate all HIV positive pregnant women to register at the nearest ART centre in the interest of their own and their baby's health.** It is to be ensured that the pregnant women are initiated on ART immediately and that they get ARV drugs regularly. However, if they are not able to come to ART centre regularly, options such as MMD, LAC or other differentiated service delivery may be explored. If there is a serious health constraint or the HIV infected women is unable to travel due any other reason, the ICTC counsellor should also provide ART preparedness counselling and fast track the ART initiation through coordination with ART centre (please refer to Section 2.4 for algorithm on rapid ART initiation and 5.6.2 for decentralised ART initiation). The ART centres should maintain a list of HIV positive pregnant women with serious health constraint or who are unable to travel due to any other reasons and follow them as required.

The baby should also be followed up to the age of eighteen months and ensure the baby undergoes EID testing and prophylaxis/treatment as per national guidelines for care of exposed child.

The ART centres should ensure the following for all HIV positive pregnant women:

- Provide ART to all HIV infected pregnant women
- To prevent vertical transmission by achieving a faster maternal VL suppression, same day ART/ rapid ART should be preferred
- Pregnant women should be prioritized and fast tracked for service delivery at ART centres
- Ensure involvement of spouse and other family members and move from an "ANC centric" to a "family centric" approach
- ICTC and ART centre coordination is also necessary to do index partner testing/HIV testing of the family members of PLHIV enrolled on ART
- Promote institutional delivery for all HIV infected pregnant women
- Provision of care and treatment for associated conditions (STI/RTI, TB and other opportunistic infections (OI).
- Provide counselling and support on exclusive breast/replacement feeding (EBF)/ERF.
- Provide antiretroviral prophylaxis to infants from birth up to a period of 6 weeks to 12 weeks, based on National Guidelines for HIV care and Treatment 2021.
- Integrate follow-up of HIV exposed infants into routine healthcare services including immunization.
- Ensure provision of Co-trimoxazole Prophylactic Therapy (CPT) and Early Infant Diagnosis (EID) using HIV nucleic acid testing (NAT) at 6 weeks of age onwards as per the EID guidelines. ART to be provided if NAT positive.
- Strengthen follow-up and outreach through ANMs, ASHAs and CSC and other outreach workers to support HIV infected pregnant women and their family.
- ART centre and ICTC should closely coordinate to share information and deliver relevant service to the women presenting directly in labour

In the ART centre, mothers need to be counselled about ART adherence throughout the period of pregnancy and breastfeeding, to reduce HIV transmission to baby. The HIV positive pregnant women should be provided counselling on the following aspects:

- Benefits of ART and importance of adherence for prevention of vertical through ART and better maternal and child health outcomes
- Need to continue lifelong ART
- Counselling for institutional delivery so that interventions for PPTCT can be taken
- Follow up schedule of exposed child
- Counselling for infant feeding should begin in the antenatal period and all pregnant PLHIV should be informed about infant feeding options and take right decision
  - Exclusive breast feeding is recommended feeding option of choice
  - Avoid mixed feeding during 1st six months of life
  - When breast feeding is not feasible, replacement feeding is advised only if all six criteria are met
- Counsel on family planning services to prevent unwanted pregnancies in HIV-positive women

7.3.2 Guidance regarding use of dolutegravir (DTG) in women of childbearing potential and those pregnant

DTG is a potent antiretroviral drug with superior virological efficacy, is well tolerated and has minimal adverse effects. In addition, DTG quickly suppresses the VL; and thus, reduces the chance of transmitting HIV to the baby as well as to the sexual partner and improves maternal outcomes. Regarding concerns on neural tube defects, latest evidence shows that the potential risk is comparatively much less than previously anticipated and is almost comparable with non DTG based ART regimens. Based on immense benefits of DTG and newer evidence available, use of DTG is recommended for all HIV positive women including those of childbearing potential and those already pregnant.

- Accordingly, woman of child-bearing age should be provided appropriate information and counselled on the immense benefits of DTG-based regimen and slight risk associated with use of DTG in order to make informed choice. She should be provided medical guidance that is appropriate to her situation and supported in making informed choice. In case of her non willingness for DTG based regimen despite adequate and optimal counseling, alternative options such as efavirenz based regimen may be considered
- Women who are on DTG based regimen and become pregnant, should continue to be on DTG based regimen and should be adequately counselled
- All newly diagnosed pregnant women (irrespective of the duration of pregnancy) should be provided DTG based regimen as the preferred regimen
- All women, who are pregnant and are not on DTG based regimen, should be shifted to DTG based regimen as soon as possible.

7.4 Management of HIV-Exposed Infants

"HIV-exposed infant/child": Defined as infants and children born to mothers infected with HIV, until HIV infection can be reliably excluded or confirmed in them.

7.4.1 Components of care of HIV-exposed infant:

a) Infant feeding

- Exclusive breastfeeding up to 6 months as it maximizes the chances of survival of the infant. When breast feeding is not feasible, replacement feeding is advised only if all six criteria are met (availability of safe water and sanitation, affordability, prepare it frequently in a clean manner, exclusively replacement feeding for first 6 months, family support, access health care)
- Mixed feeding increases the risk of transmission of HIV and should be avoided
- Continued breastfeeds in addition to complementary feeds after 6 months up to 2 year for regardless of infective status of the infant.

b) **ARV prophylaxis:** All HIV exposed infants should be initiated on ARV prophylaxis (as per National Guidelines for HIV care and Treatment 2021) soon after birth for a duration of 6 to 12 weeks depending on duration of maternal ART and mode of feeding EBF/ERF.

c) **Early infant diagnosis:** The diagnosis of HIV infection in infants younger than 18 months is different from that in adults. The standard diagnostic tool for HIV infection in adults, testing for antibodies to HIV antigens, has limited utility in new-borns and infants because of the trans-placental transfer of maternal antibodies which are present in an infant's blood for up to 18 months after birth (until the level of maternal antibody falls below limit of detection at 18 months) making it difficult to differentiate maternal from infant antibody. Therefore, use of qualitative nucleic acid testing (NAT) is recommended in infants for diagnosing HIV.

Early infant diagnosis (EID) testing details:

- *Age of Infant at first testing:* 6 weeks or more
- *At ICTC level:* Collect a dried spot (DBS) of babies between 6 weeks to <6 months of age for NAT testing and send to the lab
- EID testing algorithm given in National Guidelines for HIV care and Treatment 2021 should be followed for diagnosing HIV and follow up actions
- Two types of infants will need HIV testing (age appropriate test as per EID algorithm)
  - Infants who are known HIV exposed
  - Sick Infants <18 months with signs and symptoms of HIV and whose mother is absent or unable to be tested (referred by paediatrician)
- *Repeat:* If previous test is negative: repeat testing at 6 months, 12 months, 18 months and months after cessation of breastfeeds.
- Apart from the pre-fixed testing time-points, anytime the HIV exposed child develops signs and symptoms of HIV infection, he/she should be tested with age appropriate test
- ***Children diagnosed as HIV positive through EID should be immediately linked to ART centres for enrolment and ART initiation***
- Confirmation of HIV status of all babies at 18 months or three months after stopping breast feeding, whichever is later, using all 3 antibody (rapid) tests, irrespective of previous result and ART initiation status

D. **Co-trimoxazole prophylaxis:** CPT reduces morbidity and mortality in HIV exposed/infected children. It protects from Pneumocystis jiroveci infection, malaria and diarrhoea.

- All HIV exposed infants should get co-trimoxazole prophylaxis from the age of 6 weeks
- Continue CPT until child is proven HIV negative on all three serological tests at 18 months of age or later if still being breastfed

E. **Immunization and Vitamin A supplementation**

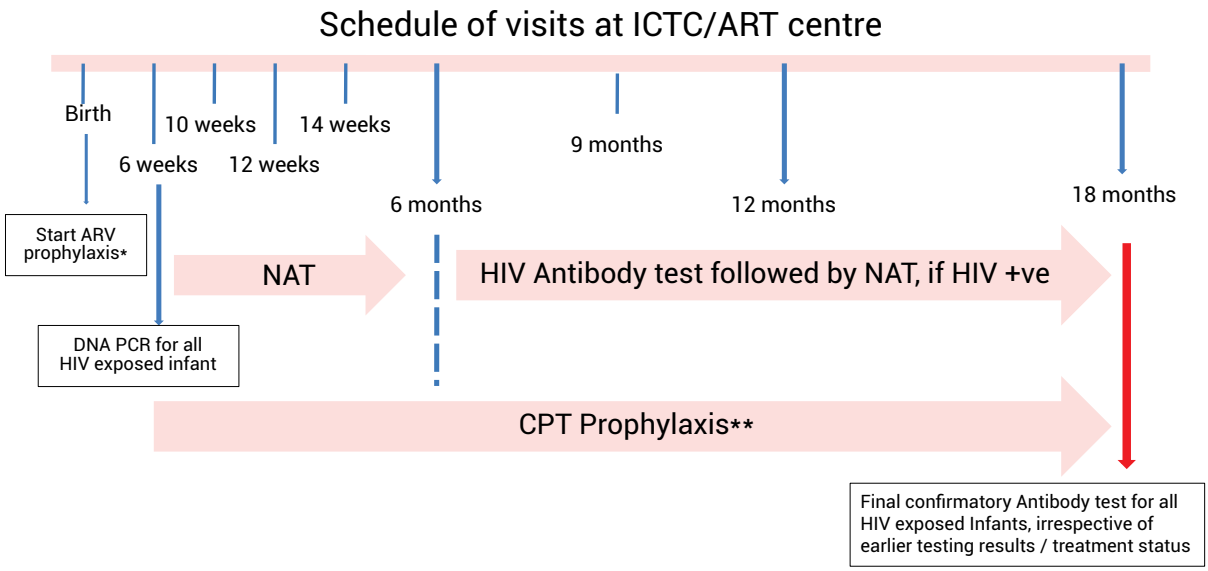
- Asymptomatic HIV exposed babies should be given all the vaccines in the National Immunization Programme
- BCG should be given to all HIV exposed infants at birth but if delayed avoid BCG in symptomatic CLHIV
- Live vaccines should be avoided in severely immune compromised (CD4<15%) and/or symptomatic infants and children
- Rotavirus vaccine and pneumococcal vaccine should be given in HIV exposed infants due to their risk for diarrhoea and pneumonia
- Inactivated Japanese Encephalitis (JE) vaccine is safe for use in CLHIV
- Give additional boosters as required especially for Hepatitis B and Hepatitis A, (check for sero-conversion)
- Vitamin A supplementation as per the national immunization schedule

Desirable vaccines (not available via national schedule) -inactivated Hepatitis A, inactivated Influenza vaccine, Varicella vaccine

F. **Growth and development:** Growth and nutritional evaluation should be done during every visit by maintaining a growth chary.

G. Schedule of follow up for HIV exposed infants and children <18 months: All HIV exposed infants and children will be followed-up until 18 months of age for care, monitoring and the final confirmatory HIV antibody test at 18 months or three months after stopping breast feeding, whichever is later. If HIV negative, follow-up will be done at ICTC (in case child is being breast fed at 18 months, the last follow up should be till testing is done 3 months after complete stopping of breast feeding). For those who are HIV positive, follow up should be done at ART centres. The schedule of visits for follow up care is given in Figure 13

Figure 13. Care of HIV exposed infants and children



Children diagnosed as HIV positive through EID should be linked to ART centres for ART initiation

*Duration of ARV prophylaxis in the infant will depend on ART duration in mother and type of feeding
**CPT Prophylaxis till 18 months if child is HIV –ve at 18 months or later if still being breastfed

7.4.2 Role of ART centres in care of exposed child

All HIV exposed infants and children will be followed-up by ICTC for DBS testing. Those found reactive with two DBS tests will be referred to ART Centre for enrolment and ART initiation with the following documents:

- DBS report
- Referral form

This referral will be facilitated by the PPTCT/CSC outreach staff. Such patients will directly report to the counsellor at the ART centre. If baby is found to be HIV infected at any stage, ART should be initiated, and CPT should be continued until 5 years of age.

A. SMO/MO

1 Overall, in-charge of HIV exposed infant/child at ART centre

2 Clinically assess infant/child for signs and symptoms of HIV and OIs

3 Ensure all HIV infected infants/children are followed up at ART centre and managed according to paediatric guidelines (Ensure clinical and developmental assessment, CPT, feeding advise, immunization, growth monitoring and nutritional evaluation at each visit to ART centre)

4 Initiate ARV in all HIV positive infants

5 Ensure every child goes to ICTC from which referred for a definitive diagnosis at 18 months by antibody test

6 Ensure documentation in ART centre documents as applicable

B. Counsellor

1. Check documents brought with infant/child referred from ICTC

2. Coordinate with ICTC counsellor to ensure that all HIV infected infants/children enrolled in care at ART Centre
3. Do the preparedness counselling of parents/caregiver for ART initiation of infants/children referred from ICTC and fill the consent form
4. Ensure follow up and management of these infants/children at ART centre
5. Do counselling for regular follow up visits at ART centre, adherence to ARV drugs and CPT
6. Counsel mother/caregiver for definitive antibody test at 18 months at ICTC
7. Coordinate with PPTCT ORW to track any HIV exposed infant/ child who has missed a visit and ensure infant/child is continued on care, support and treatment for HIV exposed infant/child

7.5 Care of Children with HIV

Addressing HIV/AIDS in children, especially below 5 years, is a major challenge globally. HIV disease progresses very rapidly in young children, especially in the first few months of life. HIV infected infants frequently present with clinical symptoms in the first year of life. Multiple risk factors in children living with HIV impact the trajectory to survive thrive and reach their full developmental potential:

- Low birth weight or premature birth
- Being more prone to pneumonia (including Pneumocystis pneumonia), tuberculosis (TB), bloodstream infections, diarrhoeal disease
- Severe acute malnutrition due to suboptimal nutrition, resulting in poor growth
- Health challenges experienced by mother or caregiver due to HIV status

Elements of care for children with HIV: Early identification, prompt treatment, and effective monitoring and care for infants, children, and adolescents living with HIV can enable them to live long and fulfilling lives. This begins in pregnancy and continues throughout the life-course.

Essential components of care for children with HIV include:

1. Early identification of positive pregnant woman and ensuring ART
2. Early infant diagnosis and prophylaxis
3. Index testing
4. Rapid ART initiation
5. Counselling and support
6. Ensuring routine care: ensuring nutrition and effective monitoring growth and development
7. Immunization and vitamin A supplementation
8. Preventing TB, pneumocystis pneumonia, bacterial infections and other infection
9. Management of advanced HIV disease
10. Monitoring children on ART and ensuring retention

7.5.1 Early identification of positive pregnant woman and ensuring ART:

Early identification of positive pregnant woman and ensuring ART is a critical step to improve maternal and child health outcomes and prevent risk of vertical transmission. For details, refer to Section 7.3

7.5.2 Early infant diagnosis and prophylaxis

Refer to Section 7.4 for details

7.5.3 Index testing services

Testing children as a part of family testing of positive parents. Refer to Annexure 3 for more details.

7.5.4 Rapid ART Initiation

Rapid ART initiation, within seven days, should be offered to children with no contraindications. Children who present with severe acute malnutrition or TB or other illnesses that require hospitalization need to be

stabilized first. In hospitalised children, initiating antiretroviral therapy should be encouraged as part of the child's hospital admission. This will help in ensuring ART initiation since referral after discharge may lead to linkage loss.

7.5.5 Counselling and Support

Counselling always involves the child and the child's caregiver. During counselling always respect the child's identity and emotions and protect the "best interest" of the child, including the right to participate in decisions that affect them, non-discrimination and confidentiality of information.

7.5.5.1 Child_centred counselling: The following are some of the key features of child-centred counselling.

- Develop of rapport between the child, caregiver and counsellor
- Use age-appropriate language to facilitate both the passage of information to the child and the expression of their feelings. Interactive tools such as drawing, storytelling, plays, drama are media through which a child can be helped to express themselves
- Focus on the child's needs and is tailored to the child's physical and psychological development
- Strive to promote the child's potential and abilities
- Build self-esteem and respect the child's identity and emotions
- Protect the "best interest" of the child, including the right to:
  - participate in decisions that affect them
  - non-discrimination
  - confidentiality of information
- Always involve the child and the child's caregiver

7.5.5.2 Key aspects for counselling of a child:

i. Preparation for ART initiation:

- Prepare care giver for ART initiation so that s/he
  - understands about HIV infection in children, benefits and adverse effects of ART
  - understands the importance of taking ART on about time every day and able to ensure treatment adherence
  - assumes the primary responsibility to directly observe daily ARV intake of the child
  - store ARV drugs appropriately
- Demonstrate correctly mixing/measuring of the prescribed ARV drugs
- It is important to alert care givers about the minor adverse effects of ARV drugs, such as nausea, headache and abdominal discomfort, which may recede over time or respond to change in diet or method and timing of medication administration

ii. Adherence:

- The ART team can ensure adherence by encouraging the use of the 'ART adherence colouring books' such as 'My ART Calendar' published by NACO.
- Children who do not know their HIV status should be explained why they need to take ART by using culturally and age-appropriate explanations and by avoiding the words "HIV" or "AIDS"
- Care givers should be counselled on supporting treatment adherence in children. It is advisable that children who have not been disclosed should not be present during the sessions to have more open and transparent discussion with caregivers. Encourage caregiver to take the responsibility to directly observe daily ARV intake of the child
- Assess adherence and the issues of child, parent/caregiver at each visit
- Align the due date with family member/care giver (if they are also on ART) as part of family centric approach
- Pill pick up dates may also be aligned with immunization schedules or other hospital visits
- A case management approach for children who are having poor adherence or unsuppressed viral load may be adopted by involving CSC ORW

iii. Disclosure:

Disclosure of HIV diagnosis to infected children is a complex process that presents a challenge to both families and health care providers. Timely disclosure helps child to develop a better understanding of HIV and related conditions and has health benefits such as improved adherence to medicines, reduced psychological distress, increased likelihood of appropriate disclosure to others, and better engagement in HIV-related care.

The timing of disclosure to the child cannot be a universal date or age. Disclosure of HIV status is continuous and progressive process. Disclosure should follow a planned process, with levels of disclosure over time. Child should be prepared gradually to accept the full and complete knowledge of having HIV infection.

It is recommended that caregivers and all children aged 5 years or more should start being prepared for disclosure:

- Partial disclosure (6-9 years)
- Full disclosure (10-12 years)

Disclosure of HIV infection status to children should take the following factors into consideration:

- Their age, psychosocial maturity, the complexity of family dynamics and the clinical context.
- The exact diagnosis and prognosis of the disease.
- Child's ability to cope with knowledge of life-threatening infection.
- Child's circumstances-e.g. when informing school going children-discrimination in schools, communities and families remains a serious problem.
- For young children, it is enough to say that there are germs in the body that can make them very sick. Older children will not be satisfied with such a simplistic answer and may demand more details. Interactive communication tools like storytelling can be used to communicate with these children.
- Counsellors and caregivers should be prepared for such questions. Obstacles to disclosure of HIV diagnosis to children may include the following and should be appropriately addressed while disclosure:
  - Fears regarding a decrease in the child's will to live
  - Fears regarding retaliation or discrimination based on stigma
  - Parental guilt about prenatal transmission of HIV infection
  - Child's difficulty in keeping a secret
  - Parent's denial and/or difficulty confronting their own illness
- Parents and caregivers must be supported through the process of disclosure of the HIV status to the child and explained about benefits of disclosure.
- Disclosure can be done at home also by caregivers. Role of ART centre staff is to encourage, support and guide them in this process. If the caregiver desire/ requests, disclosure may be done together (by the caregiver along with the support of the MO/counsellor). Parents/caregivers should be encouraged to disclose the status along with the support of the counsellors.
- Counsellors should provide continuous psychosocial support. Disclosure of HIV status to children should include continued counselling about disclosure and its impact, for both the child and parents.

Please refer to Annexure 14 for details on disclosure counselling.

iv. Coping - learning to live with a chronic illness: With advances in HIV medicine, this infection has become a chronic manageable illness. For the individual, it introduces the challenge of living with the illness daily and factoring it into whole life decisions. The monthly visit to the ART centre offers the counsellors an opportunity to explore these challenges with the children.

7.5.5.2 Key aspects for counselling of parents/caregivers:

In addition to the above components, caregivers should also be counselled on the following issues:

- Acceptance of HIV in child
- Nutrition including infant feeding options
- Immunization advisory
- Adolescence issues
- Planning for the future

Please refer to chapter 'Issues Related to Paediatric Counselling' in National Guidelines for HIV care and Treatment 2021 for more details on details on counselling in children

7.5.6 Ensuring routine care

7.5.6.1 Ensuring nutrition: Exclusive breastfeeding up to 6 months should be ensured as it maximizes the chances of survival of the infant. When breast feeding is not feasible, replacement feeding is advised only if all six criteria are met (availability of safe water and sanitation, affordability, prepare it frequently in a clean manner, exclusively replacement feeding for first 6 months, family support, access health care)

Although exclusive breastfeeding is recommended during first 6 months, practicing mixed feeding is not a reason to stop breast-feeding in the presence of ARV drugs.

Continued breastfeeds in addition to complementary feeds after 6 months up to 2 year for regardless of infective status of the infant.

For children >2 years age, appropriate nutrition, based on clinical condition, should be encouraged.

Irrespective of child's HIV status, the breastfeeding may be continued up to 24 months or beyond

7.5.6.2 Effective monitoring nutrition, growth and development

Children affected by HIV more often experience growth and developmental delays and will benefit from early identification and referral to relevant support services.

Growth and nutrition: Growth and nutritional evaluation should be done by staff nurse during every visit

- Weight - every visit to the ART centre
- Height (length for children up to 2 years of age)-3 monthly
- Plot them weight-for-height and height-for-age on white cards
- Mid-upper arm circumference (MUAC) among children 6 months–5 years old
- Identify child at risk of malnutrition

Document and accurately interpret growth charts in white card for early identification of children with growth faltering or malnutrition and link to nutrition support programmes such as Nutritional Rehabilitation Centres (NRCs). NRCs are being set up in the health facilities for inpatient management of severely malnourished children, with counselling of mothers for proper feeding and once they are on the road to recovery, they are sent back home with regular follow up.

For more details on assessment/classification of nutritional status and nutritional needs of HIV infected children, please refer to chapter 'Nutrition in HIV Infected Infants and Children' in National Guidelines for HIV care and Treatment 2021.

Developmental assessment: Developmental assessment at each visit should include assessment of milestones in the following domains:

- Gross motor
- Fine motor
- Language
- Social skills

Developmental assessment using screening tools (given in white card) and red flag signs should be done at each visit for early identification of developmental delay and neurological deficit. If milestones are delayed, children should be referred to Paediatrician for a detailed assessment and appropriate management for better prognosis.

7.5.7 Immunization and Vitamin A supplementation

HIV infected children are more susceptible to infections and more likely to develop serious complications thereof. Thus, there is an increased need for vaccination against all vaccine preventable diseases. It is important to ensure that they receive all recommended immunizations. Counsellor should inform the caregiver when the next immunization is needed and should review immunization records to identify any missed immunizations and arrange to redress as soon as possible.

- Asymptomatic HIV exposed babies are to be given all the vaccines in the National/State Immunization Programme.
- BCG should be given at birth. But if not given at birth, it may be delayed in symptomatic CLHIV until antiretroviral therapy has started and they are confirmed to be immunologically stable (CD4 >15%).
- Live vaccines avoided in severely immune compromised (CD4 <15%) and/or symptomatic infants and children
- Rotavirus vaccine should be given in HIV exposed infants due to their risk for diarrhoea
- Inactivated Japanese Encephalitis (JE) vaccine is safe for use in CLHIV- use only where indicated
- Give additional boosters as required especially for Hepatitis B and Hepatitis A, (check for sero-conversion)
- Vitamin A supplementation as per the national immunization schedule
- Desirable vaccines (not available via national schedule) - inactivated Hepatitis A, inactivated Influenza vaccine, Varicella vaccine, Pneumococcal conjugate vaccine

Table 15. National Immunization Schedule

Age	Immunization Schedule
At Birth	BCG, OPV-0, Hep B Birth Dose
6 weeks (1 1/2 months)	OPV-1, RVV-1, fIPV-1#, Pentavalent-1, PCV-1@
10 weeks (2 1/2 months)	OPV-2, RVV-2, Pentavalent-2
14 weeks (3 1/2 months)	OPV-3, RVV-3, fIPV-2, Pentavalent-3, PCV-2
9-12 months	MR-1, JE-1#, PCV Booster, Vit A*
16-24 Months	MR-2, DPT-Booster-1, OPV-B, JE-2#, Vit A*
5-6 Years	DPT-Booster-2
10 Years	Tetanus and Diphtheria (Td)
16 Years	Td
Pregnant Mother	Td-1 and Td-2 or Td booster

@ PCV introduced in select states/districts

#JE vaccine given in selected endemic districts

Vitamin A to be given every six months till five years of age

BCG: Bacillus Calmette-Guerin; DPT: Diphtheria-Pertussis-Tetanus; Hep B: Hepatitis B; Pentavalent vaccine: DPT+ Hep B + Hib (Haemophilus influenza type b); JE: Japanese Encephalitis: MR: Measles and Rubella ; OPV: Oral Polio Vaccine; Td: Tetanus and adult diphtheria; fIPV: Fractional Inactivated Polio Vaccine; RVV: Rotavirus Vaccine; PCV:Pneumococcal Conjugate Vaccine

Source : https://www.nhp.gov.in/universal-immunisation-programme_pg, last updated on Oct 29, 2020

7.5.8 Preventing TB, pneumocystis pneumonia, bacterial and other Infections

Co-trimoxazole prophylaxis: Co-trimoxazole (CPT) prophylaxis is an effective and proven strategy for reducing morbidity and mortality in children with HIV infection. It not only protects the infant from pneumocystis pneumonia, but also from malaria, diarrhea due to isospora and cyclospora, toxoplasmosis and bacterial infections. All HIV exposed infants should receive CPT from the age of 6 weeks until HIV is reliably excluded. In all those confirmed to be HIV-infected, CPT should be continued till 5 years of age.

Age group	CPT guidelines
All HIV-infected infants and children up to 5 years of age	Regardless of WHO stage or CD4 counts or CD4 %
All HIV-infected children >5 years of age	WHO Stage 3 and 4 regardless of CD4 OR CD4 < 350 cells/cmm regardless of WHO staging

TB preventive treatment (TPT)

- All children living with HIV (more than 12 months of age) who do not report poor weight gain, fever, current cough, or history of contact with a TB case, are unlikely to have active TB and should, therefore, be offered TPT.
- As per current guidelines, Isoniazid (INH) should be given for 6 months to all CLHIV after ruling out active TB disease through symptom screening.
- If a baby is born to a microbiologically confirmed TB mother, assess the new-born for active TB. Non-specific features suggestive of neonatal TB include fever, low birth weight, hepatosplenomegaly, irritability, feeding intolerance. If the child has any of these features, investigate for active TB infection and treat accordingly. If the child has none of the above features or is negative for active TB infection, give TPT for six months.
- Infants aged <12 months living with HIV who are in contact with a person with TB and who are unlikely to have active TB on an appropriate clinical evaluation, should receive TB preventive treatment.
- It is important to follow up children initiated on TPT and ensure completion.
- All children on TPT should also be counselled on adherence for TPT, adverse effects and regular follow-up.
- For children on TPT, 4S screening should be done during every visit to exclude active TB.
- If a child develops TB symptoms during TPT treatment, evaluate for TB and refer for drug susceptibility testing (DST).

7.5.9 Management of advanced HIV disease in children:

All children younger than five years (who are not already receiving ART and clinically stable) are considered to have advanced HIV disease. This is based on the rationale that most children younger than five years usually present for care with advanced immunosuppression, younger children have an increased risk of disease progression and mortality regardless of clinical and immune condition and that varying age-dependent CD4 cell count definitions for advanced immunosuppression among children younger than five years make definitions based on CD4 cell count difficult to implement in programmatic settings.

Advanced disease management (ADM) package:

A package of services shall be provided to CLHIVs with advanced HIV disease to reduce morbidity and mortality by early diagnosing, treating or preventing appropriate causes of opportunistic infections

Components:

1. **Screen and diagnose for OI** (TB, cryptococcus infection among adolescents and other infections) and malnutrition
   - Screen for **TB** using a clinical algorithm supplemented by X-ray
     - o Use the following diagnostic tests to confirm TB as applicable:

- Rapid molecular diagnostic on (induced) sputum, stool, gastric aspirate or nasopharyngeal aspirate or other extrapulmonary samples if relevant
- Lateral flow urine lipoarabinomannan (LF-LAM) assay (as and when available in the program)

- Screen **cryptococcal infection** among adolescents (health facility with availability of CrAG test are encouraged to use the test)
  - Serum or plasma or blood cryptococcal antigen screening followed by lumbar puncture if positive or symptomatic
- **Malnutrition**
  - Weight-for-height
  - Height-for-age
  - Mid-upper arm circumference among children 2–5 years old

2. **Treat for OI and malnutrition:** Based on the diagnosis, child should be treated for OI (TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis) and severe acute malnutrition according to National Guidelines for HIV care and Treatment 2021
3. **Prophylaxis and preventive (pre-emptive) treatment:** TB preventative therapy, co-trimoxazole to prevent severe bacterial infections and PCP, and fluconazole to prevent the development of cryptococcal meningitis (if CrAg positive without meningitis)
4. **Rapid ART, if serious opportunistic infections are ruled out**
5. Give **child-centred tailored counselling** to people with advanced HIV disease to support their care

7.5.10 Monitoring children on ART and ensuring retention

7.5.10.1 Monitoring after initiation of ART in children

Follow-up and monitoring including clinical, adherence and laboratory, is essential in children initiated on ART. At each monthly visit, the patient should be monitored for clinical symptoms, nutritional assessment including weight, height, head circumference (children less than 5 years) and mid upper arm circumference, developmental assessment, 4S screening, development of any new OI and adverse effects of drugs. Adherence to ART must be assessed at each visit and adherence must be reinforced through counselling at each visit.

The follow-up for children on ART is recommended as below:

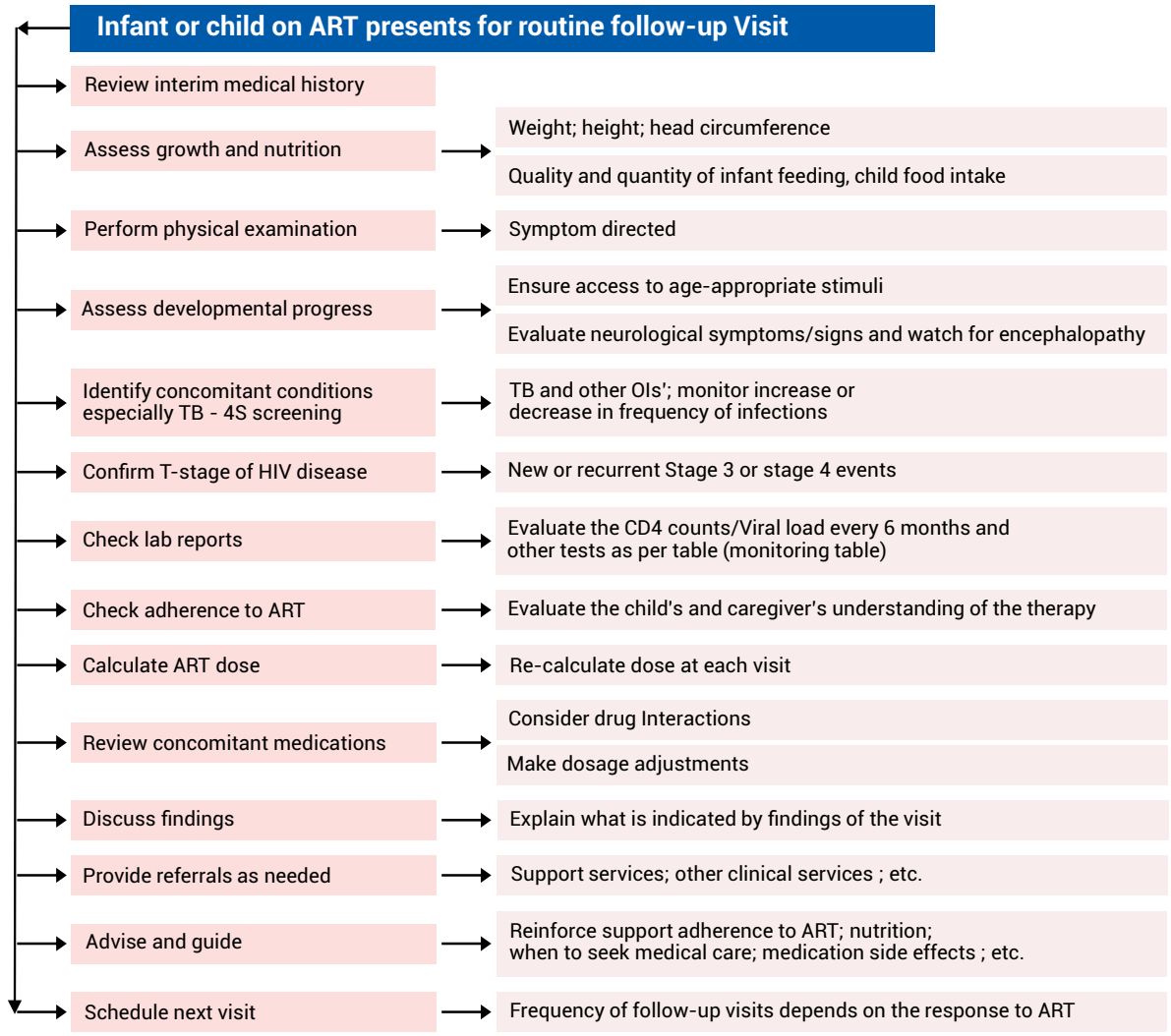
Clinical monitoring

- Monthly clinical evaluation: growth, development and nutrition
- TB screening: 4 symptoms screening (4S screening)
- Treatment adherence evaluation: at every visit
- Assess for adverse effects of ART/OI drugs and IRIS (immune reconstitution inflammatory syndrome)
- Check for any drug interactions
- Check for age and weight appropriate dosing/regimen and make possible adjustment

Lab monitoring:

- Viral load testing at 6 months and 12 months after ART initiation and then once every year
- CD4 count (%) to be monitored every six months for children up to 5 years. After that follow adult guidelines for virologic monitoring and CD4 monitoring

Figure 14. Monitoring of children on ART–routine follow up visit



7.5.10.2 Ensuring retention on ART through child centric differentiated package:

Children have a lifetime of ART management ahead of them. It is essential to have sustained adherence from childhood through adolescence to adulthood to reduce the risk of morbidity and mortality.

Child friendly services:

- Enablers, which facilitate adherence and retention on ART, should be considered.
- Children should be provided service delivery options so that they spend limited time in health facilities, manage uninterrupted school attendance and increased time with peers.
- Dedicated time/days (such as late afternoon and/or weekends) for children should be considered at ART centre. If feasible, availability of a paediatrician should be ensured on that day.
- Since children often depend on family members to access ART services, family-centred approach should be considered and visit frequency and **due dates schedules should be aligned with the family.** This will help in maintaining and improving clinic attendance and may also affect retention for the family as a unit.
- ART due dates should be scheduled with the school calendar in mind.
- Efforts should be made to link children to community-based Link ART centres /refill groups where they can get ART refills during school holidays, after school hours.
- During every interaction, child should be counselled about treatment, adherence and gradually prepared for disclosure in age appropriate manner.
- Care givers should be counselled on supporting treatment adherence in children.

As discussed, in Section 4.4 on patient centric differentiated care packages for retention, differentiated care packages for stable and unstable children should be considered.

Stable children: Children grow rapidly in the first two years of life, but thereafter when growth is more gradual, ART doses do not have to be adjusted frequently, and dosage changes may only be required three times until a child reaches 10 years. The average number of weight-based changes that occur between two and ten years of age is three. Thus concerns about underdosing in the setting of growth are tempered by the fact that in the older child, dose adjustments occur infrequently.

Children (>2 years age) shall be termed "stable", if fulfilling ALL the following criteria:

- on ART for at least 6 months;
- suppressed viral load;
- treatment adherence >95% in each of last 3 months;
- on the same regimen (with no dose or formulation change) for at least 3 months; and
- with no current illnesses/medical condition (including malnutrition*) which requires further management.

* *defined as weight for age is less than -2SD OR weight for height/length is less than -2SD*

For children >10 years of age, adult definition of stable PLHIV should be followed.

Stable children should be provided package 'B' and models such as MMD and decentralized ARV drug refill should be considered for children to ensure lifelong retention on ART

Unstable Children: Children who do not fulfil any of the above criteria would be categorized as **unstable and should be considered under package 'C'** and provided appropriate care as discussed in 7.5.9. *For details on differentiated care packages, please refer to Section 4.4 on patient centric differentiated care packages for retention.*

7.6 Adolescent Friendly ART Services

Adolescents, aged 10 to 19, experience rapid physical, cognitive and psychosocial growth. This affects how they feel, think, make decisions, and interact with the world around them. Adolescents living with HIV face considerable challenges and have unique needs and vulnerabilities. Multiple studies have found that adolescents living with HIV are often less likely to start ART after a positive HIV diagnosis; more likely to have sub-optimal adherence, more likely to become lost to follow up, more likely to have unsuppressed viral load and therefore having poorer health outcomes than adults.

Adolescents in HIV care may have two entry points:

1. Children living with HIV who transition in adolescence
2. Those who acquire infection during adolescence

7.6.1 Key issues specific to adolescent HIV care:

- Developmental changes during adolescence often make it difficult to understand and accept an HIV diagnosis and understand health implications thereof.
- To grow and develop in good health, adolescents need information, including age-appropriate comprehensive sexuality education; opportunities to develop life skills; health services that are acceptable, appropriate and effective; and safe and supportive environments.
- Adolescents experience both personal and health system barriers to maintaining optimal levels of adherence and continued engagement with care as they progress through major milestones in development.
- There may be delayed growth and pubertal development that may be further worsened by progressing HIV illness and malnutrition.
- Adolescence is a time when individuals will need to transition between child health (paediatric) services and adult health services.
- Delayed or unintended disclosure to adolescents can contribute to living with an increased sense of stigma, shame and fear.

Guiding principles for care of adolescents with HIV

a. HIV testing and treatment services should be adolescent-friendly and include mental health support to help improve linkage among adolescents.

b. It is essential to provide pre-and post-test counselling at the testing sites in an age-appropriate way that is non-threatening and clear.

c. Disclosure of HIV status:
   - Timely disclosure helps adolescents to develop a better understanding of HIV and related conditions and has health benefits such as improved adherence to medicines, reduced psychological distress, increased likelihood of appropriate disclosure to others, and better engagement in HIV-related care.
   - Disclosure of HIV status is a continuous process. It occurs throughout adolescence and ranges from informing a young person of their own HIV status (either at diagnosis or later, depending upon their age) to the adolescent independently sharing their HIV status with others when he or she is ready to do so.
   - Though, the timing of disclosure to the child cannot be a universal date or age, children should be prepared gradually to accept the full and complete knowledge of having HIV infection.
   - Parents and caregivers must be supported through the process of disclosure of the HIV status to the child/adolescent and explained about benefits of disclosure.
   - Disclosing to a child about his/her HIV status should be done in the context of his/her ability to understand and cope with the news of his/her HIV status. Ideally, disclosure to the adolescent should involve one of the parents or a caregiver. **Please refer to Section 7.5.5.2 part (iii) and Annexure 14 for details on disclosure counselling.**

d. It is critical that ART staff practice non-judgmental adolescent friendly care and support; and follow age-appropriate counselling/health education. Adherence and retention barriers of adolescents is different from that paediatric age group and that of adults; and address the barriers through age-appropriate counselling and strategies. Given the importance of mental health in adolescent adherence, incorporating monthly psychosocial assessments into adolescent models may be considered. In this regard, the ART counsellor would leverage the support of other service providers/programmes (mentioned below).

e. Counsellors should foster relationships with adolescents by creating a balance between appropriate health supervision, while listening to adolescent's voices regarding their health. It is also important to openly discuss involvement of caregivers with adolescents when it appears that caregivers could be helpful in providing emotional and tangible support to adolescents, while respecting adolescents' confidentiality if they chose not to have certain personal information shared with caregivers.

f. Visits taking place at ART centres should be provided during extended adolescent-specific service hours (such as late afternoon and/or weekends). This may benefit adolescents, as a group, from additional adherence support interventions during visits at ART centres. Involvement of peer volunteers may be considered where feasible.

g. Family centric care should be provided where other family members are also on ART.

h. Transition to adult: ART staff should keep tracking the age of adolescents and deliver appropriate services as the adolescents turn to adults e.g. change in dosage of medications; addressing the psychosocial, sexual and mental health. The prevention needs (sexual/drug use/other high-risk behaviours) should be addressed, in collaboration and coordination with other service providers/programmes.

i. Adolescents who are also members of key populations face additional challenges in accessing and retaining in HIV treatment programmes.

7.6.2 Enhancing care cascade (including linkage to treatment, adherence and retention) among the adolescents:

Ensuring adherence to treatment, long-term retention, and optimal outcomes during the complex and often-difficult phase of transition from childhood to adulthood, is critical. ART centres need to respond to the specific needs by incorporating attributes of adolescent-friendly services into HIV care, including reproductive and sexual health care, peer-based activities, mental health and psychosocial support services. Differentiated

care services encompassing holistic needs of adolescent could play an important role in enhancing retention in adolescent groups and therefore improving their quality of life.

Counselling:

- Age appropriate continuous counselling on ART adherence retention, nutrition, disclosure of HIV status, developmental changes and transitioning to an adult.
- Children should be prepared gradually to accept the full and complete knowledge of having HIV infection and considerable effort needs to be undertaken to ensure that adolescents living with HIV become aware of their status in a timely manner. The understanding and acceptance of a child may wax and wane in response to the individual's stage of development and also in response to changes in his/ her life. Counsellors should be alert to these changes or life events and should support the client when needed.
- Since, adolescents experience rapid physical, cognitive and psychosocial growth, they should be provided information on linkages: age-appropriate sexuality education; linkages with schemes to develop life skills; and access to health services including SRH services.
- Approaches such as peer mentoring, support groups engaging adolescent volunteers and peer navigation focused on caregivers should be considered. CSC and other CBOs/NGOs should be of support for this purpose, especially for KP PLHIV / adolescents.

Differentiated care:

- Facilitate dedicated adolescent services such as flexible appointment systems considering the school timings; dedicated time/days (such as late afternoon and/or weekends) for adolescents should be considered at ART centre.
- ART due dates should be scheduled with the school calendar in mind.
- Stable adolescents should be considered for multi-month dispensation.
- Efforts should be made to link adolescents to community-based Link ART centres/refill groups where they can get ART refills during school holidays, after school hours.
- Family centric care should be provided where other family members are also on ART.
- Involvement of peer volunteers may be considered where feasible.
- Strengthen community-based packages for the children of KPs.

Linkages:

- Leverage resources from existing networks like youth clubs in villages/colleges–Red Ribbon Clubs (RRC), National Service Scheme (NSS), National Cadet Corps (NCC), Indian Red Cross clubs, Self Help Groups, TI NGO, etc.
- Leverage the support of schools, orphanage homes, childcare homes, NGOs working for street children and children living in urban slums, and other community groups, as required.
- Establish linkages with swaddhar schemes, ujjwala schemes and rehabilitation centres, particularly for adolescent KPs, as required.
- Linkages with existing programmes for adolescents and youth:
  - **Raashtriya Kishore Swaasthya Karyakram (RKSK):** Key drivers of RKSK are community-based interventions like, outreach by counsellors; facility-based counselling; social and behavior change communication; and strengthening of **adolescent friendly health clinics** across levels of care. The objectives of the programme is to improve nutrition, improve sexual and reproductive health, enhance mental health, prevent injuries and violence, and prevent substance misuse.
  - **Kishore Shakti Yojana (KSY)** programme of women and child welfare department - the broad objectives of KSY include improving the nutritional, health and development status of adolescent girls, promoting awareness of health, hygiene, nutrition and family care, linking them to opportunities for learning life skills, and helping them gain a better understanding of their social environment.
  - **Rashtriya Yuva Sashaktikaran Karyakram (RYSK):** this scheme aims to help NGOs in setting up youth development programmes; and the programme also runs youth hostels.

CHAPTER 8

LINKAGES AND REFERRALS

Mechanisms for establishing linkages and referral systems are necessary to meet immediate and long-term needs of PLHIV. This chapter describes about in referral and out-referral to/from ART centre to provide comprehensive care to PLHIV to improve their quality of life.

8.1 'In referrals' to ART centres

8.1.1 Linkage with Integrated Counselling and Testing centres (ICTC)

The Integrated Counselling and Testing centre (ICTC) is the first interface for the entire range of preventive, care and support services provided under the National AIDS Control Programme. The key functions of an ICTC include not only the early detection of HIV, provision of basic information on modes of transmission and promoting behavioural change, but also linking of clients with appropriate prevention, care and treatment services. 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 IMS. Post-test counselling session at ICTC should place adequate emphasis on benefits of ART and importance of adherence, positive living, the need to involve caregiver and regular follow up. The ICTC counsellor should also explain the detailed process of registration at ART centre and ART initiation. For co-located ICTC and 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 positive pregnant women, services of PPTCT 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 IMS. The ICTC counsellor will thereafter make a list of PLHIV who are not registered at the ART centre and shall follow them up by phone/ home visits. This follow up should be coordinated by DAPCU/JD (BSD) at SACS. It should be ensured that all PLHIV, including positive pregnant women get rapidly initiated on ART.

8.1.2 Linkages with in-patient facilities:

PLHIV often may get admitted in hospitals for some serious clinical conditions and are then diagnosed HIV positive. Therefore, ensuring linkage of PLHIV 'in-patient' care with ART centre, for ART initiation and for ongoing HIV care upon discharge, is critical. Initiating antiretroviral therapy is encouraged as part of the hospital admission, since referral after discharge may lead to loss to follow-up and failure to initiate antiretroviral therapy.

The SOP for the linkages of such PLHIV with ART centre is as follows:

- The focal point of contact at ART centre (preferably staff nurse or medical officer) for all indoor referrals must be clearly identified and shared with all the departments of the hospital.
- All new diagnosis from the wards/inpatient services, should be routed through ICTC to the ART centre.
- Counsellor should conduct ART preparedness counselling of newly diagnosed PLHIV/their caregivers.
- In case, patient is not able to visit and only indoor file was sent with the patient's relatives for the enrolment at the ART Centre, bedside counselling should be provided by the ART counsellor.

- The patient must visit the ART centre before discharge from the hospital and counselled appropriately as per NACO ART guidelines .
- ART staff nurse should carefully follow up each admitted PLHIV so that ART is initiated before discharge. The baseline workup and ART initiation is to be ensured before discharge/ transfer from the hospital, if not already on ART.
- **Initiating antiretroviral therapy should be encouraged as part of the hospital admission, since referral after discharge may lead to loss to follow-up and failure to initiate antiretroviral therapy.**
- The information about availability of ART near the patient's residence should be provided at the time of enrolment at ART Centre.
- The decision about appropriate ART regimen, CD4 testing and viral load testing should be taken as per the National Guidelines for HIV care and Treatment 2021.
- Staff nurse should coordinate for package of services under advanced disease management (ADM), particularly for diagnosis and management of TB.
- A logbook to be maintained for daily visits by the staff nurse in hospital wards/ in patient departments (preferably in afternoon hours) which shall be monitored by SMO/MO of ART centre on regular basis.

8.1.3 'In referral' from private sector

NACO is committed to universal access to ART to all PLHIV. With the expansion of ART services, PLHIV who are availing ART from private sector may want to get enrolled in the national programme. The SOP for enrolling PLHIV taking ART from private sector are as follows:

- Enrolment in ART centre should be routed through ICTC to the ART centre. PLHIV should have HIV report from ICTC under national programme for enrolment in ART centre. If the person reaches ART centre directly, s/he should be properly guided to undergo HIV testing at ICTC and reassured that the ART will be started as soon as the basic work up is done.
- While the patient is under this brief preparatory phase (may be a day or two) at the ART centre, s/he should be advised to continue the same ART s/he is on so that there is no disruption in continuity of ART.
- Baseline clinical evaluation and investigation should be done, if necessary.
- Consent for enrolment into the programme and ART initiation should be taken (Annexure 2). The consent should also cover that the patient will be given best suitable ART (as per the recommendations from the national programme) which may or may not be similar to the patient's regimen from the private sector.
- PLHIV should be offered appropriate regimen based on availability under national programme.
- It is advisable to conduct viral load testing before initiating ART if the patient is on ART from private sector regularly for more than 6 months.
- For PLHIV who are virally unsuppressed, routine referral procedures to SACEP will be followed, as per NACO guidelines. If the regimen is appropriate and available under national program, patient can be continued on the same regimen from ART centre for next 3 months while s/he undergoes step up adherence counselling. VL test is repeated after 3 months and if the repeat VL is unsuppressed, patient is referred to SACEP.
- The second line ART will be provided after evaluation and approval of SACEP as per the National Guidelines for HIV care and Treatment 2021.

8.2 'Out Referrals' from ART Centres

Considering the medical and psychosocial needs of PLHIV, linkages and referral system need to be set up with other departments within the institution where ART centre is located and with service providers and organization outside the institution.

8.2.1 Referrals within the health facility

For comprehensive care, PLHIV need access to various departments/services depending upon disease stage and occurrence of opportunistic infections. To facilitate effective referral system, the "ART team" constituted at the time of the establishment of the ART centre with specialists from the departments of medicine, microbiology, obstetrics & gynaecology, paediatrics, dermatology/venereology, chest diseases and others should meet at least once in a quarter to review ART services and interdepartmental linkages. If it is not possible to conduct a dedicated ART team meeting, then agenda items related to ART centre and interdepartmental linkages issues must be included in other institutional quarterly meetings. Nodal officer/ SMO ART centres should keep separate minutes for this section of the meeting.

ART centre should have established referral and linkage mechanism with all the relevant departments and ART nurse shall be responsible for tracking the in and out referrals of ART centre within the hospital. Hospital referral form/green book may be used for this purpose. Efforts should be taken to avoid discrimination as well as reduce the time spent in several queues at hospital level. Any issues at different OPD, indoor and investigation facilities, in service delivery for PLHIV, must be brought in the notice of nodal officer ART centre and same to be discussed in the quarterly ART team meeting to improve the quality of services for PLHIV. The ART centre team also needs to have regular meetings in order to identify and resolve programmatic issues. The format at Annexure 15 or hospital referral forms may be used for referrals with proper guidance to patients.

8.2.1.1 Linkages with other outpatient departments and services: The PLHIV attending ART centre may have opportunistic infections or comorbid conditions for which they may need referral to OPD clinics/ services like antenatal clinics and gynaecology, paediatric, skin and venereology, chest diseases/tuberculosis, medicine, surgery, non-communicable disease (NCD) or other OPD.

8.2.1.2 Linkages with 'In patient' services of various departments for admitted PLHIV: PLHIV with advanced HIV disease, comorbid conditions may require in-patient services in various departments of the hospitals.

The SOP for the linkages of such PLHIV with ART centre is as follows:

- Staff nurse should coordinate with concerned departments for admission
- Staff nurse or medical officer should coordinate for package of services under advanced disease management (ADM), particularly for diagnosis and management of TB
- ART Staff nurse should carefully follow up each admitted PLHIV so that ART is initiated before discharge, if not already on ART. Counsellor should conduct ART preparedness counselling for PLHIVs/ their caregivers
- A logbook to be maintained for daily visits by the staff nurse to hospital wards/ in patient departments (preferably in afternoon hours) which shall be monitored by SMO/MO of ART centre on regular basis

8.2.1.3 Linkages for investigations: Due to lifelong ART, the PLHIV needs to undergo several follow-up investigations for the monitoring purpose and for the early diagnosis of comorbid conditions (blood and urine tests, molecular tests for TB, Radiological investigations etc). It is to be ensured at the ART centre level that there should not be any linkage loss because of these investigations. The preference may be given to the PLHIV, in case hospital follow the appointment system for any investigation.

8.2.2 Referrals outside the health facility

PLHIV may require referral outside the institutions for medical as well as psychosocial support.

8.2.2.1 Referral to SACEP: Patients with suspected treatment failure, severe adverse effects and complicated clinical cases of drug are referred for review by the panel of experts called State AIDS Clinical Expert Panel (SACEP) at Centre of Excellence/ART plus centres for further evaluation and timely switch/substitution to appropriate ART. SACEP referrals also cover PLHIV with drug related complications or management of severe

OIs that cannot be managed at ART centres. Each ART centres attached to designated CoE or ART Plus centre should refer the PLHIV for SACEP review. Tele SACEP using teleconferencing mechanisms can also be conducted wherever possible.

In most cases, e-referral to SACEP (i.e., sharing of patient treatment records, viral load test details, CD4 test, clinical records, treatment adherence details and RRF form) is preferred. SACEP reviews the documents and recommendation of the SACEP will be shared with the referring ART centre over an email. In some cases, SACEP may request for physical referral of patient. Please refer to Section 6.2 for details.

8.2.2.2 Referral to other government hospitals: PLHIV with certain conditions, advanced HIV disease (AHD) or comorbidities, may need a referral to facility that is outside the institution where ART centre is located. For such scenarios, organisations and facilities which could deal with advanced HIV disease and comorbidities (e.g. medical colleges) should be identified within a district/region and linkages be established in coordination with DAPCU. The ART centre counsellor should coordinate all the referrals to other government hospitals. and should maintain account of all the referrals made to the facilities outside the hospital. The format at Annexure 15 should be used for this purpose.

8.2.2.3 Referral for psychosocial support: For improved social protection and wellbeing, PLHIV may need referral for range of services related to psycho-social needs, spiritual health, nutrition, income generation programmes and other special needs

The following steps would help in establishing linkages within a district/region:

1) Mapping of such organizations in the district/region;
2) Consultation for setting up linkages and referrals systems including procedures and schedules; and
3) Evolving mechanisms for referrals and feedbacks.

The care coordinator/counsellor shall serve as focal points for dissemination of information regarding these services. The counsellor should identify such needs and suggest the place of referrals. Hence, it is important that the counsellor has a list of centres for referrals and is also acquainted with the person to whom referral is to be made. The various possible places for linkages and referral may include the following:

1) Care and support centres: Care and support centres should coordinate for linkages with social protection schemes provided under government and NGO schemes
2) NGOs actively working in the field of HIV/AIDS including those involved in targeted interventions (TI) for key populations and vulverable groups (FSW, Migrants, Truckers, IDU, MSM, TG etc.)
3) Rehabilitation centres etc.

The format at Annexure 15 may be used for referrals.

8.2.2.4 Transfer out to other ART centres: The following steps are to be followed while transferring the PLHIV to another centre:

1) Request by PLHIV/ willingness for transfer out to a nearest ART centre
2) Counsellor to identify the nearest ART centre in patient's vicinity for transfer out and discuss about feasibility with the patient
3) SMO/MO will examine the PLHIV to ascertain that s/he doesn't have any condition that can't be managed at recipient ART centre and approves transfer out on white card and green book. (Preferably preparedness counselling should be done and ART initiated before transferring out the PLHIV)
4) PLHIV on ART must be dispensed one/multi-month ARV drugs and provided appropriate information and contact details about the recipient centre
5) Data manager of parent ART centre to complete entry for transfer out in IMS and generate transfer out form. A copy of transfer out form should be given to PLHIV. Original white card should be retained at parent ART centre and scanned copy sent to recipient centre, where a new white card is created and new HIV care and ART number is allocated by recipient ART centre.

6) Recipient ART centre to provide confirmation in IMS once the patient has reached. Recipient centre will download the details of PLHIV from IMS, attach it to new white card of PLHIV and assign ART enrolment number as per guideline.

7) Transfer out will be confirmed only when patient reaches recipient ART centre and transfer has been accepted in IMS by recipient ART. After confirmation of transfer by recipient ART centre, the parent ART centre shall change status in their MLL as "transferred out".

Sometimes the patient reaches to the recipient ART centre without notifying the parent ART centre and seeks transfer. In such cases, e-transfer shall be considered once the following actions have been completed:

1) Recipient ART centre to send request via email/phone to parent ART centre for transfer out
2) Parent ART centre to officially transfer out the patient to recipient ART centre in IMS and also send scanned copy to recipient centre
3) Recipient ART centre to provide confirmation in IMS and download the details of PLHIV from IMS, attach it to new white card of PLHIV and assign ART enrolment number as per guideline.

Note: *In certain cases, a PLHIV, registered at one ART centre, may reach another ART centre for ART refill while travelling or during some restrictive situation. In such cases, PLHIV shall be provided ART refill as a stop gap/ temporary arrangement to continue ART and patient would be labelled as* ***"in transit"*** *by the ART centre dispensing ARV drugs.*

CHAPTER 9

PLHIV WITH COMORBIDITIES

9.1. Prevention and Management of TB in PLHIV

To mitigate the dual burden of HIV and TB coinfection and to ensure seamless access to quality services, the National AIDS Control Programme (NACP) and the National Tuberculosis Elimination Programme (NTEP) of the Government of India have introduced single window services for prevention and management of HIV-TB coinfection at ART centres.

The following components are part of the single window services approach:

- Four-symptom (4S) screening for TB in PLHIV and fast-tracking of all PLHIV with presumptive TB
- Provision of molecular diagnostics (CBNAAT/TrueNAT) for all PLHIV to ensure early TB diagnosis and identification of drug resistance
- Provision of anti TB treatment (ATT) for all HIV-TB co-infected patients at ART centres
- Provision of TB preventive treatment (TPT) for PLHIV to prevent TB as primary and secondary prophylaxis
- Airborne Infection Control (AIC) measures to reduce TB transmission at HIV care settings

This chapter is broadly divided into the following sub-sections:

1. Prevention of TB (Intensified case finding, TPT and AIC)
2. Early detection of TB in PLHIV
3. Management of HIV-TB coinfection (ATT and ART)
4. Drug logistics, recording, and reporting

9.1.1 Prevention of TB

There are four broad strategies to prevent TB disease in PLHIV, as described below:

1. Intensified case finding/screening for TB symptoms and fast tracking of TB presumptive cases
2. TB preventive treatment (TPT)
3. Early ART initiation
4. Airborne Infection Control (AIC)

9.1.1.1 Intensified case finding/Screening and fast tracking of PLHIV with presumptive TB

Intensified case finding (ICF) and fast tracking of presumptive TB cases is one of the critical interventions for prevention of ongoing transmission of TB and to rule out active TB disease prior to initiation of TPT. The following operational steps are recommended at ART centres for fast tracking of TB presumptive cases

ART centre staff will screen all patients for TB during every visit to the ART centre using the **4-symptom complex— (current cough, fever, weight loss, and night sweats) among adults and adolescents. In children, the 4-symptom complex includes current cough, fever, poor weight gain, and history of contact with a TB case.**

Care Coordinator will screen all patients for 4 symptoms and document the status in the Patient Visit Register and the patient's Green Book. Patients with any one or more of the four symptom/s should be marked/ stamped as 4S+ve (4S positive) and fast-tracked to the staff nurse (by skipping the counsellor) who will do a detailed assessment to determine the patient's 4S status. The staff nurse will record the 4S screening status

in the patient's green book using the detailed stamp. All the 4S+ve PLHIV will be referred to the SMO/MO who will finally ascertain the 4S status of the patient and mark the patient's 4S status in the patient's white card (patient treatment card). This information should be entered in the IMS/MLL by data manager. All 4S positive cases determined by the SMO/MO are called presumptive TB cases.

Patients marked as 4S negative by the care coordinator will follow the routine patient flow at the ART centre. The counsellor will screen all the 4S negative patients (using 4 symptoms complex tool) and record the 4S status in the green book using the detailed stamp. Following the normal flow at ART centres, all the 4S negative PLHIV will be then referred to ART SMO/MO who will finally ascertain the 4S status of the patient, determine eligibility for TPT, and mark the patient's 4S status in the patient white card. This information on 4S status and TPT should be entered in the IMS/MLL by data manager.

Care coordinator to educate patients with cough to cover their face with handkerchief or provide face masks. IEC materials on cough etiquette should be displayed in the ART centre.

9.1.1.2 TB preventive treatment

TB preventive treatment (TPT) is the treatment offered to individuals who are considered at risk of TB disease in order to prevent the progression of latent TB infection to active TB disease. It is important to rule out active TB before initiation of TPT. As per current guidelines, isoniazid (INH) should be given for 6 months to all PLHIV after ruling out active TB disease.

Ruling out active TB

All adults and adolescents living with HIV should be screened for TB with a clinical algorithm. Those who do not report any one of the four symptoms **(current cough, fever, weight loss, and night sweats)** are unlikely to have active TB and should be considered for TPT.

All children living with HIV (more than 12 months of age) who do not report poor weight gain, fever, current cough, or history of contact with a TB case, are unlikely to have active TB and should, therefore, be considered for TPT.

The counsellor at the ART centre will screen all the 4S negative patients and record the status in the green book. The medical officer will finally ascertain the 4S status and determine eligibility for TPT. The medical Officer will initiate TPT if there is no contraindication and document the same in the white card.

All patients should also be counselled on TPT adherence, side effects and regular follow-up.

For patients on TPT, 4S screening should be done during every visit to exclude active TB. PLHIV on TPT who have completed 3 months on TPT may also be provided MMD or linked out to LAC, if fulfilling the criteria for stable PLHIV (Section 3.1.3). They should be provided after proper counselling on adherence and side effect and should be asked to report back at the earliest if they have persistent nausea or loss of appetite (more than a day) for evaluation of liver function tests. The information on TPT initiation and follow -up and completion should be documented in white card by S/MO and then entered in IMS by data manager.

9.1.1.3 Early ART initiation

Early ART initiation carries positive impact on TB. Combined use of ART and TB preventive treatment (TPT) reduces the risk of developing active TB in PLHIV significantly. ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 cell count, among people living with HIV (except in PLHIV with TB meningitis where ART should be initiated with 4 to 8 weeks of initiation of treatment for TB meningitis). For those with CD4 cells <50/cm, strict clinical and lab monitoring is recommended after ART initiation. This will prevent the complications of TB and improve patient outcomes.

9.1.1.4 Airborne infection control (AIC) activities at ART centres

NACO has been focusing on strengthening infection control activities at ART centres in order to prevent occurrence of various infections among PLHIV who are already immune compromised. The national *Guidelines on Air Borne Infection Control in Healthcare and Other Settings,*[1] has identified ART centres as one of the high-risk settings for TB transmission. Presence of robust systems and policies is vital to control airborne

transmission of TB in PLHIV and health care providers at ART centres. Implementation of these precautions requires periodic risk assessment of all health care activities. Details of AIC practices are described in Section 16.2.1.

9.1.2 Early detection of HIV-TB

Early detection of TB entails identification of persons with presumptive TB, prioritization for molecular diagnostics (CBNAAT/TrueNAT) to reduce diagnostic delays. The following operational steps are recommended to be followed at ART centres for TB diagnosis:

i. Identification of persons with presumptive TB

- ART centre staff will screen all patients for TB during every visit to the ART centre using the 4 symptom complex
- The SMO/MO shall ascertain the presumptive TB cases (refer to Section 9.1.1.1 for details).

ii. Referral for TB diagnosis

- The SMO/MO shall refer the presumptive TB cases to respective DMCs for rapid molecular diagnostics and/or other appropriate investigations, indicate the same in the green book and send the patient to the nurse for referral and guidance.
- Patients should be referred for symptoms and signs directed investigations for TB such as sputum/ appropriate specimen test by molecular diagnostic and/or other required diagnostic tools.
- Molecular diagnostics like CBNAAT/TrueNAT is the preferred TB diagnostic technology in PLHIV wherever appropriate biological specimen from anatomical site is available for testing.
- The staff nurse shall prepare the TB laboratory referral form with all the relevant information.
- All patients referred to CBNAAT/DMC/TrueNAT facility and other relevant investigations should be documented in the HIV-TB line list prepared by staff nurse in hard copy and then recorded as soft copy in excel format by data manager.
- In case of sputum, only one sputum sample (spot sample) is required for TB diagnosis using CBNAAT/ TrueNAT technology in PLHIV. However, in situations where CBNAAT/TrueNAT) technology is not available, smear microscopy can be performed for which two sputum samples (spot-spot sample) are enough.
- All PLHIV diagnosed for TB should undergo drug susceptibility testing before ATT initiation, in accordance to NTEP guidelines.
- Biological specimen collection and transportation shall be facilitated by district NTEP staff.
- Lab technician of the DMC will perform the test and share the result report with the ART centre on same day.
- In instances where CBNAAT/TrueNAT lab is not co-located in same facility as ART centres, DTO will ensure sample collection and transportation mechanism to the nearest CBNAAT/TrueNAT lab using NTEP funds. In such cases patients should not be asked to travel to give samples to CBNAAT/TrueNAT labs.
- After the result of TB diagnosis is available, it should be documented in the HIV-TB line list and white card by nurse and entered in IMS by data manager and HIV-TB register generated.
- ART centres should coordinate with NTEP to minimize the turnaround time for return of results.
- Specimen for TB diagnosis should not be collected at the ART centre to prevent risk of TB transmission to other immunocompromised PLHIV.

9.1.3 Management of HIV-TB coinfection

9.1.3.1 Anti TB treatment

a. TB categorization and treatment initiation

- Based on the lab reports and/or clinical investigations, the SMO/MO shall establish TB diagnosis. All PLHIV diagnosed with drug sensitive TB should be initiated on daily ATT at the ART centre as per

1. Ministry of Health and Family Welfare. 2010. Guidelines on Airborne Infection Control in Healthcare and Other Settings. Government of India

the guidelines. Existing National guidelines for ART initiation/continuation/modification in HIV-TB coinfection shall be followed.

- **Recording and reporting formats:** The details about TB diagnosis, treatment, follow up and completion are to be recorded by the SMO/MO in section 7 of white card and the entered in IMS/MLL by data manger. Staff nurse should maintain the HIV-TB register. TB Treatment card for these patients will be prepared by staff nurse and will be duly signed by SMO/MO. One copy of the TB treatment card is to be handed over to the patient for documentation of adherence and follow up in the field.
- All the TB-HIV coinfected patients should be dispensed 28 days ATT and CPT by ART pharmacist at the ART centre.
- The due date or the next date of visit to ART centre should be adjusted by the counsellor/SMO/MO/ pharmacist based on the ATT schedule. At the completion of TB treatment, the leftover ART pills need to be adjusted while giving the next date of visit.
- For management of Drug resistant TB, patient's, TB patient's referral to the concerned drug resistant TB centre (DR TB centre) should be ensured by NTEP (District DRTB and HIV-TB Coordinator) and the updated information has to be communicated to the ART staff nurse to complete the recording in the HIV-TB line list and TB register.
- The ART data manager should take the patient details from staff nurse and register the patient on NIKSHAY portal.
- The ART counsellor should ensure proper counselling of all the HIV-TB co-infected patients regarding adherence, and possible adverse effects of ATT.

b. Patient registration and adherence

- After the patient has been initiated on ATT by ART centre, s/he will be enrolled in Nikshay by data manager, as per NTEP guidelines. Concerned STS/TBHV will also identify treatment supporter for TB-HIV co-infected patients and is responsible for follow-up and ongoing retrieval action. If the patient belongs to a different district HIV-TB coordinator will coordinate with his/her counter part of the other district for follow-up of patient.
- District DR-TB and HIV-TB coordinator is ultimately accountable for treatment support, adherence and direct benefit transfer (DBT) for all TB-HIV co-infected patients.
- Any adverse drug reactions identified by the ART staff or the NTEP staff should be informed immediately to the local MO at the peripheral health institution (PHI) and the ART MO.

c. TB treatment follow-up and outcomes

Sputum follow-up testing by smear microscopy must be done at the end of intensive phase of ATT and end of ATT treatment (following the NTEP guidelines). The follow-up sputum examination shall be done by sputum microscopy at the DMC and not by CBNAAT/TrueNAT. In case of extra-pulmonary TB patients, they should be evaluated clinically/or by other diagnostic tests that were used earlier for diagnosis by the ART medical officer. All follow-up sputum/other examination details must be documented in TB treatment card.

- The treatment outcome will be assigned by the ART SMO/MO in the white card and will be updated in the TB treatment card and TB register by the ART staff nurse
- Data manager with the help of staff nurse shall update TB treatment outcomes in the NIKSHAY portal and MLL/IMS.
- In case a patient on ATT is transferred out to any other ART centre, the NTEP referral/transfer out form needs to be completed with relevant information and sent along with ART transfer out form. HIV-TB coordinator should be kept informed about transfer out.

9.1.3.2 Antiretroviral treatment

In HIV-TB coinfected persons, ATT should be started first. ART is to be initiated as soon as TB treatment is tolerated (between 2 weeks and 2 months). The HIV-TB co-infected patients with CD4 count <50 cells/cmm, need to be started on ATT first and then ART within 2 weeks with strict clinical monitoring.

9.1.3.3 Drug dispensing and inventory management

- DTO with the support of district HIV-TB and PMDT/DR TB coordinator should ensure availability of drugs (for all weight bands) for anti TB treatment and TPT, and recording and reporting formats at ART centre.

- ATT and TPT drugs will be dispensed to the eligible patients by the ART pharmacist based on weight bands.
- Pharmacist will maintain the inventory of stocks for ATT drugs at the ART centre and send report of ATT/TPT courses utilized and left on a monthly basis to the DTO.

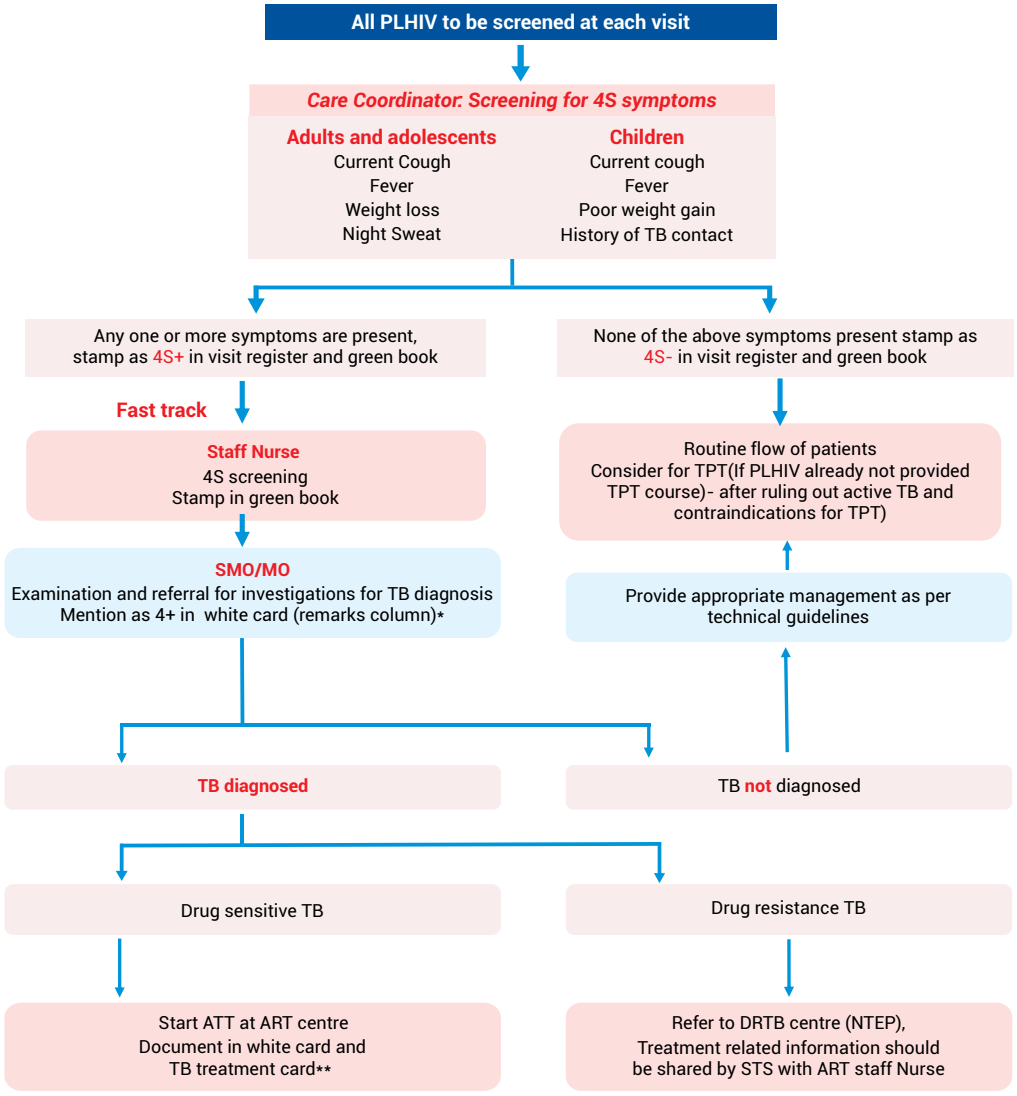
9.1.3.4 Recording and reporting

Recording and reporting of the HIV-TB activities will be done in the revised HIV-TB tools.

- HIV-TB line list: To be auto-generated from IMS. Soft copy to be maintained at ART centres and reviewed on monthly basis. Information on DR TB patients to be obtained from STS and details completed in HIV-TB line list. Soft copy of HIV-TB line list to maintained for each financial year.
- HIV-TB register: To be auto-generated from IMS by financial year.
- TB laboratory referral form: To be used for referral of PLHIV for TB testing to a NTEP facility.
- TB treatment card: To be maintained for PLHIV on TB treatment (duplicate copy not required) and kept at ART centres.

Note: For details, refer to "Guidelines on Prevention and Management of TB in PLHIV at ART centres" Dec 2016

Figure 15. Snapshot of 4S screening, TB diagnosis, treatment and TPT consideration



* For all PLHIV diagnosed with 'Rif sensitive TB' on NAAT, sample should also be sent for first line LPA. If INH resistance is detected, refer to DR TB centre.

** Information to be captured in NACO IMS and NIKSHAY. HIV-TB line list and HIV-TB register to be autogenerated from IMS

Table 16. Roles and responsibilities of NACP and NTEP staff in management of TB at ART centres

Nodal Person	Responsibility
NACP (SACS, DAPCU and ART Centres)	
JD-CST/ In-charge and Regional Coordinator	- Ensure training of ART staff on HIV-TB activities - Ensure availability of recording and reporting formats to the ART centres - Provide updated HIV-TB tools to the ART centres - Instruct ART centres to ensure availability of stamps (Care coordinator, staff nurse, counsellor and SMO/MO stamps) - Monitor activities through regular field visits and review meetings.
DAPCU	- Facilitate monthly HIV-TB coordination meetings at the district and ensure key implementation challenges are discussed and addressed. - Monitor activities through regular field visits and review meetings. - Coordinate with the district NTEP team to ensure regular supply of drugs, consumables and recording and reporting formats. - Ensure smooth roll out of the new HIV-TB initiatives in the district.
Nodal Officer ART centres	- Monitor and mentor all the staff on HIV-TB related services including infection control practices - Overall, in charge to ensure smooth implementing of HIV-TB services at the ART centre. - Provide guidance to ART centre staff in case of complicated cases and adverse effects of drugs
ART SMO/MO	- Screen all patients visiting the ART centre at every visit using the 4 symptom complex screening tool - Ascertain the final 4S status of all patients - Record the 4S status of the patient in the patient white card - Determine the final eligibility of patients for IPT - Initiate TPT for all eligible patients - Refer all the 4S positive patients for TB diagnosis through the staff nurse - Interpret the TB results and recording the same in the patient white card using the stamp. - Initiate the patient on relevant treatment - Assess any adverse effects for ATT and TPT at every visit - Screen the 4S status of all patients on TPT at every visit and recording the same in the patient white card - Determine the outcome of ATT treatment and record the same in the patient white card as well as the TB treatment card - Ensure correct and timely reporting - Attend regular HIV-TB coordination meetings to discuss the progress, gaps and challenges in implementing HIV-TB services at the ART centre.
Staff Nurse	- Screen all the PLHIV referred by the care coordinator for TB using 4 symptom complex screening tool - Record the TB symptom of the patient using the detailed stamp in the patient green book. - Fill TB referral form, facilitation TB referral and updating TB results status - Record and updating HIV-TB line list and TB register - Coordinate regularly with the HIV-TB coordinator STS/STLS to ensure effective coordination between ART and NTEP for smooth functioning and uninterrupted service delivery. - Share the details of all patients initiated on ATT at the ART centre/transfer of HIV-TB patients to another ART centre, with the HIV-TB coordinator on a daily basis.

Counsellor	- Screen all the PLHIV referred by care coordinator for TB using the 4 symptom complex screening tool - Record the TB symptom of the patient using the detailed stamp in the patient green book. - Counsel on ATT/TPT drug adherence and possible adverse effects and follow up. - ATT/TPT pill counting, provision of due date or next date of visit based on the ATT schedule.
Care Coordinator	- Act as first point of contact for all patients visiting the ART centre. - Screen of all patients visiting the ART centre at every visit using the 4 symptom complex screening tool. - Record of 4S status in the patient visit register and the patient green book. - Educate the patients with cough on cough etiquette, to cover their face with hand kerchief or provide face masks (if available)
Pharmacist	- Dispense Daily ATT and IPT drugs at the ART centre. - Maintain inventory and preparation of ATT and IPT stock reports. - Identify drug requirements and indenting for drugs - Educate patients about storing the drugs, due date
Data Manager	- Record in the HIV-TB line list and master line list in soft copy - Update TPT and TB treatment status in MLL/IMS - Timely and correct reporting in the revised formats. - Registration, follow-up sputum test details and TB treatment outcomes in NIKSHAY portal
NTEP (STC and DTC)	
STO	- Monitor activities through field visits and review meetings - Develop linkage plan to ensure all ART centres are linked to CBNAAT/TrueNAT testing facility. - Ensure availability of drugs, and other consumables
DTO	- Assign the responsibility to coordinate with ART centres for smooth implementation of HIV-TB activities - Ensure registration of PLHIV for TB treatment through HIV-TB Coordinator - Ensure sample collection and transportation mechanisms in the district for CBNAAT/ TrueNAT testing. - Conduct monthly HIV-TB coordination meetings to review the progress and monitoring of activities. - Ensure regular uninterrupted supply of lab referral forms, TB treatment card to the ART centres. - Ensure regular uninterrupted supply of ATT and TPT drugs.
District PMDT and HIV-TB Coordinator	- Coordinate with all NAAT sites for early detection of presumptive TB cases - Assist DTO in identifying treatment supporter for PLHIV, ensuring direct benefit transfer and management of drug logistics at NACP sites - Identification and training of treatment supporters for HIV-TB patients and maintenance of a directory of such treatment supporters at TU and district levels - Maintain district level HIV-TB records and reports - Ensure that records and Nikshay entries of all TB HIV patients in the district are updated regularly - Supervise ART/Link ART treatment observation centres once in a quarter - Coordinate with field staff to ensure drug availability - Update treatment cards and Nikshay entries - Assist DTO in providing training to staff of health facilities under his/ her jurisdiction to carry out TB HIV related activities - Visit all HIV-TB patients in each TUs every month and all DMCs every quarter - Visit all treatment observation centres in the district once in every quarter

	- Verify records, cards and TB lab register; ensure treatment cards at DTC, TU and PHI as well as Nikshay entries are updated at least once monthly - Conducting periodic visits to the ART centres to ensure effective coordination between RNTCP and ART centres for smooth functioning and service delivery - Ensuring identification of treatment supporter, patient follow-up and LFU tracking - Ensuring DR TB patient's referral to the concerned DR-TB centre and treatment initiation and providing information to the ART staff nurse to complete the line list - Coordinate with ART centre on weekly basis and update the NIKSHAY ID/TU number in the treatment card available at ART centre and HIV-TB line list
Senior Treatment Supervisor (STS)/ Tuberculosis Health Visitor (TBHV)	- Identifying trained treatment supporter for all TB-HIV co-infected patients for DOT provision - Ensure patient adherence and follow ups - Interview MPHS/ MPWs at PHC sub-centre regarding implementation of TB HIV activities - Help DTO in identifying/training suitable treatment supporters for diagnosed HIV-TB patients to be initiated on therapy - Visit all HIV-TB patients in each TUs every month and all DMCs every quarter - Verify records, cards and TB lab register; ensure treatment cards at DTC, TU and PHI as well as Nikshay entries are updated at least once monthly
STLS	- In consultation with DTO and MO-TC, ensure all PLHIV with presumptive TB are diagnosed at the earliest; facilitate transport of sputum specimens of these presumptive TB to the designated NTEP-certified lab - Visit all microscopy centres, review lab records, check stocks of conical tubes, packing materials, lab form and specimen transport boxes and ensure that cool chain is maintained - Ensure Nikshay entries from all labs

9.2. Management of HIV-Hepatitis Coinfection

The Government of India launched the National Viral Hepatitis Control Programme (NVHCP), under the National Health Mission, in 2018. This is a comprehensive plan covering the entire spectrum from Hepatitis A, B, C, D and E, and the whole range from prevention, detection and treatment to mapping treatment outcomes. It envisions to provide free of charge screening, diagnosis, treatment and counselling services to all, specially to people belonging to high-risk groups.

HIV and hepatitis B (HBV)/hepatitis (HCV) share similar transmission routes. In general, concurrent or sequential infection with these viruses usually results in more severe and progressive liver disease, and a higher incidence of cirrhosis, hepato-cellular carcinomas (HCC) and mortality.

Viral hepatitis is an increasing cause of morbidity and mortality among people living with HIV, including those on ART. There are certain population groups like recipients of multiple blood / blood products transfusion, patients on haemodialysis, PWID, MSM, female sex workers, sexual partners of infected people, prisoners etc which are at a higher vulnerability to get infection with hepatitis B and hepatitis C.

To ensure adequate synergies between the two national programmes, and for the optimal benefit to the PLHIV, the following key activities are recommended:

9.2.1 Activities at the ART centre

9.2.1.1 Screening PLHIV for hepatitis B and C: The ART centres should ensure that PLHIV, especially belonging to certain population groups like recipients of multiple blood / blood products transfusion, those with altered liver function tests, patients on haemodialysis, PWID, MSM, female sex workers, sexual partners of infected people, prisoners etc, are screened for hepatitis (HBsAg and Anti-HCV) at least once, and then the repeat testing may be done annually for those who have a persisting risk. The modality of testing through linkage to the institutional lab/ NVHCP will be done by the SACS in coordination with state NVHCP nodal officer. The ART centre should maintain a record of all PLHIV screened in white card of the PLHIV.

9.2.1.2 Management of PLHIV coinfected with hepatitis B and C: ART centre would refer the PLHIV found Hepatitis B/C positive to the designated hepatitis treatment centre along with the necessary details of the ARV regimens, for further evaluation/confirmation and management. Hepatitis C coinfected PLHIV will need to be treated for 12 weeks if they do not have cirrhosis and for 24 weeks those with cirrhosis. The drug interactions between ARV and Hep C drugs need to be considered. For Hepatitis B, the treatment is lifelong in most cases and Tenofovir needs to be continued even when PLHIV is on a non-Tenofovir based ART. For details of ART and hepatitis treatment, refer to National Guidelines for HIV care and Treatment 2021 and the National guidelines on diagnosis and management of hepatitis, NVHCP, 2018.

9.2.1.3 Hepatitis B vaccination: The PLHIV who are negative for HBsAg on screening, should be provided vaccination for hepatitis. The same should be documented by the ART centre in white card. Similarly, the ART centre staff should also be vaccinated for hepatitis B. An OM dated 29 May 2018 has been issued by MD NHM regarding vaccination of health care workers.

9.2.1.4 Recording and reporting: The ART centres would document the information regarding screening, treatment and vaccination in the white card of the PLHIV. This information would be captured in IMS. Reports would be generated at SACS level and shared with NACO and NVHCP.

9.2.1.5 Referral and linkages: Those ART centres that do not have facility for screening or treatment for hepatitis within the institution, should refer the PLHIV to the nearest designated centre for testing and treatment.

9.2.2 Coordination with NVHCP

SACS in coordination with NVHCP should identify clear linkage mechanisms for screening and treatment for hepatitis for each of the ART centres.

9.2.2.1 Supply of testing kits: Anticipated need for the screening of PLHIV should be done based on existing registrations at ART centres and expected new registration in next one year. The kits will be supplied from NVHCP, but the requirement must be timely communicated for inclusion in state PIP. ART centre where the screening is not available within the institution, the JD(CST) will coordinate with nodal officer (NVHCP) to ensure linkages for screening of PLHIV registered at ART centre. The mechanisms can differ from state to state, and this coordination of JD(CST) with state NVHCP programme will ensure that the PLHIV are screened and appropriately managed.

9.2.2.2 Drug supply or linkage development: Anticipated need for drugs to treat hepatitis B and C in PLHIV should be made based on existing data and this should be calibrated from time to time, based on the results of the screening in PLHIV. Anticipated number of patients should be communicated to state NVHCP so that the supplies can be factored in the state PIP under NVHCP. For ART centres that have a 'treatment centre' in the same facility, the hepatitis medicines can be delivered through the 'treatment centre' for the coinfected. For the ART centres that do not have a 'treatment centre' within the health facility, clear linkages with nearest designated centre should be developed where the hepatitis coinfected PLHIV can seek care. It is of utmost importance for the management of HIV-hepatitis coinfected individual to be registered with the treatment centre under NVHCP, since chronic hepatitis can also have its complications like cirrhosis, fibrosis, portal hypertension, etc.

9.2.2.3 Availability of hepatitis B vaccination: The state nodal officer (NVHCP) should facilitate the availability of vaccine to NACP. The supply and mechanism should be decided by JD(CST) and state nodal officer for NVHCP.

9.2.2.4 Monitoring and supportive supervision: The in-charge CST at SACS should include the review of the HIV-Hepatitis related activities at ART centre in the supportive supervision visits. S/he may also organize joint monitoring visits along with the state nodal officer (NVHCP) once every quarter or six months to collectively address any issues in implementation.

9.3. Non-Communicable Diseases and Mental Health among PLHIV

Widespread access to antiretroviral therapy (ART) has transformed HIV disease from a life-threatening condition to a manageable chronic condition by increasing longevity and favourable treatment outcomes in PLHIV. PLHIV who are on treatment, live near normal life spans and are facing different health challenges due to ageing. They are more likely to develop non-communicable diseases (NCD).

Non-communicable diseases in PLHIV result from a mix of chronic immune activation, medication adverse effects, coinfections, and the aging process itself. Non-communicable diseases are now becoming one of the leading causes of non-AIDS related morbidity and mortality in PLHIV.

Under NACP, proportion of ageing population is increasing steadily. Therefore, prevention and timely referral for management of NCD in PLHIV is very critical.

Common NCD in PLHIV are as follows:

- Cardiovascular disease
- Type 2 diabetes
- Cancer
- Mental health issues, including depression

Strategies for prevention and management of NCD in PLHIV include:

- Health promotion
- Screening for early detection
- Referral to diagnosis and management

9.3.1 Health promotion

Health promotion is critical to promote healthy lifestyle and reduce the specific risk behaviours, e.g., unhealthy diets, physical inactivity, tobacco and harmful drinking etc for prevention of NCD. All PLHIV should be counselled on health behaviours and comprehensive healthy lifestyles and provided information on strategies for the prevention and risk reduction of NCD by addressing modifiable factors.

Health behaviour	Counselling message
Physical activity	• Engage in moderate levels of physical activity for 5-7 days per week (at least 30 minutes/day) • Yoga & meditation
Weight control	All individuals who are overweight or obese should be encouraged to lose weight through a combination of a low-calorie diet and dynamic physical activity
Diet	• Restrict salt to less than 5 grams (1 teaspoon) per day • Fatty food: limit fatty meat, dairy fat, and fried food • Eat a diet high in fruits and vegetables
Tobacco cessation	• Encourage all non-smokers not to start smoking • Strongly advise all smokers to quit smoking and support them in their efforts
Avoidance of alcohol	Use of alcohol should be avoided by everyone as far as possible
Adherence to treatment	If the person is prescribed medication for NCD: • Explain the dose and how many times a day to take the medication • Explain how to take with ARVs along with additional medications • Importance of adherence to medicines for NCD along with ART • Explain the need to take the medicines regularly as advised even if there are no symptoms

9.3.2 Screening and early detection

- Screening and early detection of non-communicable diseases especially diabetes, high blood pressure and common cancers is an important component of HIV care.

- ART centre shall screen PLHIV for diabetes, hypertension, cardiovascular diseases and common cancers and identify individuals who are at a high risk of developing NCD warranting further investigation/ action. Such screening shall involve simple history (such as family history of diabetes, history of alcohol, tobacco consumption, dietary habits etc.), general physical examination, calculation of BMI, blood pressure monitoring, blood sugar estimation etc.
- Routine screening and management of mental health disorders (depression and psychosocial stress) should be provided for people living with HIV in order to optimize health outcomes and improve their adherence to ART.

PLHIV who are at risk of a particular NCD should be screened for early detection and timely management as per the details given in table below:

Table 17. Strategy for screening of PLHIV for hypertension, diabetes, mental illness and cervical cancer

Screening for	How	For whom	When	Action
Hypertension	Blood pressure measurement	All PLHIV	• At ART initiation • Every six months • At every visit, if hypertension diagnosed	• BP>140/90mmHg* in PLHIV aged >18 years; or • BP>15/90 mmHg in PLHIV >60 years: – Refer for further work and management – Counselling for lifestyle modification (avoid alcohol/ tobacco use and high salt, increase in fruits and vegetables intake, physical activity and stress management)
Diabetes	Random blood glucose	All PLHIV	• At ART initiation • Every six months • At every visit, if diabetes diagnosed	If Sugar Random >120mg /dl): - Refer for further workup and management - Counselling for lifestyle modification (avoid alcohol / tobacco use and high sugar intake, increase physical activity and stress management)
Screening for cervical cancer	Visual inspection with Acetic Acid (VIA)/ cervical PAP smear (at the concerned department)	All women and girls who have initiated sexual activity	• At ART initiation • Every 3 years • Women who have been treated should receive follow-up screening at 1 year	– If screened positive, refer to gynaecologist/lady medical officer wherever available, or NCD clinic at CHC/DH, for confirmation
Screening for and management of mental health issues	PLHIV has at least one of the core symptoms of mental health illness (depression) for at least 2 weeks: 1. Persistent depressed mood or sadness 2. Markedly reduced interest or pleasure doing things	All PLHIV**	• At ART initiation • At each visit	PLHIV who have either of the core symptoms, should be referred to undergo thorough screening for depression

* Patient with severe hypertension (BP ≥180/110 mmHg) should be referred for management to appropriate level of care

** All PLHIV should receive basic screening for and management of mental health issues and substance use

9.3.3 Referral for diagnosis and management

- The PLHIV screened positive for NCD shall be referred to NCD clinics/higher health facilities for further diagnosis and treatment.

o **In district hospital:** For ART centres in district hospitals, PLHIV should be referred to NCD clinic. Under National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS), all districts will have regular NCD clinic for screening, management, counselling and awareness generation etc. for non-communicable diseases, including comprehensive examination and management of patients with common NCD.

o **In medical college:** For ART centres in medical college, PLHIV should be referred to appropriate specialty department in medical colleges .

- PLHIV who have any of the symptoms of mental health disorders (depression and psychosocial stress) should be referred to undergo thorough screening for mental health conditions

o **In district hospital:** For ART centres in district hospitals, PLHIV should be referred to NMHP (National Mental Health Programme).

o **In medical college:** For ART centres in medical colleges, PLHIV should be referred to psychiatry/other appropriate specialty department in medical colleges.

9.3.4 Recording and reporting

Documentation of screening and referral should be documented in white card in patient follow-up section (section 13) and investigation section. Details regarding comorbid condition should be documented in section 9 of white card. These details would also be captured in IMS.

9.4 HIV and Leishmaniasis

Leishmaniases is a slow progressing vector-borne neglected tropical disease caused by >20 species of the protozoan parasite of genus leishmania. The parasite primarily infects reticuloendothelial system and may be found in abundance in bone marrow, spleen and liver. It presents as a severe systemic form visceral leishmaniasis (VL) or kala-azar, mucocutaneous leishmaniasis (MCL) and cutaneous leishmaniasis (CL). In India, leishmania donovani (italics) is the only parasite causing this disease.

Disease Burden in India: India has high burden of leishmaniasis. Burden of disease in India is mainly due to VL in the eastern states (Bihar, Jharkhand, Uttar Pradesh and West Bengal) with small pockets of CL in Rajasthan, Himachal Pradesh and Kerala. VL is endemic in 54 ditricts of eastern states; sporadic cases reported from a few other districts also.

9.4.1 HIV and Leishmaniasis coinfection

Studies from Bihar show 1.8-5.6 % of VL patients were HIV-positive (Burza et al CID 2014; Plos Neg Trop Dis 2014). HIV and Leishmania co-localize in the same host cell (macrophages and dendritic cells), mutually reinforcing each other's pathogenic effects. Control of VL depends on effective T helper cell type1 response (IFNγ & TNFα). CD4 T-cell depletion and skewing towards a Th2 immune response are hallmarks of HIV infection. Therefore, a concomitant HIV infection increases the risk of developing active leishmaniasis; reduces the likelihood of a therapeutic response; and increases the probability of relapse of visceral leishmaniasis (VL). Leishmaniasis increases HIV replication and progression. Visceral leishmaniasis is an AIDS defining illness in PLHIV.

9.4.2 Strategies for managing HIV and leishmaniasis coinfection

9.4.2.1 Bidirectional screening/testing

HIV testing in leishmaniasis patients: HIV testing should be offered to

- All patients diagnosed with VL as per National Vector Borne Disease Control Programme (NVBDCP) guidelines [Patients with signs/symptoms of VL (fever >2 weeks, hepatosplenomegaly, pancytopenia) residing in or h/o visit to endemic areas or positive on testing with rk-39 immunochromatographic (ICT) test or positive LD bodies in Bone marrow or splenic aspirate]
- All persons with a past history of VL (HIV status unknown)

Patient should be offered HIV testing with appropriate linkage to ICTC/F-ICTC where counselling and testing for HIV should be done with informed consent as per national guidelines

Leishmaniasis screening in PLHIV in endemic areas

- The medical officers at ART centres should suspect for VL in all HIV positive individuals having fever >2 weeks duration, hepatosplenomegaly and pancytopenia residing in or h/o visit to endemic areas at baseline as well as follow up visits.
- Such patients should be referred for VL testing with rk-39 (RDT). Those with rk-39 positivity should be immediately linked to facility where VL treatment is available.
- Those with rk-39 negative but high clinical suspicion for VL should undergo bone marrow/splenic aspiration for confirmation of diagnosis as per National Vector Borne Disease Control Programme (NVBDCP) guidelines.

9.4.2.2 Management of coinfected patients

Anti-leishmaniasis Treatment:

- For anti-leishmaniasis treatment patient needs to be linked or referred to nearest health facility for Kala as per National Vector Borne Disease Control Programme (NVBDCP), with instructions to follow up at ART centre.

Antiretroviral therapy:

- ART can be initiated as soon as the patient can tolerate it after starting treatment for leishmaniasis.

9.4.2.3 Coordination (in endemic areas): There should be close coordination between NVBDCP and NACP for cross referral.

- Quarterly meeting at state level and monthly meeting at district level is recommended in endemic states.
- SACS may hold monthly meetings involving both programme and all stakeholders.

9.4.2.4 Recording and reporting: Status of coinfection needs to be captured in white card as well as in green book. The information should also be entered in IMS also.

CHAPTER 10
CARE and SUPPORT CENTRES

A care and support centre (CSC) is a community-based service delivery point which provides counselling, psychosocial support, outreach activities, linkages to welfare schemes and enabling environment for PLHIV. CSC serves as an extension of treatment services for providing care and support to enhance retention, adherence, positive living, referral, linkages to need-based services for PLHIV. CSC are community-based service delivery points that play vital role to reduce stigma and discrimination through effective treatment literacy activities in coordination with local PLHIV networks. The community-based CSC are an integral part of the national response to meet the needs of PLHIV, including those from high-risk groups and women and children living with HIV. The goal of CSC is to improve the survival and quality of life of PLHIV.

10.1 Major Objectives of CSC

- Early linkage of PLHIV to care, support and treatment services
- To improve treatment adherence and education for PLHIV
- To leverage positive prevention activities
- To improve social protection and wellbeing of PLHIV

10.2 Major Activities under CSC

- **Intensified peer support services for prevention of LFU:** CSC reach out to PLHIV who are newly initiated on ART and those with less than 80% ART adherence for last three months and ensure they are retained in treatment with improved treatment adherence.
- **Tracking of LFUs and MIS cases:** Staff at CSC follows various strategies, like contacting the patients on phone, meeting them at mutually convenient places and also home visits for those who agree to it, to link back lost to follow up (LFU) and MIS cases to ART centres for continuation of treatment.
- **Follow up of all family members of PLHIV for HIV testing and early linkages to the treatment if found positive:** Tracking of discordant couples, partners and children for follow up HIV testing along with providing preventive counselling and if found positive linking them to the treatment.
- **Counselling and support group meetings:** Intensive peer support and adherence counselling is being provided to all PLHIV.
- **Intensified case finding for TB amongst PLHIV:** PLHIV who have not yet been screened for TB symptoms and follow up screening after every 6 months is carried out by the CSC team.
- **Sensitization of state and national government stakeholders to:** enhance linkage to social protection schemes, reduce stigma and discrimination experienced by PLHIV and provide better livelihood options for PLHIV.

CSC have been spearheading local resource mobilization initiatives and leveraging additional direct support services such as nutritional items, educational items, transportation support, and many other household and clothing materials for the PLHIV community.

10.3 Coordination between ART Centres and CSC

10.3.1 Information displayed at ART centre relevant to CSC: ART centres should display the following information about CSC.

- Location and address of CSC
- Services provided by the CSC
- Contact details of staff

10.3.2 Referral and linkages: PLHIV registered in ART centre and under active HIV care should be referred for registration in CSC for receiving the following care and support services:

- **Intensified peer support services for prevention of LFU:** Intensified peer support services shall be provided to the PLHIV at least for the initial 3 months for better treatment adherence. Essential services in first 3 months include:
  - Treatment preparedness and treatment adherence counselling during home visits by ORW or as per the convenience of the PLHIV.
  - Provision of basic information about adverse effects, OI management and home-based care during patient's visit to CSC
  - Referral of family members/spouse for HIV testing during the home visit
  - Address verification
- **Intensified peer support for optimal adherence:** Intensified peer support for optimal adherence shall be provided to PLHIV with poor adherence, particularly during step up counselling period
- **Linkages and referral services to improve social protection and wellbeing of PLHIV:** PLHIV shall be provided/linked to various services and schemes to improve social protection and wellbeing of PLHIV
  - Linkage to welfare schemes
  - Linkages to social entitlements
  - Referrals to other service providers
  - Training on home based care
  - Life skill education and vocational training
  - Discrimination response Team

10.3.3 Community level follow up for index testing services

Follow up spouse/partners, children of PLHIV for HIV index testing at community level and early linkages to the treatment if found positive.

10.3.4 Case management approach for PLHIV with advanced HV disease/comorbidities and children /adolescents to ensure VL suppression and retention:

PLHIV with advanced HV disease/comorbidities need greater support to cope up with treatment and for retention on treatment. Program data indicated retention as well as viral load suppression rates in children and adolescents are low. CSC will support case management approach for children and adolescents which includes timely referrals for ART refill and VL testing; age appropriate counselling for disclosure and adherence; linkage to government schemes.

Lists to be shared with CSC for follow up and tracking: The following groups of PLHIV are outreach priorities of CSC for follow up and tracking

1. PLHIV enrolled in HIV care but not initiated on ART ipt (weekly)
2. PLHIV who are MIS and LFU ript (weekly)
3. PLHIV newly initiated on ART for follow up for first three months (monthly)
4. PLHIV who are virally unsuppressed and undergoing step up counselling or PLHIV with less than 80% treatment adherence or (monthly)
5. PLHIV with advanced HIV disease/comorbidities and children/adolescents for case management approach (monthly)

**Lists of PLHIV under these groups should be shared by ART centre and feedback provided by CSC on a weekly basis.*

10.3.5 Meetings to address the gaps in CSC Services

ART-CSC Coordination Meeting: The ART and CSC will have a coordination meeting in each month which will be led by the Nodal officer/SMO/MO in charge of ART centre. DAPCU, ART staff, CSC team should participate.

The nodal officer may involve other stakeholder if s/he feels so by including individual/organization which would enhance the care and support services. The aim of this meeting is to validate the progress made by CSC team on last month and give suggestion/inputs on plan of action. SACS must keep a tracks so that meetings happen as per prescribed frequency, in a structured manner and actions taken in timely manner

Frequency	• Once in a Month (Preferably 5th of every month)
Line list to be cross verified and feedback entered in ART records	• List of - to be initiated on ART - newly initiated on ART - On ART MIS - On ART LFU - PLHIV virally unsuppressed or those with <80% adherence - PLHIV with advanced HV disease/comorbidities and children/ adolescents • MPR of CSC, feedback of tracker after outreach activities
Points to be discussed	• Cross referrals between ART centre and CSC • Progress made on MIS and LFU tracking • Any barriers made known at field level are to be shared with ART centre • Any other locally relevant issues

State Oversight Committee (SOC) Meeting: This committee consists of SACS and CSC officials, conducts half yearly meeting to review the CSC programme in the state and addresses the gaps and challenges in its implementation.

PART II :
GUIDELINES FOR IMPLEMENTATION OF SERVICE DELIVERY MODELS

CHAPTER 11
SETTING-UP ART CENTRE

This chapter describes step wise approach for setting up ART centres.

11.1 Steps for Setting up ART centres

Provisional identification of the site for setting up ART centre is done while finalising annual action plan for the state. The steps for setting up new ART centre are discussed below.

Activities	Responsibilities
Step 1. Identification of the proposed site for the new ART centre	SACS (discussion with NACO during AAP planning)
Step 2. Provisional sanction (during April every year as per annual action plan (AAP)	NACO
Step 3. Meeting between SACS, Dean/Med. Superintendent, HOD (Med.) of proposed ART centre and DAPCU/Regional Coordinator (CST), NACO to identify the space for centre and to constitute ART team	SACS/RC/Institution/ DAPCU
Step 4. Feasibility visit of the site by an expert team constituted by SACS/DAPCU/ RC and approved by NACO	NACO
Step 5. Submission of feasibility report in prescribed format to NACO	Expert team
Step 6. Issue of final sanction after examination of feasibility report	NACO
Step 7. Opening a bank account and release of funds to the centre by SACS (for initiating refurbishment etc.) *Not applicable for PPP model ART centres under NACP not financially supported by NACO*	Institution/SACS
Step 8. Training of ART team (multidisciplinary faculty team)	NACO/SACS
Step 9. Recruitment of contractual staff at ART centre (by steering committee at the institution as per operational guidelines for ART centres)	Institution/DAPCU/SACS
Step 10. Refurbishment of ART centre	Institution
Step 11. Training of all contractual staff recruited	NACO/SACS
Step 12. Provision for CD4/VL testing/linkage plan	NACO (Lab Services)/ SACS
Step 13. Linkage with NACO IMS and supply of M&E tools	NACO & SACS
Step 14. Visit to ART centre after final sanction, recruitment of staff, refurbishment has been done	RC/SACS/DAPCU
Step 15. Supply of ARV drugs to new centres	NACO/SACS
Step 16. Operationalization of ART centre	Institution/SACS/DAPCU
Step 17. ART centre to be declared functional (after receipt of first Report/MPR in IMS at NACO)	CST Division, NACO

Note: *The steps from number 7-14 are to be done simultaneously and not sequentially. However, it should be ensured that time interval between the recruitment of contractual staff and operationalization of the centre is not too long. For example, if refurbishment is likely to take long time, the staff should be appointed close to the time it is likely to be completed. Meanwhile if the staff has been appointed and centre not ready, the staff should be deputed to a nearby centre for hands on training.*

11.2 Criteria for Site Selection for ART centre

The following criteria are recommended for site selection to set-up ART centres in government as well as non-government sector.

1. Districts/Regions with high HIV prevalence

- Districts/ Regions with high HIV sero-prevalence at ICTCs (> 500 positives detected over the last five years in the catchment area)
- Geographic distribution of existing CST facilities in the state and their catchment area to be considered while proposing new ART centres
- Proposed site should be accessible and well connected by public transport
- Sites for centre to be carefully mapped to avoid any duplication of facilities
- *The above criteria may be relaxed in hilly terrains, desert areas, tribal regions and other areas with difficult accessibility*

2. LAC/ LAC plus centre with high patient load may be considered for upgrading as ART centre subject to availability of basic minimum infrastructure and other facilities/services
3. In medical colleges, as per MCI guidelines (as per the Gazette of India issued the Board of Governors in supersession of Medical Council of India)
4. Willingness and capacity of the institution where ART centre is proposed, to be assessed after site identification, based on the following parameters:
    - Services provided and human resource available in critical departments in the hospital (medicine, microbiology, obstetrics & gynaecology, paediatrics, dermatology/venereology) to be taken into consideration
    - Availability of adequate space for setting up ART centre within the hospital campus, preferably in/ near medicine OPD
    - Commitment and ownership by the institution to manage ART centres as integral part of hospital in terms of implementation of services provision of quality care to PLHIV, day-to-day functioning of centre, infection control practices, maintenance of hygiene and daily cleaning
    - Willingness to assign minimum one faculty from departments of medicine, paediatrics, obstetrics & gynaecology and microbiology to support the ART centre on a daily basis and also involve other faculty members/residents in the functioning of the centre
    - Willingness and preparedness to provide necessary investigations (except CD4 and viral load) free of cost to the PLHIV, essential drugs for the treatment of OI or management of adverse-effects available in the hospital pharmacy
    - Agreeing to follow ART technical and operational guidelines prescribed by NACO
    - Commitment to regularly provide information on facilities, services and outcomes in prescribed formats to SACS and NACO. Usually, the sites for ART centres are selected during the formulation of the annual action plan (AAP) for states but can be considered at any time based on need/justification.

11.3 Feasibility Assessment for ART centres

A feasibility assessment team comprising of officers from NACO/SACS and one ART expert visits the identified site after the provisional administrative sanction is issued for setting up new ART centre.

The team is finalized by SACS with the approval of PD. The team assesses feasibility of starting the ART centre based on the checklist (Annexure 16). The feasibility report is then submitted to NACO for the issuance of final sanction on examination of the report. SACS should ensure that a copy of the ART operational guidelines is shared with the identified institution prior to the feasibility visit. The institution should appoint HOD Medicine as **nodal officer for ART** (or a senior faculty member from department of medicine nominated by HoD). The identified nodal officer should be telephonically briefed by SACS/RC/TE on the purpose of visit so that probable sites within the institution and members of multidisciplinary "ART team" are identified prior to visit and meet all faculty members nominated to be part of "ART team".

The feasibility team shall visit the site at the institution on a prefixed date. They will also meet the head of the institution and the multidisciplinary team besides visiting the proposed site for ART centre. Written consent of the institution for rolling out of ART services in accordance with the operational and technical guidelines needs to be taken. Space, commitment, availability of free investigations and hospitalisation without discrimination are key criteria for approval by the team.

11.4 Preparedness of Institution

Once final sanction is accorded to an institution to establish an ART centre, the team of 10 (or more) faculty members from the departments of medicine, paediatrics, obstetrics & gynaecology, surgery, microbiology, biochemistry, pathology, chest & TB, community medicine and dermatology (and/or venereology) constituted by the hospital during feasibility visit is deputed for blended training curriculum of NACO. In case of ART centres in district hospitals and other peripheral health facilities, the number of specialists in the team can be relaxed to 5-6. The team is to be headed by the head of the institution (Dean/ Medical Superintendent/CDMO). The nodal officer is either the Head of Department of Medicine (or a senior faculty of the department of medicine, designated by the HOD as the nodal officer). For day to day functioning, nodal officer may designate a deputy nodal officer from the department. In case of district hospitals, senior most physician will be the nodal officer. In case physician is not available, paediatrician may be the nodal officer of the ART centre at such facilities. Medical officers and other contractual staff appointed in the ART centre will also undergo induction training at NACO designated ART training institutes. The CST official at SACS/RC/TE shall visit this site again and report to NACO if the centre is ready to start functioning in the prescribed format (Annexure 17).

11.5 Support from the Institution

ART centre is an integral part of the institution and the hospital administration should provide support for smooth implementation of services as well as for providing quality care to PLHIV without stigma and discrimination. Faculty members and residents from departments of medicine, paediatrics, and other departments should be involved to support the ART centre on a daily basis. The institutional ownership to run ART centres as integral part of hospital, in terms of day-to-day functioning of centre, infection control practices, maintenance of hygiene and daily cleaning etc, is critical. There is no separate provision for cleaning staff/attendant from NACO/ SACS and this is responsibility of the institution. The level of hygiene and cleanliness of the ART centre should be of the highest standards, keeping in mind the lowered immune status of people living with HIV/ AIDS.

All laboratory investigations at baseline and for monitoring (follow-up) of PLHIV shall be done free of cost. All investigations, other than CD4 and VL testing, shall be done by health facility where the centre is located. No additional funds shall be provided from NACO for baseline investigations and follow up investigations. Support for CD4 and viral load testing shall be provided by NACO/SACS.

It is of utmost importance that the ART centre is run with positive and synergistic team spirit. While job responsibilities outlined in these guidelines are desirable in an ideal situation, the nodal officer can redistribute the tasks in a given situation and specific requirements in a manner that would improve the quality of services provided by the centre.

11.6 Infrastructure

11.6.1 Location and access to ART centre

The ART centre should ideally be located near the Medicine OPD. If this is not feasible, a suitable place should be identified within the same campus which is accessible to patients keeping in mind cross-referral to and from various departments. Signage depicting directions to the ART centre should be clearly placed in the institution at strategic locations, including ICTC, so that there is no difficulty in locating the centre within the hospital. Such signages shall be designed and put in place by the SACS/ART centre at strategic points. All signages should have ART logo "**We Care for You**" in the display board.

11.6.2 Space for ART centre

A minimum of 1000 square feet area is required for an ART centre expecting on an average 500 patients on ART. However, more space needs to be identified in the beginning itself if anticipated patient load is more than 500. This anticipation needs to be done at the time of feasibility visit and required area to be identified in the beginning in order to avoid congestion in the centre at a later stage. Scope for further expansion of the centre should also be considered while selecting the sites. Sample floor plan for ART centre is placed at **Annexure 18**. It should have adequate number of rooms/cabins each measuring at least ten feet by ten feet (10' x 10') for the following staff/services listed below:

1) Examination room: for medical officer to examine the patients (1 for each MO).
2) Counselling room: for individual, group and family counselling (1 counsellor per room).
3) Pharmacy: for storing ARV & OI drugs with a window or counter for dispensing the drugs. The medicines should be stored in a manner that is safe from theft, direct sunlight, exposure to moisture, rodents and other factors that could harm or destroy the drugs. Ideally these should be stored in hospital store and indented on monthly/ need based manner.
4) Laboratory: for collection and storage of samples and carrying out tests by the lab technician.
5) Office Space: for registration, record keeping and data entry by data manager.
6) Waiting area: There should be adequate area where patients and accompanying persons can wait and where group counselling can also be conducted. Television and other audio-visual facilities should be installed here for patient's educational purposes. IEC material should also be displayed in this common waiting area. Attention should be paid to avoid the air borne infection by adhering to infection control and prevention practices such as adequate ventilation/windows, seating arrangement with physical distancing etc.
7) Considering the specific need of the ART centre based on expected patient load, adequate space should be identified and made available.
8) It must also be ensured that adequate toilet facility is made available for the patients visiting the centre.
9) Provision for clean drinking water also needs to be ensured.

The ART centre should be kept neat and tidy and should maintain highest standards of cleanliness and hygiene, have proper ventilation, lighting, electric supply and water supply for effectively carrying out examination, counselling, laboratory tests and record keeping while helping to prevent the spread of nosocomial infections.

11.6.3 Furniture and general equipment

The ART centre should be furnished adequately from the grant to the ART centre as per the financial guidelines discussed in the finance section and must have the following:

1) Tables, chairs and other seating facilities for staff and patients.
2) Examination table with side screens, pillow, rubber sheet etc.
3) Office shelves for supplies, records and stationery, drugs storage etc.
4) Appropriate furniture for computer and printer and office stationaries.
5) Secured cupboards (with locks) for storing patient records, ARV drugs and other medicines, laboratory kits, consumables and other equipment.
6) Appropriate bins and covers for waste disposal systems.

These items are to be initially procured from the one-time grant of Rs. 2 lakhs provided to ART centre at the time of establishment.

The need for refurbishment, furniture, equipment, computers should be assessed on regular interval (ideally annually) by nodal officer. The procurement of necessary things for ensuring smooth functioning of ART centre and quality care of PLHIV should be done whenever required from the funds available under AAP with approval from PD SACS.

11.6.4 Medical equipment and accessories

A set of general medical equipment like a weighing machine, height measurement pole, blood pressure (BP) apparatus, stethoscope, tuning fork, hammer, torch, tongue depressor should be available for each medical officer at the ART centre. Ophthalmoscope, pulse oximeter, digital camera can also be purchased. These items should ideally be provided by the hospital but if not possible, then can be purchased from the one time grant as well as the recurring grant for the centre. All these items should be recorded in the fixed asset register available with the data manager at the ART centre. ART centres are not allowed to purchase EPABX, photocopier, and laptop. In addition, IEC material such as models and charts, demonstration and counselling aids, like penis model for condoms should be made available at the centre by the SACS.

11.6.5 Linkage for CD4 and VL testing

All PLHIV should get the CD4 count and VL test done as per guidelines. Each ART centre should have access to CD4 testing either directly or by a clear linkage mechanism for regular and uninterrupted testing. All ART centres should also have linkages for VL testing, as specified by NACO/SACS. The centre must follow the SOP for specimen collection and transportation (and not patients) from testing site to the identified testing facilities. The CD4/VL testing facilities should be utilised optimally. All ART centres should also have linkages for VL testing.

11.6.6 Computers, accessories & audio-visual equipment and internet

All ART centres are provided with funds for the procurement of a desktop computer, printer, web camera, speaker and UPS in the initial one-time grant. The computer, other hardware and internet should conform to currently acceptable specifications as per specifications given at Annexure 19. In addition, a broadband connection with minimum 30 Mbps unshared connection or other (if broadband is not available in the concerned town or city) internet connection. Internet connection (router) should be connected with UPS for uninterrupted sessions. Expenditure on Internet connection including recurring expenses can be incurred out of the operational cost provided to the ART centre every year. An external hard disk of at least 500 GB should be purchased by the centre from the operational grant for keeping a backup of all data stored in the computer.

Apart from all these the following free software's should also be available

1) WinRar (freeware)
2) Team viewer (freeware)
3) PDF reader (freeware)
4) Antivirus (freeware)
5) Browser

Additional computer, printer and scanner can be procured from annual recurring grant whenever second data manager is appointed or as required. For educational purpose, a TV should be procured and installed in the waiting area for display of IEC material. This should be procured from initial one time non- recurring grant.

Apart from internet connection, ART centre should have phone connections for external and internal (hospital) communication. The phone number and email of the centre should be displayed at a prominent place in the waiting area.

11.6.7 Final operationalisation of ART centre

The ART centre after initial preparatory work like refurbishment of the centre, purchase of furniture, recruitment & training of contractual staff, supply/linkage of CD4 machine etc. have been done shall be again inspected by RC/SACS official. Only after receiving a satisfactory report from the team, the centre shall be supplied with ARV drugs and declared as functional after submission of first monthly report.

11.6.8 Display of information

Proper display of the following in the ART centre should be ensured:

1) The ART logo "**We Care for You**" at the entrance of the centre
2) Name and designation of all the staff in the centre including nodal officer
3) The timings of the ART centre along with list of holidays displayed in bold letters in local languages
4) List of facilities/ services available in the ART centre
5) The list of nearby ART centres, LACs, LAC plus centres, CSC and other facilities
6) Information on fast tracking of patients with respiratory symptoms, pregnant women, children and elderly
7) Request patients to report to the ART centre in case of change of contact details
8) The SACS shall prepare standard boards for display of such information at all ART centres
9) Information regarding various welfare schemes provided by different government departments and other agencies to PLHIV
10) IEC materials developed by NACO/SACS related to care, support & treatment and other services
11) Instruction to the patients to report to the "Emergency/Casuality" in case of any complication/emergency

11.6.9 Installation of complaint/ suggestion box

A complaint/ suggestion box (along with paper and pen) must be installed in the waiting area of ART centre so that it is visible and accessible to PLHIV. It should be opened in the presence of the nodal officer weekly. All grievances that can be resolved locally must be disposed at the centre itself. Serious or unresolved issues, if any, must be referred to/taken up in the **State Grievance Redressal Committee** (SGRC). A register should be maintained where all complaints received and action taken should be entered. PLHIV Network/ KP members should be involved in the meetings for review of grievances at the centre.

11.6.10 Working hours & holidays

Working hours for ART centre are from 9 am to 4 pm or (8:00- 3:00 pm) with a lunch break for half an hour. In case the OPD closes at 2 PM, the ART centre should still be open till 4 PM for updation of records. All records should be completed on the same day after disposal of patients.

If the hospital follows OPD split timings (like Gujarat, Rajasthan), ART centres timings should be aligned with those timings, but the total working hours should not be less than 7 hours.

The ART centre will observe same holidays as the medicine OPD of the institution. The ART centre shall remain closed on Sundays and other gazette state holidays. In states where medicine OPD is open on public holidays, ART centre should also be open and half of the staff should be present at the centre (on rotational basis).

CHAPTER 12

CENTRE OF EXCELLENCE AND ART PLUS CENTRES

12.1 Centres of Excellence (including Paediatric Centres of Excellence)

12.1.1 Background: The HIV/AIDS epidemic has progressed into a more complex one necessitating comprehensive care, effective health delivery systems, trained and motivated workforce and operational research. PLHIV have a varying need ranging from management of advanced disease, complicated OI, HIV related illness, coinfections and comorbidities. Therefore, HIV care requires a comprehensive care approach that meets the multitude of care challenges. Also, constantly evolving HIV treatment guidelines and patient management protocols require continuous training and upgrading of skills among providers. Hence, the model of Centres of Excellence (CoE) in HIV care were established in 2008 to serve as model treatment centres, impart high quality training and undertake operational and clinical research . Currently, eleven Centres of Excellence (CoE) and seven paediatric Centres of Excellence (pCoE) are functioning and are providing comprehensive HIV care over the years including ART, support and treatment and have been involved in training and research (list of CoE and pCoE along with state linkage plan given as Annexure 20). Paediatric centres primarily focus on care, research and training pertaining to paediatric aspects. ART centres are integral part of the overall CoE/ pCoE functioning for a given institution.

12.1.2 Objectives of CoE model

- To serve as model centres for comprehensive HIV care, support and treatment, referral and capacity building
- To strengthen the capacity of other institutions/health facilities to provide high quality HIV care through mentoring and monitoring support
- To build capacity of health system / HIV facilities to carry out operational research in HIV care, support and treatment
- To provide necessary technical support to national programme (NACO and SACS)

12.1.3 Functions of CoE

12.1.3.1 Medical functions

In addition to the existing functions of ART centres, CoE will also perform the following functions:

- Provide comprehensive care to PLHIV
- Diagnose and manage complex OIs, HIV associated illness and ART related adverse effects/ complications from their ART centre or referred from other linked ART centres etc.
- Conduct SACEP meetings to review the patients referred with treatment failure and severe drug adverse effects and provide recommendations to referring ART centre
- Feedback/follow up with referring ART centres as per SACEP recommendations/mentoring of linked ART plus centres
- Enhance and improve functioning of the institutional ART centres for optimal service delivery and to serve as model centres in HIV care, support and treatment for referral and trainings
- Coordination with and referral to other specialty departments as per requirement

12.1.3.2 Training and mentoring functions

- Training of different categories of health care providers as per prescribed NACO curriculum through designated faculty / national trainers.
- Facilitate the blended clinical trainings in the region and monitor the progress of the participants on completion of courses
- Mentoring of attached ART centres/ART plus centres through telemedicine / e-discussions / case-based learning/ distance learning sessions / sharing of good practices / CMEs / feedback / onsite visits etc. on clinical as well as programmatic issues for quality improvement
- On-site visit/ virtual review to the ART centres attached to the CoE to review performance and provide support for gap mitigation, in coordination with SACS
- Conduct Post Graduate Diploma Programme in HIV Medicine (PGDHIVM) started by NACO in collaboration with Indira Gandhi National Open University (IGNOU)
- Mentor ART plus centres to execute regular SACEP and provide technical support to strengthen the technical competencies of the ART plus centre staff

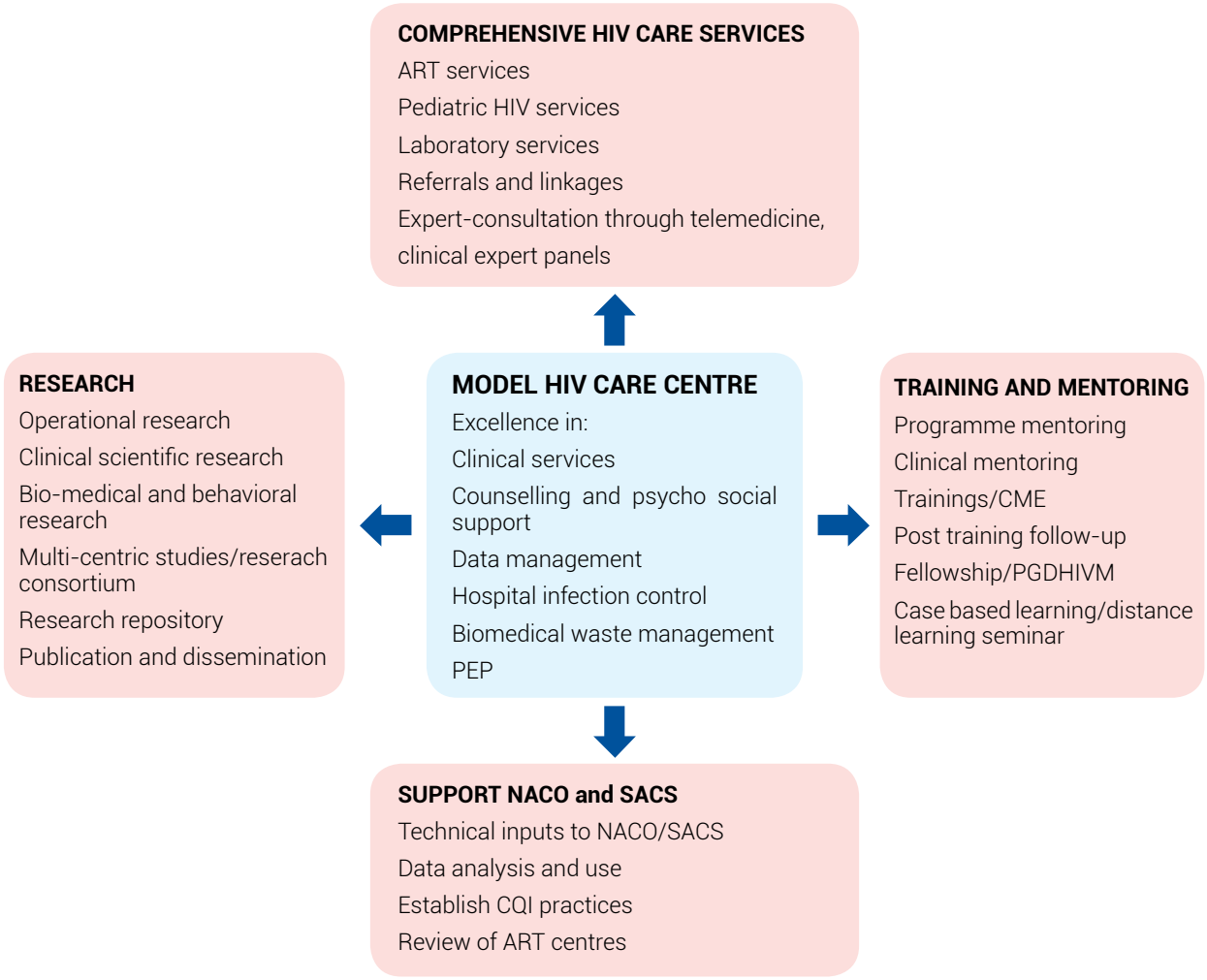
12.1.3.3 Research related functions

- In depth analysis of data of various services including ART centres linked to them
- Conduct operational research for National AIDS Control Programme (NACP)
- Serve as repository of information related to HIV/AIDS
- Plan research activities for the CoE and attached ART centres in consultation with NACO/SACS
- Support SACS in analysis of routine programme data to monitor performance of ART services and take corrective actions
- With prior approval of NACO, build partnerships with organizations for multi-site and multi-country collaborations for research studies

12.1.3.4 Technical support to national programme

- Provide technical inputs to NACO/SACS in formulating / modifying national policies
- Support NACO/SACS in data analysis and use for programme improvement
- Help in establishing and improving CQI practices at the ART centres through on-site/virtual mentoring
- Support SACS to review performance of ART services; plan and implement corrective actions

Figure 16. Functions of centres of excellence



12.1.4 General guidance for CoE functioning

Institutional commitment and ownership are must for optimal functioning of CoE. The head of the institution (Dean/Principal/Medical Superintendent) is the overall in charge of the CoE. However, day to day functioning of the CoE is supervised by Programme Director/Deputy Programme Director. The institution should provide necessary infrastructure and other resources for the smooth functioning of the CoE. ***CoE is upgradation of the ART centres for providing excellent comprehensive HIV care services to PLHIV and ART centres of such institutions are considered as ART plus centres for all operational and administrative purposes. There should be a functional integration of ART centre with CoE including task sharing by staff (particularly SMO/ MO/Research Fellow-Clinical).*** In addition, CoE should be linked to department of paediatrics, ANC services, services under NTEP and other national programme, NCD, laboratory services and inpatient care to ensure comprehensive HIV care. To ensure holistic services, CoE should coordinate with care and support centre (CSC), Link ART centres (LAC), ART plus centres etc. and outreach services. Staff of the institution should be trained and/or sensitised in paediatric HIV service delivery as well as to reduce stigma and discrimination.

12.1.5 Human resources at CoE and their roles and responsibilities

Faculty members and residents of the institution should support the functioning of the CoE. Efforts should be made to involve as many faculty members in the functioning of CoE so that there is greater ownership of the centre by the institution. ART centre staff will also be part of CoE. Additional staff for the functioning of the CoE will be provided by NACO as per approved scheme.

Staff of the institution should be sensitized and trained in HIV service delivery as well as to reduce stigma and discrimination. Training in HIV should be provided on mainstream HIV knowledge and skills to all medical and paramedical staff in the institution. This will ensure that all departments deliver HIV services in a comprehensive and integrated manner.

Steering committee

It should be constituted at CoE and headed by the head of the institution. Members of this committee should include the Programme Director (CoE), Deputy Programme Director (CoE), APD/CST in charge of concerned SACS and a NACO representative/RC (CST). This committee should meet once in 3 months for review and ensure smooth functioning of the CoE.

CoE team

The "CoE team" in the institution is a multidisciplinary team headed by the head of the institution (Dean/ Principal/Medical Superintendent/CMO). It should consist of trained faculty from the departments of medicine, microbiology, obstetrics & gynaecology, paediatrics, community medicine, dermatology and venereology. In paediatric CoE, involvement and contribution of faculty from paediatric sub-speciality departments within the institution on paediatric HIV care is expected. This team should meet quarterly to review the functioning of the CoE. Members of this team will also be engaged as resource persons in various training programmes organized by NACO/SACS after their certification as national trainers.

Each CoE will have one programme director and one deputy programme director and they will be identified from the institution in consultation with the head of the Institution.

Programme Director CoE

The roles and responsibilities of Programme Director are the following:

- Person in-charge of the CoE and all activities related to the CoE and the ART centre including comprehensive HIV care, SACEP, training, post graduate diploma in HIV medicine (PGDHIVM), mentoring and research;
- Responsible for all administrative issues related to the CoE;
- Provide strategic direction to the plans and activities of the CoE;
- Devise work-plans and timelines for moving activities forward;
- Ensure timely implementation and reporting of all activities related to CoE and ART centre including comprehensive HIV care; training, mentoring, and research;
- Ensure functional integration of ART centre with CoE including task sharing by staff;
- Focal person for all communication and correspondence related to functioning and activities of CoE with NACO/SACS/other linked facilities etc.;
- Oversee reports on CoE activities, training and other critical issues;
- Maintain financial control and monitors CoE budgets on a periodic basis to make sure that budgets are spent according to approved allocation;
- Provide inputs to NACO and SACS on technical issues;
- Conduct need based visits/ virtual mentoring to the attached ART centres and provide feedback to SACS based on the observations so that corrective measures can be planned;

Deputy Programme Director CoE

Deputy Programme Director will coordinate and facilitate the functioning of CoE along with Programme Director CoE. S/he will represent the Programme Director in his/her absence.

Additional staff at CoE

In addition to the staff available with ART centre, the CoE would be provided additional human resource on contractual basis. Contractual appointments for the CoE will be carried out by the steering committee. The procedure for the selection of contractual staff for CoE shall be similar as is done for the ART centres. There shall be periodic performance assessment for CoE staff. Extension of the contract of the staff will be purely

based on this assessment (PMDS form). The following are the contractual positions provided for CoE. For details on the qualifications/eligibility criteria, roles and responsibilities and recruitment process, please refer to the Section 13.5.

a) Research fellow (clinical)–1

b) Research fellow (non-clinical)–1

c) SACEP coordinator–1

d) Data analyst–1

e) Training and mentoring coordinator–1

f) Laboratory technician–1

g) Nutritionist–1

h) Social workers/outreach workers–2

Additional staff at pCoE

a) M&E and research officer –1

b) pCoE coordinator–1

c) Nutritionist–1

12.1.6 Infrastructure at CoE

The institution must provide adequate infrastructure for the CoE, ART centre, ICTC, paediatric care, PPTCT services, laboratory services and in-patient services. The institute should provide adequate space and preferably a basic structure that could be developed into a proper centre with assistance from NACO to have provision for the following:

- Office space
- Facilities for SACEP review
- Facilities and equipment for training, telemedicine/teleconference and research
- Library with internet
- Other facilities as per requirement/scheme

12.1.7 Services at CoE

CoE should serve as model centres in HIV care and should demonstrate best practices and function as a site of learning for the attached centres and lead the attached ART centres by example and provide every assistance and support to them so as to improve the quality of care rendered at these centres. All CoE should serve as "**model HIV care centre**" and should have excellence in following domains:

- Clinical services
- Counselling and psychosocial support
- Data management
- Hospital infection control
- Biomedical waste management
- PEP

The following services should be made available at the CoE:

a) Comprehensive HIV care services, including clinical expert panel

b) Training and mentoring

c) Research

d) Technical support to national programme

a) Comprehensive care

Comprehensive care includes provision of ART, along with management of advanced disease, complicated OI, HIV related illness, coinfections and comorbidities. Comprehensive care needs to be adequately supported by in-patient management, laboratory and diagnostic services (to diagnose and manage OIs and side effects/ complications) and referrals & linkages. PLHIV should not be denied for any required service such as surgery, in-patient admission, obstetric services, etc at any stage.

i. ART services: CoE and ART staff should work together to impart ART services to enhance and improve functioning of the ART centres for optimal service delivery. All staff of CoE should be involved in the routine activities of the ART centre apart from their assigned job responsibilities. Similarly, SMO/MO (by rotation), nurse and pharmacist of the ART centre should be available for SACEP related activities. CoE are also required to provide feedback to referring ART centres on SACEP recommendations and follow up the patients accordingly.

Paediatric HIV care: pCoE/paediatric department of the CoE should be involved in paediatric HIV care at the CoE. The Programme Director of pCoE/paediatrician from CoE multi-disciplinary team should be a member of the SACEP.

In-patient care: Patients referred from attached ART centres to the SACEP may need in-patient care for management of complications, severe OIs or severe adverse effects. The CoE should function as the tertiary referral centre taking care of the complicated cases referred to the CoE from other ART centres.

ii. Expert-consultation through tele medicine: CoEs should provide guidance and expert consultation to ART centres and link ART centres for management of complicated cases or any other query related to patient management using virtual platforms/telemedicine facility/WhatsApp groups/phone call.

iii. Clinical expert panel: Details of SACEP are provided in Section 6 on, provision of second line and third ART'.

b) Training and mentoring

The institute should have the capacity to undertake training and mentoring activities. CoE should also have facilities for teleconference/telemedicine and distance education programs to complement its training and mentoring activities.

i. Training:

Undertake training of different categories of health care providers as per prescribed NACO curriculum through designated faculty/national trainers. CoE should facilitate the blended clinical trainings in the region and monitor the progress of the participants on completion of courses. The CoE should be able to perform training evaluations, do post training follow-up activities and provide technical updates to trainees. The training reports are to be submitted to NACO in prescribed format.

The CoE should have a list of trained and experienced faculty, who will serve as 'Master Trainers' for the trainings conducted at the CoE/other CoE and for national training programmes. Only those trainers identified, trained and certified by NACO as 'Master Trainers' shall be engaged as resource persons in trainings conducted at the CoE. The core faculty shall also be part of the national training resource pool and should contribute regularly to development, revision and updating curricula, training and mentoring and participate in programme management and policy decisions as and when required in close coordination with NACO. The CoE may be involved in orientation/refresher trainings for Regional Coordinators, officials of CST of the SACS and other stakeholders as and when required. CoE may also organize CME programmes, conferences, courses on research methodology, scientific writing and scientific workshops. CoE should conduct post graduate diploma programme in HIV medicine (PGDHIVM) started by NACO in collaboration with IGNOU.

ii. Mentoring Rapidly evolving

patient management guidelines and decentralization of HIV care, support and treatment services necessitates for continuous mentoring of health care providers to keep them updated and motivated so that they can perform their duties efficiently and effectively. CoE should plan, organize and carry out both programmatic

and clinical mentoring to improve quality of ART services. A core group of mentors need to be identified and trained on mentoring. This team of mentors will comprise of programme director, deputy programme director, faculty, ART SMO/MO, research fellow, data analyst. Mentoring shall be for ART Plus centres, ART centres, LAC, LAC plus, CSC linked to the CoE and for the trainees from the same institute and other facilities.

Mentoring by CoE should be done with following objectives:

- support decentralized delivery of high-quality HIV prevention and care, support and treatment services at all levels
- support the application of classroom learning to clinical care
- maintain and progressively improve the quality of care using measurable indicators
- improve the motivation of health care workers
- mentor ART plus centres to execute regular SACEP and provide technical support to strengthen the technical competencies of the ART plus centre staff

Modes of mentoring: Mentoring support can be provided through on-site visits or distance mentoring.

On site mentoring: On-site mentoring shall be done through site visits by the mentor. During these visits, mentors may:

- provide direct one-on-one mentoring of health care workers during patient consultations.
- conduct short training sessions for staff on various HIV topics.
- lead case discussion training sessions highlighting management of complex cases.
- identify and address system challenges that affect the provision of quality care, such as patient flow, tracking defaulters, referral and record-keeping systems.
- supervise completeness and correctness of data entry and other M&E tools in all registers/software etc.

Distance mentoring: Distance mentoring can be done through virtual meetings with sites/telemedicine/ e-discussions/case-based learning/**distance learning seminar (DLS)**/email/phone call etc. The CoE may choose one or more of these techniques or may devise any other modalities of their own to achieve the goal of distance mentoring.

SACEP meetings also provide opportunity to CoE to understand functioning of referring ART centres regarding patient preparedness, adherence counselling, clinical management practices being followed. CoE can mentor these ART centres through structured feedback and follow-up on referrals made to SACEP. Tele-SACEP may be considered to provide real-time mentoring and feedback to referring ART centres. Further role of CoE in mentoring and monitoring are provided in Section 18.4.

c) Research

CoE should function as primary sites for undertaking operational research for the National AIDS Control Programme. Research prioritized by NACO should be undertaken by CoEs. Each CoE should ideally participate in at least one major operational research (for the CoE and attached ART centres) every year that addresses the impending needs of the national programme so as to be helpful in formulating / modifying national policies, in consultation with NACO/SACS. The CoE should participate in pilot research projects and multi-centric studies as identified by the programme. CoE shall serve as repository of information related to HIV/ AIDS. CoE may build partnerships for multi-site, multi country partnership with prior approval of NACO for research studies planned.

The CoE should assist NACO in reviewing projects / proposals received from SACS, HMSC, ICMR and other collaborative agencies. Staff of the CoE should form a peer group to provide technical assistance to the research activities at NACO.

The CoE should have the capacity to undertake analysis of data of various services, particularly of the attached ART centres. under their mentoring.

Research related trainings: The CoE may conduct trainings that help improve the capacity for doing research. These trainings will focus on research methods, data analysis and technical writing. The target audience for such trainings will be programme directors, deputy programme directors, clinical and non-clinical research fellows and data analysts from the other CoE. These trainings could be offered to other staff within the institution and can be facilitated by staff of the CoE.

d) Technical support to national programme

Based on evidence, data analysis and clinical experience, CoE should provide technical inputs to NACO/SACS in formulating/modifying national policies. The expertise at the CoE should be available for NACO/SACS to support data analysis and use. CoE by means of on-site/virtual mentoring to the ART centres should help in establishing and improving CQI practices. CoE should support respective SACS to review performance of ART services and provide support for gap mitigation.

Details can be referred to "Scheme for Centres of Excellence in HIV Care, January 2012" and "Scheme for Paediatric Centres of Excellence in HIV Care, 2011".

12.2 ART Plus Centres

Patients experiencing treatment failure are required to be reviewed by SACEP for switch to appropriate ART. Therefore, NACP rolled out the model of ART plus centres to expand the network of facilities for review of patients with suspected treatment failure or severe adverse effects for further evaluation and timely switch/ substitution. Select ART centres across the country have been identified as ART Plus centres and trained to conduct SACEP review, following the same referral procedure as adopted for the Centres of Excellence.

With the scale up of VL testing, number of PLHIV requiring SACEP review/ expert consultation is increasing. Therefore, NACP has decided to decentralize the SACEP by expanding the ART plus centres.

12.2.1 Objectives of ART plus centres

- Serve as referral centres in HIV care, support and treatment for management of PLHIV with complex OIs, HIV associated illness and ART related adverse effects/complications
- Decentralize SACEP review for patients with treatment failure or severe drug adverse effects
- Strengthen the capacity of attached ART to provide high quality HIV care through mentoring and monitoring support

12.2.2 Eligibility criteria

- Criteria for selection of ART centres for up-gradation to ART plus centres is as follows:

- All ART centres in medical colleges
- ART Centres in select district hospitals with patient load >3000 on ART, if there is no medical college in the same district. Criteria may be relaxed in hilly terrain and hard to reach areas.
  - Prior to this up gradation, feasibility assessment (Annexure 21) should be done by SACS and approval should be taken from NACO. Also, appropriate capacity building activities for SACEP and other technical areas should be considered.
  - While planning for upgradation of ART centres into ART plus centres the following criteria to be fulfilled:
    - Willingness of the institution
    - Active involvement of nodal officer in the functioning of ART centre
    - Identification/nomination of SACEP members by institute
    - Willingness of SACEP team members to undergo training

12.2.3 Functions of ART plus centre

i. Medical functions: In addition to the existing functions of ART centres, ART centre will also perform the following functions:

- Provide comprehensive care to PLHIV
- Diagnose and manage complex OIs, HIV associated illness and ART related adverse effects/

complications from their ART centre or referred from other linked ART centres etc.

- Conduct SACEP meetings to review the patients referred with treatment failure and drug adverse effects (Details in Section 6)
- Counselling, monitoring and follow up of PLHIV on alternative first line and second/third line ART
- Feedback/follow up with referring ART centres on patients as per SACEP recommendations/mentoring of linked ART plus centres
- Select ART Plus centres shall be authorised to do prescription of 3rd line ART after e-review (e-referral /telemedicine). These ART plus centres shall be selected (based on capacity and functioning of SACEP) by SACS in consultation with CoE (checklist at Annexure 22)

ii. Training and mentoring functions

- Facilitate the blended clinical trainings in the region and review the progress of the participants
- Mentoring of attached/linked ART centres through telemedicine/e-discussions/distance learning/ sharing of good practices/onsite visits etc.

12.2.4 Roles and responsibilities ART plus centre staff with respect to SACEP review

- Nodal officer would be overall in charge for smooth functioning of SACEP and involvement of institutional faculty
- SMO/MO in charge shall support the proceedings of SACEP meeting with support of staff nurse/ counsellor
- Data manager at ART plus centre shall download the patient information in SACEP meeting format for review during the SACEP meeting and share the SACEP recommendation with referring ART centre.

CHAPTER 13
HUMAN RESOURCES

13.1 ART Team

All institutions with ART centre should constitute a ten-member multi-disciplinary ART team headed by the Head of the Institution (Dean/Principal/Medical Superintendent/CMO). It should consist of trained faculty from the departments of medicine, paediatrics, microbiology, obstetrics & gynaecology, community medicine, surgery, psychiatry, chest & TB, dermatology, and venereology. If the ART centre is located at hospitals without the faculties from all specialties or at the district or subdistrict hospitals with limited specialists, five-six members may also constitute the team. This team should meet at least once in a quarter under chairpersonship of head of the institution (Dean/Medical Superintendent/CDMO) and discuss the functioning of the ART centre, inter departmental referrals/linkages and other relevant cross cutting issues to ensure stigma free high-quality treatment and care of PLHIV. The nodal officer of ART centre as a member secretary of the ART team should ensure that this meeting is convened once in a quarter. The meeting may also be combined with other institutional quarterly meetings of all these specialists. The SMO/in-charge MO of the ART centre should assist the nodal officer in preparing the meeting agenda before the meeting and minutes after the meeting. The meeting minutes should be circulated to all the members when signed by the head of the institution and a copy should be filed at the ART centre.

The ART centres in public health system are provided with contractual staff to support day to day functioning of the centres.

13.2 Recruitment Process for ART Centre Staff

For the contractual appointments, SACS or DAPCU or concerned Institute (under guidance from SACS) should give an open advertisement in local newspapers/SACS website/institution website in consultation with the concerned institution. Optionally, the advertisements should also be posted on the 'Notice Board' of the institution and if possible, should be circulated through emails to get good participation. Applications should be received at the institution (in the office of head of institute or department of medicine in the medical colleges). The designated person should check for the applicant's eligibility for the posts as per the advertisement.

A steering committee should be constituted at the institution where the ART centre is located. The institutional head (Dean/Superintendent) should head this committee. The nodal officer of the ART centre will be the Member Secretary of the steering committee and RC/SACS representative will be special invitee. This committee is the authority to make all contractual appointments/renewal of contracts for the ART centre. Interviews of eligible applicants should be conducted by the steering committee of the concerned institute to select the most suitable candidates. The offer letters of selected candidates should be signed by the head of the institute. The staff appointments should not be made by SACS centrally but in exceptional circumstances, SACS can do so after prior approval from NACO. As these appointments are to be made by the institution, the ART staff are not transferable from one centre to another. The day-to-day administrative control of contractual staff lies with the nodal officer. However, the staff is also accountable to the SACS and NACO. The staff should respond to their directives and/or guidance from time to time.

For the post of SMO/MO, walk-in interview can be conducted on the date specified in the advertisement. Aptitude of candidates should be given due weightage in the selection process. The institution shall send the list of selected candidates to the SACS for their information. However, appointment, performance appraisal and contract renewal will be done by the institution every year. All contractual appointment shall be made on yearly basis. A contractual service agreement (CSA) shall be signed between the institution and the concerned staff. For contractual staff, an annual appraisal system based on PMDS has been devised based on which continuation should be decided (Annexure 23). The steering committee can also terminate the appointment

at any time with due notice/ salary for notice period if a situation arises for it. The vacancy created should be filled up from either "wait list" of candidates (valid for 1 year) or through a fresh recruitment protocol as mentioned above. The upper age limit for contractual engagement of senior/medical officers in the National AIDS Control Programme is up to 70 years and for the other staff shall be as per state governments norms.

While there is provision of medical officer on contractual basis for ART centre through NACP, some states have also appointed medical officer from the state government to work at ART centres. The states are encouraged to post medical officers through regular cadre for ART centres in addition to the existing medical officer for uninterrupted patient care. In case, position of medical officer is vacant, it is the responsibility of the institute to manage the ART centre by deputing /posting doctor (medical officer/ resident) from the institute.

The leave entitlement of ART contractual staff (mentioned in the contractual service agreement) is as follows:

Annual/Accrued leave: Accrued leave will be credited in advance to the leave account of contractual staff as under:

a. 15 days leave on 1st April and 15 days leave on 1st October of the financial year and Sick leave of 10 days per annum.
b. Female contractual staff with less than two surviving children are entitled to 24 weeks of maternity leave with full pay. Alternate arrangement on locum basis in case of maternity leave or LWP

All ART centres should have an attendance register where all staff should sign daily at the time of coming and leaving along indicating time. After verification of the attendance from the register by the SMO/nodal officer, attendance should be sent to the concerned SACS. To avoid delay in salary disbursement, SACS will send the salaries directly to the account of ART centre staff through e-payment. Hence, the ART centre should send the attendance/leave record of each contractual staff in ART centre to SACS monthly.

13.3 Staffing Pattern for ART Centres

All ART centres are provided with manpower in proportion to the number of patients on ART at each centre. However, manpower structure for ART centres will be periodically reviewed and revised by NACO based on the increase in patient load and other requirements in the programme. (SACS/ Institutions are advised to follow the instructions of NACO in this regard from time to time). Currently approved staffing pattern for ART centre is as follows in the given table.

Table 18. Staffing pattern for ART centres

Position	Number of patients on ART					
	<500#	500-1000	1000-2000	2000-3000	3000-4000	4000 & above
SMO	SMO positions will be continued only at CoE and ART plus centres, where SACEP is functional.					
MO	1	1	1	2	2	2
Lab Technician*	1	1	1	1	1	1
Counsellor	1**	2	3	4	4	4
Pharmacist	0	1	1	1	1	1
Data Manager	0	1	2	2	2	2
Staff Nurse	1**	1	1	1	2	3
Inst. Nurse	0	1	1	1	1	1
Care Coordinator	0	1	1	1	1	1

#The current models of FI-ART (without LT) and HR lite ART centres are integrated into overall HR scheme of ART centres with low load (<500 PLHIV on ART).

**Additional lab technician to be appointed in centres with FACS calibur CD4 machines performing ≥1000 tests per month and in centres with FACS Count CD4 machines performing > 500 test per month.*

***At ART centre with patient load <500 (or FI ART centre) the counsellor shall function as counsellor cum data manager and will be responsible to carry out responsibilities of both. The staff nurse at these centres shall also perform CD4 sample collection and transport to the linked CD4 laboratory.*

Note: Staffing pattern/HR support is likely to revise under NACP V

13.4 Human Resources at ART Centres and their Job Responsibilities:

a. Nodal Officer of ART centre (Head, Dept. of Medicine/ another faculty member nominated by the HOD):

1. Overall responsibility of the functioning of the ART centre, reporting to NACO, participation in review meeting, coordinate and develop referral system and linkages with other departments of the hospital.
2. Supervise and mentor ART centre medical officers in clinical management of complicated cases including those with advanced HIV disease.
3. Ensure that PLHIV are not discriminated in the hospital and are not denied admission/care.
4. All administrative matters relating to the centre including sanctioning of leave of contractual staff, annual performance appraisal of the staff etc as per NACO guidelines.
5. Establish links with other facilities developed under NACP, NGOs, positive networks etc.
6. Ensure adherence to the highest standards of quality and excellence in patient care.
7. Review and monitor the functioning of the centre periodically in depth, and ensure submission of reports as required. Once in a week the nodal officer should sit with the ART staff to review the functioning of the centre, record completion, computerization, etc. The data manager should prepare minutes of the meeting and SMO/ MO should ensure that appropriate action is taken as per the minutes.
8. Scrutinize the monthly progress report of the ART centre, approve it and send to NACO.
9. Mentor and monitor the functioning of LACs attached to the ART centre. For monitoring and mentoring, staff from nodal ART centre, should visit the Link ART centre and the TA/DA for the same shall be paid from the operational costs provided at the ART centre as per the NACO/ SACS norms. If required, mentoring support may also be provided through teleconferencing.
10. Mentor and monitor the functioning of any differentiated ART delivery models linked to the ART centre.
11. Sign all documents related to referrals to SACEP at CoE/ART plus centres.
12. Ensure posting of other faculty members and resident doctors in the department to ART centre on rotation basis to ensure that every member is oriented in the functioning of the centre. A roster indicating name of faculty deputed on day to day basis and PG student's rotation to ART centre should be prepared every month and displayed at the centres.
13. Ensure multidisciplinary ART team meeting once in a quarter under the supervision of head of the institution.
14. Conduct annual performance appraisal of contractual staff based on PMDS format.
15. Make suitable alternative arrangement in consultation with the concerned SACS when female contractual staff proceeds on maternity leave.
16. Sign attendance of ART centre staff every month before it is sent to the SACS.
17. Conduct physical verification of the ARV drug stocks (once in 3 months) and sign the stock register.
18. Review the actions initiated on the complaints received in the complaint box from the PLHIV every fortnight.
19. Act as focal point for interaction with NACO/SACS/CoE etc.
20. Act as a team leader to constantly guide and mentor all ART staff.

b. Senior Medical Officer (SMO)

Eligibility criteria:

1) First preference should be given to candidates with MD in Medicine or any other clinical discipline

2) If candidate is not available as per para 1 above, candidates with MBBS + Diploma in any clinical discipline having minimum 3 years of experience can be considered

3) In the event of unavailability of candidates as per para 1 & 2 above, candidates with MBBS + Fellowship in

HIV Medicine/ PGDHIVM (IGNOU)/Diploma in Public Health having 3 years of experience can be considered for the post of SMO.

The candidate should have working knowledge on computer, MS office, usage of internet and electronic mail.

However, each proposal for relaxation of qualification as explained at para. 3 above should be sent to the Project Director of the concerned SACS for approval, provided that two earlier attempts failed to recruit SMO with qualifications as indicated at para 1 & 2 above. In case SMO cannot be recruited due to non- availability of qualified candidates, an MO can be recruited in place of SMO (and be given the salary of MO).

Job responsibilities

Medical responsibilities:

1. He/she should conduct the initial evaluation of PLHIV (clinical and lab) and initiate PLHIV on ART.
2. He/she should conduct the clinical and lab monitoring of PLHIV initiated on ART (including CD4 count, adherence, viral load testing and other lab investigation).
3. He/she should identify PLHIV with advanced HIV disease and ensure management of all patients with advanced HIV disease at ART centre or must ensure referral and linkages to appropriate facilities e.g. lab, in-patient departments etc.
4. He/she should refer difficult/ complicated cases to the nodal officer or other specialist for further expert opinion and interventions including admission and inpatient care, if required. It includes referrals to other departments for treatment of OIs, STI, etc.
5. He/she should provide OI prophylaxis and preventive treatment as per guidelines.
6. Prevention and management of TB coinfection: He/she should perform 4S screening and take decision about TPT initiation or referral for TB diagnosis for all PLHIV attending ART centre. Initiation of ATT, CPT and ART should be ensured, as per National Guidelines for HIV care and Treatment 2021.
7. He/she must update the prescribed columns in white cards and green books.
8. Ascertain eligibility for differentiated care (MMD, LAC, other DSD models).
9. He/she should refer "suspected/confirmed treatment failure" cases, "complicated cases" to the SACEP at the CoE/ART plus for screening and initiation/modification/switch of ART, if required. The nodal officer of the ART centre must countersign all such referrals
10. He/she should act as focal point for care of exposed babies and EID for HIV exposed babies found "reactive" with DBS at ICTC and referred to ART centre.

Administrative responsibilities:

1. He/she is the functional team leader of the ART centre under the overall guidance of the nodal officer. The SMO must supervise the administrative and medical functions of the ART centre on a day-to-day basis.
2. He/she should provide leadership to staff to work as a cohesive team and ensure implementation of national operational and technical guidelines.
3. He/she should ensure implementation of national operational and technical guidelines at ART centres.
4. He/she should also coordinate and monitor the linkages with CSC, other NGO's and networks.
5. He/she must co-ordinate and monitor the LAC/DSD models launched in the ART centre and ensure that the standard guidelines are being followed. Responsibilities with respect to Link ART centres/ LAC plus/ linked ART refill (DSD) sites:
    - He/she has to mentor and monitor the functioning, recording, and reporting of LAC/LAC plus/DSD site along with the nodal officer.
    - He/she must follow out-referral and in-referral of patients and communicate with the Link ART centre.
    - He/she must take decision to link out willing patients to the nearest LAC based on eligibility criteria.
    - He/she must do the clinical review of patients referred back to the nodal ART centre from LACs.
6. He/she should monitor the consumption and availability of drugs (ARV, ATT, OI and other drugs), CD4/VL

kits, other consumables and alert the concerned authorities in case of impending shortage well in advance so as to enable adequate replenishment without disruption of ART care and support to PLHIV. Ensure that there is adequate drug stock available for multi-month dispensation to patients.

7. He/she should verify the staff attendance register daily and get it approved by the nodal officer at the end of the month before forwarding the attendance to the SACS.
8. The SMO must assist the nodal officer in carrying out the annual performance appraisal of the contractual staff based on the PMDS format which should then be approved by the nodal officer.
9. He/she must attend or ensure appropriate representatives are sent for monthly coordination meetings held at the district level, ART centre-CSC coordination meetings, HIV-TB meeting, DAPCU coordination meeting. The SMO must attend review meetings by NACO/ SACS and training programmes conducted for medical officers.
10. He/she must be aware of all communications sent from NACO/SACS to the ART centre and should update the nodal officer about them on a day to day basis.
11. H/she must ensure that all records, registers, cards and IMS software are updated daily and reports are sent to the concerned authorities on time. All reports should be checked by the SMO before taking approval from the nodal officer for sending them to the concerned authorities.

Besides all the above, any other duty assigned by ART centre in-charge/SACS/NACO pertaining to ART services.

c. Medical Officer (MO)

***Eligibility criteria**: ART Medical Officer (MO) should essentially be an MBBS,* with working knowledge of computer, MS office, usage of internet and electronic mail.

Job responsibilities

The medical responsibilities of medical officer are same as that of senior medical officer.

In the ART centre where position of SMO is not sanctioned/vacant or in absence of SMO, one of the medical officers (based on preference criteria given below) shall be the focal point for all the administrative functions of the SMO and serve as MO-in-charge.

Criteria in the order of preference

1) MD in Medicine or any other clinical discipline

2) MO with MBBS + Fellowship in HIV Medicine/Diploma in Public Health

*3) Senior most MO by durat*ion of service

d. Counsellor

***Eligibility criteria:** He/she should hold a master's degree in social work (preferably specialized in medical & psychiatric social work). If no candidate with the above qualification is available, candidates with master's degree in sociology may be considered. Qualified and competent PLHIV, if available, should be given preference while appointing counsellors. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

1. Work under the guidance and supervision of SMO/MO/nodal officer
2. Register PLHIV in HIV care and complete the details in prescribed documents
3. Provide ART preparedness counselling to all PLHIV
4. Encourage and help patients to identify caregiver and provide appropriate treatment education and adherence counselling to care giver
5. Perform 4S screening for TB in all PLHIV and record the findings in the green book
6. Counsel all PLHIV with presumptive or confirmed TB on cough etiquettes

7. Support management of patients with advanced HIV disease under the guidance of SMO/MO
8. Address issues related to ART:
    a. Adherence counselling and monitoring, identification of barriers to adherence and support PLHIV with possible solutions to overcome barriers to adherence
    b. Do pill count for PLHIV during follow up visits and assess ART adherence
9. Enhanced adherence counselling for patients with poor adherence
10. Counsel PLHIV for VL testing
    a. Step up counselling to PLHIV with unsuppressed viral load, e-referral to SACEP
    b. Focussed counselling for second-and third-line patients
11. Provide emotional, social, and psychological support to patients and/or direct them to the concerned person or organization for adequate support
12. Counsel PLHIV for family and partner testing
13. Counsel patients on positive living, role of ART in prevention, proper condom usage and dispense condoms
14. Confirmation and updation of contact details and address during every visit
15. Complete the required sections in the recording and reporting tools maintained by the ART centre
    a. Issue green book for the first time to the new patients
    b. HIV care registers (fill in prescribed columns)
    c. White cards (make white cards for all patients and fill in prescribed columns)
    d. ART enrolment register (fill in prescribed columns)
    e. HIV exposed infant/child register
16. Referral and linkages with CSC, community-based organizations, rehabilitation centres, various support groups and social protection schemes
17. Collect and update phone number and address of PLHIV during every visit and verify the phone numbers
18. Counselling of PLHIV on follow up visits and repeat CD4 count and VL count. CD4 report and VL report of PLHIV is to be given by counsellor after proper counselling
19. Follow up for testing of spouse and children of the PLHIV
20. Contact the MIS/LFU/ PLHIV newly initiated on ART through telephone and outreach workers and bring them back to ART centre for drug collection
21. Attend DAPCU monthly meeting for feedback on ICTC-ART referral and LFU cases
22. Provide counselling on family planning and linkage with SRH services.
23. Provide counselling to pregnant women coming for PPTCT on adherence, prevention of vertical transmission and breastfeeding; link the pregnant women to appropriate services including ANC and post-natal services, immunization and EID for infant.
24. Provide patient centric package and facilitate linkage and coordination with differentiated care models (MMD, LAC, CARG etc) (Refer to Section 4 for details)
25. Facilitate linkages with CSC and to social protection/benefit schemes

Besides all the above, any other responsibilities/instructions related to the programme given by the supervisors need to be discharged/followed from time to time.

e. Pharmacist

Eligibility criteria: *Pharmacist should preferably hold a degree in pharmacy from a recognised institute. If candidate with degree is not available, diploma holder in pharmacy with 3 years of experience in health care institution can be considered. He/she must be registered in the state pharmacy council. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

1. Work under the guidance and supervision of SMO/MO
2. Dispense ARV and OI drugs (including CPT, ATT and TPT) with proper counselling
3. Advise the patients and family about the importance of adherence during each visit
4. Counsel the patient on possible drug adverse effects and report the same, if significant
5. Do pill count and report any adverse effects of drugs or any OIs. Also, update the IMS and confirm the next visit date given by the SMO/MO and inform the patient
6. Maintenance of the drug stores as per guidelines
7. Maintain and update IMS, drug stock and drug dispensing registers on daily basis; inform SMO/MO in-charge in case of any discrepancy and take his/ her signature every fortnightly in the stock register
8. Ensure that the centre, LAC and other drug refill sites has enough stock of ARV drugs for at least 3 months and inform the concerned authority about any near expiry or excess stocks well in time for relocation to other sites and ensure FEFO protocol is followed
9. Physical verification of the drugs under the supervision of the nodal officer and the SMO on a quarterly basis and document it
10. Facilitate transfer/ ensure availability of ARV drugs at LAC/DSD sites as per the number of patients linked out to the LAC/DSD sites
11. Besides all the above, any other duty assigned by ART centre in-charge.

In case the pharmacist is not available/on leave, staff nurse shall perform the job of the pharmacist.

f. Data Manager

Eligibility criteria: *Graduate (preferably in computers/mathematics/statistics/business management/ administration or related subjects), with proficient knowledge of computer, MS office, usage of internet and electronic mail. Candidates with training and experience in data management and working knowledge of health-related software would be given preference.*

Job responsibilities:

1. He/she must work under the guidance and supervision of SMO/MO
2. Ensure that all data recording and reporting software are properly installed, functioning, and updated
3. Completion of entries in IMS and MLL
4. Generate due list of PLHIV on ART, list of pre-ART/on ART MIS/LFU, due list for CD4/VL testing and other list as required for patient and programme management and share them with respective ART staff
5. Share list of pre-ART/on ART MIS and LFU with CSC for tracking and tracing, coordinate for feedback and update the feedback in IMS and white card
6. Print and share all circulars/information sent by NACO/SACS to the Nodal Officer/SMO and maintain a file for the important orders/communication
7. Maintain the attendance register for the ART centre staff and get it verified by the SMO/MO every day and by the nodal officer at the end of the month
8. Maintain the HR file including the biodata of the staff, copies of certificates, appointment letters, contractual service agreement, performance appraisal report, training details, remuneration etc
9. Coordinate with the LAC/LAC plus centres and ensure that all LAC/LAC plus related tools are complete
10. Prepare and send all the weekly/monthly/quarterly reports prescribed by NACO and SACS after approval of SMO/nodal officer
11. Assist in analysis of data under the supervision of the nodal officer of the ART centre
12. Maintain the accounts of the ART centre and the fixed assets register
13. Data managers at ART plus centre shall also function as the SACEP coordinator on rotational basis

14. Ensure regular data back-up
15. Any other duty assigned by ART centre in-charge.

g. Laboratory Technician

Eligibility criteria: *Laboratory technician should be a graduate/diploma holder in Medical Laboratory Technology (MLT) from a recognised institute. He/she must be registered in the state council. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

1. Work under the guidance and supervision of SMO/MO
2. Collect the specimen for CD4 counts at the ART centre and take these samples to the department of Microbiology, test them and give the report to the counsellor at the ART centre
3. In case the ART centre does not have a CD4 machine or CD4 testing is not possible at the same centre due to any reason, the LT is expected to transport samples of blood to a linked CD4 laboratory and to collect the results when ready (TA/DA for this visit can be booked under operational cost of ART centre as per NACO guidelines)
4. Prepare and provide CD4 and VL monthly report to ART centre
5. Maintain the stock of the CD4 kits, consumables and inform the ART SMO/In-charge MO/nodal officer of the centre as and when the stocks come to critical levels
6. Generate the "due list" for CD4 and VL testing for all patients as specified under NACO norms, through IMS
7. VL testing: Coordinate activities related to viral Load testing at the ART centre; conduct sample collection, packaging and transportation to public sector laboratory as per the linkage plan
8. Confirm address and contact details of PLHIV on VL/CD4 test date
9. Complete the details of all patients undergoing CD4 and VL testing services in the laboratory module of IMS
10. Any other duty assigned by ART centre in-charge.

    In case the LT is on leave, sample collection and transportation should be done by the staff nurse. In some situations where the staff nurse is unable to travel, the staff nurse should collect the sample, pack it as per the protocols and the care coordinator or another staff under NACP shall carry the sample to the testing lab. Additional laboratory staff provided at select sites under the NACP can also be used for laboratory work.

h. Staff Nurse

Eligibility criteria: *The staff nurse should be a B.Sc. Nursing, with working knowledge and skills with computers, Microsoft Office software and internet. If not available, GNM may be appointed. He/she must be registered in the state nursing council. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

In addition, one or two nurses (depending upon the volume of patients) should be deputed to the ART centre by the hospital (institution).

Job responsibilities:

1. Perform all paramedical functions of the centre as per requirement and support medical officers in patient consultation
2. Perform baseline assessment of the patient including pulse, BP, weight, height etc
3. Assess the physical, social, and psychological needs of the patient.
4. Support management of patients with advanced HIV disease under the guidance of SMO/MO
5. Provide need-based nursing care and support to the patients
6. HIV-TB coordination:
    a. Focal point for all HIV-TB related activities

b. Screening all the 4S positive cases referred by the care coordinator for TB using 4 symptom complex screening tool
c. Record the TB symptom of the patient using the detailed stamp in the patient green book
d. Ensure referral of presumptive TB patients to NAAT/other appropriate diagnostic tool
e. Fill TB referral form, facilitation of TB referral and updating TB results status
f. The lab form to be stamped by the nurse with the ART centre stamp to facilitate fast tracking of the patient for TB testing
g. Maintaining and updating HIV-TB line list and HIV-TB register
h. Coordinate with SMO/MO for initiation of TB treatment in PLHIV with TB coinfection. Provide counselling to PLHIV about TB treatment and ensure treatment completion
i. Prepare, update and maintain TB treatment card, HIV-TB register
j. Attend the monthly NTEP meeting along with the completed line list for the month to be shared with the concerned STS
k. Maintain the HIV-TB register at the ART centre ensuring timeliness, accuracy and completeness
l. Coordinate with data manager for preparation of HIV/TB section of MPR
m. Coordinate regularly with the HIV-TB coordinator /STS/STLS to ensure effective coordination between ART and NTEP for smooth functioning and uninterrupted service delivery.
n. Share the details of all patients initiated on ATT at the ART centre/transfer of HIV-TB patients to another ART centre, with the HIV-TB coordinator.
o. Ensure that all PLHIV receive and complete TPT. Coordinate with other staff to ensure documentation of updated information in white card for PLHIV initiated on TPT with outcomes on completion of TPT

7. Focal point for infection control practices at ART centre:
   a. Reinforce hand hygiene practices
   b. Reinforce cough hygiene in PLHIV with respiratory symptoms, including use of face covers/masks
   c. Ensure implementation of universal safety precautions and proper waste disposal at the centre
   d. Ensure availability of PEP in emergency, labor room, ICU and other critical areas
   e. Ensure implementation of IPC/AIC practices
8. Focal point for all issues related to pregnant positive women and HIV exposed child and early infant diagnosis (EID) in case counsellor not there
9. Coordinate and track the referrals made within the hospital by establishing linkages with various departments and in-patient wards
10. Streamline and guide patients at the ART centre and help in the efficient and orderly functioning of the centre
11. Dispense of ARV drugs in the absence of pharmacist as and when required
12. Counsel patients as and when required
13. Collect blood samples for CD4 testing/VL testing and arrange/perform its transportation to the linked lab during the absence of Lab technician as and when required
14. Provide reports to the doctor and other members of the ART centre multidisciplinary team
15. Any other duty assigned by ART centre in-charge

i. Care Coordinator

Eligibility criteria: *Care coordinator should be a PLHIV, with a minimum of intermediate (12th) level education. S/he must also have working knowledge of English and the local language. The candidate should also have working knowledge of computer, usage of Internet and electronic mail.*

Job responsibilities:

1. Work under the guidance and supervision of SMO/MO
2. Be the first interface with patient at centre
3. Ensure entries in the HIV visit register
4. Do the first stage 4S screening and record in patient visit register
5. Be a peer educator for PLHIV at centre and provide psychosocial support to newly registered PLHIV
6. Aid PLHIV enrolled at the ART centre, within the hospital (OP and IP)
7. Coordinate with the linked CSC and LAC
8. Keep track of drug adherence of patients on ARV, counselling them on the importance of regularity of visits and ARV dosage
9. Augment the efforts of the counsellor and other staff of the centre in promoting positive living
10. Assist in patient retrieval, where necessary and as far as possible
11. Follow MIS/LFU cases on telephone, from "daily missed list" as well
12. Emergency transfer of drugs to LAC/other ART centre (if necessary); home visit of MIS/LFU; transfer of ARV drugs/kits/consumables/blood sample to nearby CD4 Labs in absence of LT, if necessary. (TA/DA for such visits can be booked under operational cost of ART centre as per NACO guidelines)
13. Manage filing of the white cards on daily basis
14. Any other duty related to the programme assigned by SMO/MO

All the job responsibilities for ART staff are indicated under Section 13.4, indicative and any additional responsibilities for optimizing the functioning of ART centre need can be allocated by the SMO/MO in-charge with the approval of nodal officer for optimizing the functioning of ART centre. ART staff must perform the role assigned to him/her by the ART centre in charge if situation demands as decided by the centre in-charge.

13.5 Additional Staff at Centres of Excellence and their Job Responsibilities

a. Research Fellow (Clinical)-1:

Eligibility criteria:

- *First preference should be given to candidates with MD in Medicine or any other clinical discipline / Community Medicine/ Microbiology/ Ph.D. after M.B.B.S.*
- *If no candidate as per para 1 above is available, candidates with MBBS + Diploma in any medical specialties/ Public Health having minimum 3 years of experience can be considered*
- *In the event of unavailability of candidates as per para 1 & 2 above, candidates with MBBS + Fellowship in HIV Medicine/PGDHIVM (IGNOU) having 3 years of experience can be considered*

The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.

In case Research Fellow (Clinical) cannot be recruited due to non- availability of candidates as per qualification stated above, a candidate with MBBS qualification can be recruited (and be given the salary of ART centre MO).

Job responsibilities:

- Be involved in all research activities of the CoE: facilitate and monitor progress of the operational research projects, institutional research projects, multi-centre studies, collaborative projects undertaken with the CoE; PhD thesis, PG dissertations, etc.
- Be involved in planning, data compilation, analysis and preparation of presentations / publications under the supervision and guidance of the Programme Director/Deputy Programme Director
- Actively participate in training, mentoring and other capacity building programmes of the CoE
- Facilitate and coordinate expert-consultation through telemedicine/case-based learning
- Provide technical support for distance learning seminar
- Be involved in screening of cases referred for SACEP review from attached ART centres, ART plus

centres and will work closely with the Programme Director of CoE and SACEP coordinator in following the stipulated protocol for smooth functioning of SACEP and in providing appropriate alternative first line ART/second line/third line ART as per NACO guidelines; be responsible to follow-up, compile and provide SACEP feedback/recommendation to the referring centres

- Function as the SMO/MO of ART centre
- Be responsible to compile CoE reports for SACS and NACO
- Monitor ART plus centres to execute regular SACEP and provide technical support to strengthen the technical competencies of the ART plus centre staff
- Conduct site visit to ART plus /ART centre / CSC / LAC as directed by the Programme Director / SACS/ NACO
- Perform any other job as assigned by the Programme Director/ Deputy Programme Director CoE.

b. Research Fellow (Non-Clinical)–1:

Eligibility criteria: *M.Sc. (any one of the Life Science branches). The candidate should be computer literate with working knowledge of MS office, usage of Internet and electronic mail. Candidate with Ph D qualification gets higher salary.*

Job responsibilities:

- Participate in research projects conducted through CoE: operational research projects, institutional research projects, multi-centre studies, collaborative projects
- Facilitate planning, data compilation and analysis of research studies and assist in the preparation of presentations and publications under guidance and supervision of Programme Director and Deputy Programme Director CoE
- Actively participate in the training, mentoring and other capacity building programmes of the CoE
- Facilitate and coordinate expert-consultation through telemedicine/case-based learning
- Provide technical support for distance learning seminar
- Be responsible for the library and e-library
- Be involved in screening of cases referred for SACEP review from attached ART centres, ART plus centres and will work closely with the Programme Director of CoE and SACEP coordinator in following the stipulated protocol for smooth functioning of SACEP and in providing appropriate alternative first line ART / second line/ third line ART as per NACO guidelines; be responsible to follow-up, compile and provide SACEP feedback/recommendation to the referring centres
- Be involved in maintaining data related to SACEP, second line/third line and alternate first line ART
- Monitor ART plus centres to execute regular SACEP and provide technical support to strengthen the technical competencies of the ART plus centre staff
- Assist in the compilation of CoE reports for SACS and NACO
- Perform any other job as assigned by the Programme Director/Programme Deputy Director.

c. SACEP Coordinator-1:

Eligibility criteria: *Postgraduate/Graduate, with training in data management and accounting with minimum 2 years' experience in ART centre. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities: S/he will (in coordination with the research fellow of CoE):

- Screen and review all records and communications regarding referrals made to the SACEP
- Maintain SACEP schedule for review and communicate with the referring centres to ensure complete patient details and lab reports are available before SACEP review
- Organize SACEP meetings and coordinate with members of the SACEP
- Communicate with referring ART centres to share SACEP recommendation and ensure follow-up of patients as per SACEP recommendation
- Coordinate with pharmacist for patient drug transfers

- Be responsible for registration of patients, maintenance of all forms and registers related to SACEP
- Prepare and send SACEP reports to SACS and NACO
- Coordinate activities of SACEP at ART Plus Centres in the region attached to the CoE
- Be responsible for receiving and sending communications from and to the attached ART centres
- Be responsible for all data entries, maintaining and updating all records, registers and files pertaining to the CoE
- Assist the Programme Director and the Deputy Programme Director in receiving and sending all communications related to the CoE
- Work in the ART centre and perform the duties of Data Manager, whenever required
- Assist in procurements, maintaining accounts, audits, handling contingency petty cash of the CoE
- Assist the training and mentoring coordinator in communications and maintaining records
- Perform any other job as assigned by the Programme Director / Deputy Programme Director

d. Data Analyst–1:

Eligibility criteria: *M.A./M.Sc. in Statistics or Mathematics with computer proficiency. Alternatively, B.A/B.Sc. in Statistics or Mathematics with minimum 3 years of experience and computer proficiency.*

Job responsibilities:

- Support SACS in analysis of routine programme data to monitor performance of ART services and take corrective actions
- Support SACS in ART review meetings in terms of data analysis, identification of low performing sites, preparations of presentations and documenting action points from meeting
- Analyse monthly reports and other data of the ART centre / attached ART centres and provide feedback to research officers to plan for specific mentoring activities (under information to Programme Director/ Deputy Programme Director)
- Conduct data analysis of research projects of CoE, collaborative projects and projects associated with the CoE and ART centre
- Plan and prepare research protocols
- Assist in manuscript writing and preparation of publications and presentations
- Assist in dissemination of the research outcomes
- Support quality improvement of data at CoE and attached ART centres; and
- Perform any other job as assigned by the Programme Director / Deputy Programme Director

e. Training and Mentoring Coordinator–1:

Eligibility criteria: *Graduate in any discipline, preferably in social sciences with three years relevant experience. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

- Coordinate training activities of different categories of health care providers as per prescribed NACO curriculum through designated faculty/national trainers, pre training preparations and logistics for trainings at the CoE
- Facilitate the blended clinical trainings in the region and monitor the progress of the participants on course completion
- Analyse pre-test and post-test questionnaires
- Ensure post training follow-up with the participants
- Coordinate logistics of mentoring/supportive supervision activities of attached ART centres/ART plus centres through telemedicine/e-discussions/case-based learning/distance learning sessions/ sharing of good practices/CMEs/feedback/onsite visits/ etc.
- Support SACS in facilitating and arranging logistics for ART review meetings

- Prepare and submit training and mentoring reports
- Coordinate and facilitate contact classes related to the PGDHIVM programme
- Perform any other job as assigned by the Programme Director/Deputy Programme Director

f. Laboratory Technician–1:

Eligibility criteria: *B. Sc (Micro)/DMLT/DLT from an institute recognized by AICTE or State/Central Government. He/she must be registered in the state council. The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

- Perform all the laboratory tests related to ART treatment and specifically tests related to alternative first line and second line ART/third line
- Be responsible for collection, transportation of sample and performing for viral load testing
- Be responsible to maintain the line list including the due lists for CD4 testing and viral load testing
- Work as ART centre lab technician
- Perform any other job as assigned by the Programme Director/Deputy Programme Director

g. Nutritionist–1:

Eligibility criteria: *M.Sc. in Food Science & Nutrition/Biochemistry, with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

- Provide nutritional counselling to all patients at ART centre and PLHIV referred for SACEP review
- Conduct assessment of dietary habits, nutritional status and nutritional needs of the patients; and advise nutritional interventions accordingly
- Facilitate linkages with nutritional supplementation schemes of government departments and NGOs
- Closely monitor and follow up all PLHIV with malnutrition
- Support counsellors of attached ART centres in nutritional counselling in need-based manner through e-consultations
- Participate in training and research activities at the CoE; and
- Conduct e-sessions for mentoring and skill building of counsellors on nutritional assessment and counselling
- Perform any other job as assigned by the Programme Director / Deputy Programme Director of CoE

h. Social Workers -2

Eligibility criteria: *Bachelor's in social work/Psychology/Sociology (preferably one from PLHIV community), with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

- Support counselling services at ART centre, specifically initial counselling for three months in PLHIV initiated on ART, step-up counselling in PLHIV with poor adherence
- Be a peer educator for PLHIV at centre and provide psychosocial support to newly registered PLHIV
- Facilitate referral and linkages with CSC, community-based organizations, rehabilitation centres, various support groups and social protection schemes
- Support ART centre in follow MIS/LFU cases on telephone, from "daily due list"
- Perform outreach / follow up of patients whom CSC ORW are not able to bring back to care despite repeated efforts (opted out/ agreed but not come)
- Assist in data collection for research studies being conducted by CoE
- Assist in referrals to other specialty departments and provide accompanied referral on need basis
- Perform any other CoE related job as assigned by the Programme Director/Deputy Programme Director

13.6 Additional Staff at Paediatric Centres of Excellence and their Job Responsibilities

a. M&E and Research Officer-1:

Eligibility criteria: *M Sc (any one of the Life Science branches). The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail. ⁎Candidate with Ph D qualification gets higher salary.*

Job responsibilities: Role of this position is to analyse data, coordinate research activities, provide necessary technical assistance to mentoring team on the performance of the ART centres and quality of Paediatric care in the region. This position will:

- Design and update the monitoring system, which includes drafting instructions for
- Complete forms/formats and prepare computerised reporting formats
- Contribute to planning and preparing research protocols
- Be involved in all other research activities of the pCoE
- Facilitate and monitor progress of the pCoE research projects
- Participate in training, mentoring and other capacity building activities of the pCoE
- Perform analysis of monthly reports and other data, as required for the ART centres
- Compile CoE reports for NACO
- Assist in conducting surveys, formative research, needs assessment and analysis of data generated within the pCoE
- Make monitoring visits to ART centres as directed by the Director pCoE
- Be involved in quality assurance of research projects
- Carry out data quality checks
- Assist in performance analysis and assist in presentation of findings to the other members of the pCoE team
- Be involved in managing the pCoE network website
- Assist in data compilation, analysis and preparation of presentations and publications under the supervision of the Director pCoE
- Support the impact evaluation of the projects undertaken by the pCoE
- Support the analysis of all quantitative and qualitative data from projects undertaken at the pCoE
- Perform any other job related to pCoE activities, as assigned by Director pCoE

b. pCoE Programme Coordinator-1:

Eligibility criteria: *A graduate in any discipline, preferably social sciences, or related to human resource development with at least of 2 years of programme management experience (coordination of training, financial account keeping, and relationship management). The candidate should be computer literate with working knowledge of MS office, usage of internet and electronic mail.*

Job responsibilities:

- Coordinate all training activities, pre-training preparations and logistics for trainings of pCoE
- Coordinate mentoring and post-mentoring activities and logistics for mentoring
- Assist the Director pCoE in managing and maintaining the relationships and communications within the pCoE team, as well as the ART centre personnel
- Assist the Director pCoE in managing correspondence related to the functioning and activities of CoE
- Assist in maintaining documentation and communication materials with respect to the pCoE activities
- Assist the Director pCoE in timely implementation of training, mentoring, research and other capacity building activities
- Assist in tracking budgets and spend on pCoE activities

- Make site visits to ART centres as directed by the Director pCoE
- Perform any other job related to pCoE activities as assigned by Director pCoE

c. Nutritionist: Qualification and job responsibilities same as Nutritionist at CoE (Refer to Section 13.5)

13.7 Capacity Building of ART Centre Staff

To ensure uniform standards of services, adherence to operational guidelines and treatment protocols, induction training is provided to various personnel using standard curriculum, training module and tools at identified institutions. All staff (ART/ CoE/ pCoE/ ART plus/ LAC/LAC plus) should undergo induction and all other trainings prescribed by NACO.

NACO has developed blended clinical training (BCT) for medical officers, nurses, and laboratory personnel who are providing HIV diagnostic, care and treatment services at the various service delivery units under National AIDS Control Program (NACP). BCT has two key components: (1) Classroom and online clinical trainings for various cadres, (2) Information and communication technology (ICT)-enabled learning needs assessment, training scheduling and delivery, tracking of participant progress and refresher/mentorship needs through online assessments, and participant certification on successful completion.

Various training programmes organized for ART staff include:

- Orientation of "ART team" members from the institution
- Training of ART team (specialist training)
- Blended Clinical Training (BCT) of medical officers (SMO/MO) of ART centres (online and classroom)
- Blended training of counsellors (online and classroom)
- Training of data managers of ART centres
- Blended training of laboratory technicians (online and classroom)
- Training of pharmacists
- Blended training of nurses (online and classroom)
- Refresher/ re- orientation programme for ART centre team and staff

In addition, NACO/SACS/CoE/pCoE shall conduct periodic virtual training (RDLS/NDLS/ case-based learning) for continuous education of the ART staff.

CHAPTER 14

PUBLIC AND PRIVATE SECTOR ENGAGEMENT

14.1 Engagement with Public & Private Sector for Delivery of ART Services

National AIDS Control Programme recognizes and encourages partnerships and alliances with corporate/ public/private sector to achieve accelerated HIV epidemic control in India. NACO has signed MoUs with various ministries/departments of Government of India and Public Sector Undertakings (PSU) for provision of HIV services. Corporate or private sector has a significant stake in the well-being of the nation and also have a critical role to play in HIV epidemic control.

14.1.1 Public-public partnership: NACO plans to expand the HIV treatment services to various ministries/ departments of Government of India and Public Sector Undertakings (PSU) and make ART accessible to their employees, their families living with HIV/AIDS and to PLHIV's in the nearby areas.

14.1.2 Public-private partnership: NACO plans to extend ART access to more PLHIV in collaboration with not-for-profit non-governmental organizations. These collaborations shall be with the corporate/private organizations registered under the Companies Registration Act. It encourages the establishment of an ART centre to extend HIV/AIDS related treatment, care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHIV's in the nearby areas as a part of their **corporate social responsibility** (CSR).

The purpose of this public-private partnerships (PPP) is to initiate/continue the collaborative ART programme between NACO and private medical colleges/corporate sector/private hospitals (including private practitioners) for provision of high-quality provision of ART and associated healthcare and medical management of PLHIV in the country.

14.1.3 Medical colleges: The Gazette of India issued the Board of Governors in super-session of Medical Council of India dated 20 October 2020 wherein an amendment has been done on "Minimum Standard Requirement for 150 MBBS Admissions Annually Regulation, 1999". As per the amendment every teaching hospital should have Antiretroviral Treatment (ART) centre at the time of 3rd renewal for admission of 4th batch of MBBS students. Undertaking to be signed by Medical colleges is provided at Annexure 24.

14.2 Roles and Responsibilities

14.2.1 Responsibilities of NACO/SACS

- Provide ARV drugs
- Provide training or support for training to staff of ART centre
- Provide CD4 and viral load testing through linkage
- Provide regular updates on national ART guidelines
- Provide technical support through concerned State AIDS Control Society (SACS) for establishment as well as functioning of ART centre

No direct financial support shall be provided by NACO

14.2.2 Responsibilities of partner organization

- Provide infrastructure and human resources for ART centre
- Provide all health services related to provision of ART and free of cost baseline/ follow up lab investigations and treatment of opportunistic infections to PLHIV who require treatment
- Shall follow the National Operational Guidelines for ART services and National Guidelines for HIV care and Treatment 2021 (including infrastructure availability, human resources, patient care, data management tools) and guidance provided by NACO from time to time
- Report to NACO in prescribed format and frequency.

14.3 Process for Establishing ART Centres under Public/Private Partnership

- Proposal for establishing ART centre shall be sent by institute to respective State AIDS Control Society (SACS). (Alternatively, SACS may also reach the potential partner for setting up ART centre in their institute).
- Representatives from State AIDS Control Society will visit the institute and provide technical support for establishing ART centre and suggest improvement as required.
- Provisional approval by NACO based on report.
- Appointment of staff and arrangement of infrastructure as per **Operational Guidelines for ART services.** Refer to Section 11 and 13 for details.

The commencement of ART services happens only after the MoU in the form of a signed agreement between the SACS and the public/private partner (Annexure 25). No MoU is required for setting up ART centres in medical colleges. However, medical colleges are required to sign an undertaking.

CHAPTER 15

COMMUNITY INVOLVEMENT

Involvement of communities in all aspects of programme implementation is critical for the success of programmatic strategies. NACP recognizes the importance of engaging with communities in the development as well as in implementation of the interventions. This chapter describes the various approaches which programme has adopted for engaging with community.

15.1 Care and Support Centres (CSC)

The CSC since its inception in April 2013 serves as a comprehensive unit for treatment support for retention, adherence, positive living, referral, linkages to need-based services, and strengthening an enabling environment for PLHIV. CSC are community-based service delivery points, plays vital role to reduce stigma and discrimination through effective treatment literacy activities in coordination with local PLHIV networks. These community-based CSC are an integral part of the national response to meet the needs of PLHIV, including those from high-risk groups and women and children living with HIV. The goal of CSC is to improve the survival and quality of life of PLHIV.

Major objectives of CSC are as follows:

- Early linkage of PLHIV to care, support and treatment services
- To improve treatment adherence and education for PLHIV
- To leverage positive prevention activities
- To improve social protection and wellbeing of PLHIV

Major activities under CSC are as follows:

- **Intensified prevention of LFU:** CSC reach out to PLHIV who are newly initiated on ART and those with less than 80% ART adherence for last three months and ensure they are retained in treatment with improved treatment adherence.
- **Tracking of LFUs and MIS cases:** Staff at CSCs follow various strategies, like contacting the patients on phone, meeting them at mutually convenient places and also home visits for those who agree to it, to link back Lost to follow up (LFU) and MIS cases to ART centres for continuation of treatment.
- **Follow up of all family members of PLHIV for HIV testing and early linkages to the treatment if found positive:** Tracking of discordant couples, partners and children for follow up HIV testing along with providing preventive counselling and if found positive linking them to the treatment.
- **Counselling and support group meetings:** Intensive peer support and adherence counselling is being provided to all PLHIV.
- **Intensified case finding for TB amongst PLHIV** who have not yet been screened for TB symptoms and follow up screening after every 6 months is carried out by the CSC team.
- **Sensitization of state and national government stakeholders** to enhance linkage to social protection schemes, reduce stigma and discrimination experienced by PLHIV and provide better livelihood options for PLHIV.

CSC have been spearheading local resource mobilization initiatives and leveraging additional direct support services such as nutritional items, educational items, transportation support, and many other household and clothing materials for the PLHIV community.

Meetings to address the gaps in CSC Services:

ART-CSC coordination meeting: The ART and CSC will have a coordination meeting in each month which will be presided by the Nodal officer/SMO of ART centre, DAPCU, ART staff, CSC team. The nodal officer may involve other stakeholder if s/he feels so by including individual/organization that would enhance care and support services. The aim of this meeting is to validate the progress made by CSC team on last month and give suggestion/inputs on plan of action.

State oversight committee (SOC) meeting: This committee consists of SACS and CSC officials, conducts half yearly meeting to review the CSC programme in the state and addresses the gaps and challenges in its implementation.

15.2 Community based ARV drug delivery through LAC

In order to involve Communities in the implementation of ART services, NACO has approved setting up of **Link ART centres (LAC) at care and support centres (CSC), targeted intervention (TI) sites, OST sites, community-based organizations (CBO) and other NGOs** for ARV drug delivery through community. As a part of differentiated service delivery model, these sites also help to improve retention by making ART available to PLHIV within the community setting, therefore providing the advantage of flexi timings, drug refill on holidays, fast track refills. ART refills through TI NGO helps to alleviate specific challenges faced by key populations to access to ART services. These models help to lessen the issues around stigma and discrimination and address health system barriers by providing access to ART in friendly community settings.

15.3 Community ART Refill Groups (CARG)

NACP has included Community ART Refill Groups (CARG) as part of differentiated care, in difficult terrain geographies. PLHIV receive their ART refills in a group but this group is managed and run by PLHIV themselves. Generally, patient managed groups meet outside of health care facilities. CARG are self-forming groups of stable PLHIV from the same geographical area (Refer to Section 4 for details)

15.4 Community Care Coordinators at ART Centres

To minimize stigma & discrimination at ART centres, a post of care coordinator was also added to the functioning of ART centres. Care coordinator is the first interface with the patient at centre and acts as peer educator for PLHIV at centre and provide psychosocial support.

15.5 Empowering Communities through Legal Protection

The linkage between legal service authority and community has been established through local partnership and spreading awareness on HIV/AIDS Prevention and Control Act, 2017. Details are provided in Section 22

15.6 Grievance Redressal Mechanism

Complaint/suggestion box at ART centres: In order to ensure for community feedback for improving the quality of ART service delivery, there is a mechanism to capture feedback/suggestions/complaints from community through complaint/ suggestion box at all ART centres. A complaint/ suggestion box (along with paper and pen) must be installed and located in the waiting area of ART centre so that it is visible and accessible to PLHIV. It should be opened in the presence of the nodal officer weekly. All grievances that can be resolved locally must be disposed at the centre itself. A register should be maintained where in all complaints received and action taken should be entered. PLHIV network/ DLN members should be involved in the meetings for review of grievances at the centre. Serious or unresolved issues, if any, must be referred to/taken up in the State Grievance Redressal Committee (SGRC).

State Grievance Redressal Committee (SGRC):

As per the Supreme Court directives, issued in reference to Public Interest Litigation in 2008, for enhancing the extent and efficacy of treatment provided to PLHIV, all states should constitute committee for redressal of grievances to routinely review the functioning of ART services. This committee, designated as State Grievance

Redressal Committee (SGRC), is headed by the Health Secretary of the state and consists of Project Director of the SACS, Director of Medical Education, Director of Health Services, representatives of civil society/ positive network and the Nodal Officers of the ART centres. This committee shall meet every quarter and act on grievance redressal mechanism. The committee may include representative from NACO. This mechanism ensures that issues pertaining to grievances of PLHIV are brought to the notice of state authorities and SACS in a systematic manner for timely response. With regards to Supreme Court Directives to ensure quality care for PLHIV, an OM was released by 26th August 2008.

These mechanisms should be leveraged by NACO/SACS to address issues related to infrastructure, laboratory back up and other services at health facilities. A complaint/suggestion box must be installed in the ART centre. It should be opened in the presence of the nodal officer weekly. All grievances that can be resolved locally shall be disposed at the centre itself. Serious or unresolved issues, if any, shall be referred to/taken up in the State Grievance Redressal Committee (SGRC).

15.7 Establishment of mechanisms for beneficiary/community feedback

Feedback system for PLHIV/ community should be established including 'real time monitoring' to cover areas such as availability of services and commodity, quality of services, stigma and discrimination. The role foreseen for communities in strengthening the response includes:

- Support an enabling environment including moving towards zero stigma and discrimination.
- Demand generation for prevention, testing and treatment services.
- Care and support for those on ART including social protection, treatment literacy, adherence.

These feedback can be provided by community through community score card, grievance redressal mechanism (SGRC), WhatsApp groups, google/yahoo groups, community consultations, patient/ beneficiary feedback during supervisory visit, DAPCU and other coordination meetings.

CHAPTER 16

INFECTION PREVENTION AND CONTROL

Infection prevention and control (IPC) is a scientific approach and practical solution designed to prevent harm caused by infection to patients and health care workers. IPC occupies a unique position in the field of patient safety and quality universal health coverage. PLHIV are immuno-compromised and, hence, have a higher risk of acquiring infections in the hospital and community settings. Pulmonary tuberculosis, one of the most common OI caused due to airborne transmission is a good example of preventable OI in healthcare facilities. TB prevention in ART centres mainly depends on adherence to IPC strategies. COVID-19 pandemic has further bolstered the need for IPC activities in all types of healthcare facilities.

There are two tiers of recommended precautions to prevent the spread of infections in ART centres:

i. Standard precautions

ii. Transmission based precautions

16.1 Standard Precautions

Standard precautions are to be practiced for all patients, always and for all activities in the healthcare facilities. Standard precautions should be adhered in all ART centres, LAC and other Differentiated Service Delivery (DSD) sites always. Standard precautions are based on use of common practices that protect healthcare providers from infection and prevent the spread of infection from patient to patient. Standard precautions (earlier called universal work precautions) include the following components.

16.1.1 Adherence to hand hygiene practices

- Nodal officer of the ART centre should ensure availability of
  a. Hand washing station with soap and running water and clean towels
  b. Alcohol based hand rub (ABHR) solution in the ART centre for staff and patients
- Appropriate inventory of soap, paper towels and alcohol-based hand rub should be maintained by the ART staff nurse/pharmacist
- Display information (posters, signages) about hand hygiene in the waiting areas to educate patients their attendants and remind ART staff.
- ART staff must practice and adhere to WHO 5 moments of hand hygiene
  a. Before touching a patient
  b. Before clean/aseptic procedures
  c. After body fluid exposure/risk
  d. After touching a patient
  e. After touching patient surroundings
- Staff nurse and counsellors to sensitize and educate patients and attenders on hand hygiene
- The hospital Infection control committee must conduct hand hygiene audits using standard WHO tool for monitoring the adherence to hand hygiene and feedback provided to the staff

16.1.2 Respiratory hygiene/cough etiquette

Nodal officer of the ART centre should ensure:

- **Visual/ audio alert reminders** (posters, signages, voice recordings) at the entrance to ART centre, waiting areas etc. instructing patients and persons who accompany them (e.g., family, relatives, friends) to inform healthcare personnel of symptoms of respiratory infection and to practice respiratory hygiene/cough etiquette
- **Counsellors and nurses at ALL ART centres should educate and emphasize patients to**
  a. Cover their mouth and nose with a face cover/mask/tissue/cloth when coughing or sneezing
  b. Perform hand hygiene (e.g. hand washing soap and water, alcohol-based hand rub) after having contact with respiratory secretions or touching contaminated objects/materials with secretions

16.1.3 Personal protective equipments (PPE)

Goal of PPE use is to improve personnel safety in the healthcare environment through appropriate and rational use

- Nodal officer/ SMO/MO should disseminate guidance on the selection and use of PPE in healthcare settings to the ART staff
- If PPE are to be used by ART centre staff, they should be trained on correct and consistent use including donning and doffing procedures
- Not all staff require complete PPE (N-95 mask, gown, cap, shoe cover, overall) for regular duty in ART centres. Use of appropriate PPE depends on the risk assessment based on the local epidemiology and transmission details available from local public health authorities and hospital infection control committees
- SMO/MO of the ART centre should maintain inventory of PPE and periodically indent for the required gloves, surgical masks/PPE if required from the Institution head through the ART nodal officer

16.1.4 Safe injection practices, sharps management and injury prevention

- Use of injections in ART centre is very minimal. Whenever there is need for injection (either with a syringe or vacutainer for blood draw), use of gloves is a must and appropriately dispose syringes in non-chlorinated plastic bags in coloured bins/containers, and needles to be shredded and disposed in translucent, puncture, leak and tamper free containers.
- No recapping of needles should be done
- Do not use multi-dose vial
- ART staff during visit to the in-patient wards must observe for appropriate disposal of sharps in the designated sharps container

16.1.5 Safe handling, cleaning and disinfection of patient care equipment

SMO/MO and staff nurse should ensure appropriate cleaning and disinfection of frequently used OPD equipment like stethoscopes, ophthalmoscopes, thermometer, BP apparatus etc daily.

16.1.6 Environmental cleaning

- SMO/MO should ensure that ART centre is cleaned and disinfected at least twice daily (morning and evening)
- Any visible dirt should be cleaned first before disinfection by using Sodium Hypochlorite solution
- Wet mopping of the floor should be done from cleaner to dirtier area and adequate contact time to be provided
- All frequently touched surfaces (door handle, bed rails, table, arms of chair etc) should be cleaned with disinfectant

Pl refer to national IPC guidelines for health care facilities 2020 for further details.

16.1.7 Safe handling and cleaning of soiled linen:

Linen from the examination couch, towels, curtains etc must be cleaned at frequent intervals in coordination with the Central Supplies and Sterilization Department (CSSD) of the heath facility where ART centre is located.

16.1.8 Biomedical waste management

- Nodal officer of the ART centre should ensure the biomedical wastes generated in the ART centres are collected daily for disposal
- ART centre and CD4 laboratory wastes requires management at every step from generation, segregation, collection, transportation, storage, and treatment to final disposal
- National biomedical waste management rule 2016 and amendments 2018 and 2019 by Ministry of Forests Environment and Climate Change provide clear guidance for waste segregation using the colour coded containers and boxes for each type of waste generated in a healthcare facility in different areas (Table-19)

Table 19. Guidance on segregation of different types of waste at source and final disposal

Category	Type of bag/container	Type of waste	Treatment disposal options
Yellow	Non chlorinated color coded bags in coloured bins Separate collection system leading to ETP	• Human anatomical waste • Animal anatomical waste • Soiled waste • Expired or discarded medicines • Chemical waste • Micro, biotech & clinical lab waste • Chemical liquid waste	Incineration/ deep burial
Red	Non chlorinated plastic bags in coloured bins/ containers	Contaminated waste (recyclable) tubing, bottles, urine bags, syringes (without needles) and gloves	Auto/micro/hydro and then sent to recycling
White	Translucent , puncture, leak & tamper proof	Waste sharps including metals	Auto/ dry heat sterilization followed by shredding/ mutilation/encapsulation
Blue	Water proof card board boxes/containers	Glassware waste	Disinfection or auto/micro/ hydro then sent to recycling

- Certain wastes generated from ART centres and CD4 laboratories (vacutainers, nitrile glows etc) must be disinfected and sterilized before being sent to a common biomedical treatment facility for disposal ART centre.
- All infectious and toxic wastes generated in the ART centre should be disposed through the hospital bio-medical waste management mechanism of the hospital where ART centre is located and disposed safely.
- Disposal by deep burial is permitted only in remote areas where there is no access to common bio-medical waste treatment facility. This will be carried out with prior approval from the prescribed authority following the state pollution control board norms

16.2 Transmission Based Precautions

Transmission-based additional precautions are the second tier of infection control and are to be used in addition to standard precautions for patients who may be infected with certain infectious agents like novel corona virus (SARS CoV-2) causing COVID-19 disease, tuberculosis, colonizing multi drug resistant organisms

like MRSA and other emerging infectious diseases (E.g. Nipah viral disease, Ebola virus etc). These special situations require additional precautions to prevent infection transmission. Transmission based precautions include:

a. **Contact precautions:** Use contact precautions for patients with known or suspected infections that represent an increased risk for contact transmission.

b. **Airborne precautions (including droplet precautions):** Use of airborne and droplet precautions for patients known or suspected to be infected with pathogens transmitted by the airborne route (e.g., tuberculosis, measles, chickenpox, disseminated Herpes Zoster) and by respiratory droplets that are generated by a patient who is coughing, sneezing, or talking (e.g. SARS COV-2). Detailed SOP for screening and triage for COVID-19 in ART centres is given at Annexure 26)

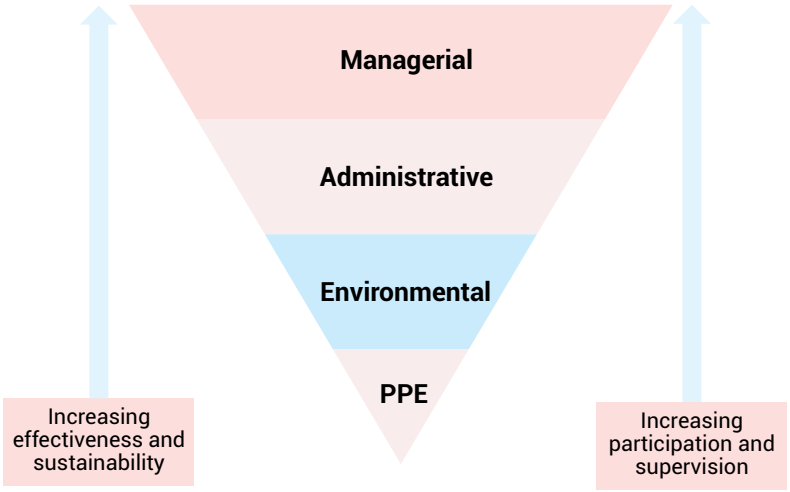
Considering the functions of ART centres, the scope of this section is confined to **airborne infection control** (AIC) practices.

16.2.1 Airborne infection control at ART centres

The national Guidelines on air borne infection control in healthcare and other settings categorize ART centres as one of the high-risk areas for air bone transmission of TB. ART centres are visited by large number of PLHIV, who commonly are vulnerable to TB infection and develop TB disease. With such a high burden of TB patients in proximity to large numbers of vulnerable patients, often very frequently visiting the ART centre, the probability for transmission are very common. Furthermore, environmental factors in ART centres may add to the risk of spread, particularly if crowding is there, natural ventilation is inadequate, or re-circulating air-conditioners are in use. Considering high burden of tuberculosis in India and the transmission risk of healthcare respiratory infections like COVID -19 and Influenza, airborne infection control becomes very critical to be emphasized in ART centres.

Effective implementation of AIC measures involves four recognized controls in a hierarchy, as presented in Figure17.

Figure 17. Hierarchy of AIC measures



16.2.1.1 Managerial control measures: Managerial controls relate to formulation of policy, establishment of AIC committees, and preparation and review of institutional AIC plans. **Hospital Infection Control Committee** (HICC), should be constituted in all hospitals.

- ART nodal officers should be part of the Hospital Infection Control Committee (HICC) / Sub committees so that they could actively advocate and ensure implementation of additional precautions to prevent healthcare associated transmission of tuberculosis

- ART nodal officer and HICC members should develop a written TB infection control plan for the hospital where ART centre is located
- All ART team members shall be trained in Airborne Infection Control Practices, with special reference to tuberculosis and other common respiratory infections like influenza, COVID-19 etc
- Conduct TB risk assessment periodically
- ART nodal officers should ensure that all the AIC measures prescribed by MoHFW and NTEP are adhered, gap analysis conducted and corrective and preventive action taken based on the risk assessment

16.2.1.2 Administrative and environmental control measures: ART centres are required to initiate the following simple administrative and environmental measures aimed at reducing exposure of HIV-infected patients to Tuberculosis:

- ART centre must be located separately from chest clinics, Designated Microscopy centres (DMC), or DOTS centres, with no shared waiting areas.
- At least 2 Guz distance (~6 feet) should be maintained between the patients at the registration desk and in the waiting area (Figure 18 & 19).
- Open and well-ventilated waiting area with unidirectional seating arrangement for patients. Have a separate, well-ventilated waiting area for respiratory symptomatic wherever possible (particularly busier ART centres).
- Ensure availability of surgical masks, tissues, and appropriate no-touch disposal receptacles.
- Adherence to ventilation standards for airborne infection control (>12 air exchanges per hour [ACH] throughout) should be ensured. All windows and ventilators should be kept opened. More than 20% of the floor area should have unobstructed opening (doors, windows and ventilators).
- Where natural ventilation is of concern, augmented ventilation through the well-planned use of supply and/or exhaust fans may be considered, if installations are properly designed and maintained, and electrical power is consistently available.
- As far as possible, use of re-circulating (split) air conditioners should be avoided as these invariably are implemented in a way that prevents adequate fresh air entry and exit.
- Arrangement of patients and staff seating should be appropriate to protect staff from droplet nuclei which may be expelled by patients by pushing out the droplet nuclei outside the room (Figure 18).
- Organizing the patient flow to avoid criss-crossing and overcrowding of patients to prevent cross-infection (Figure 20).

Figure 18. Waiting area

Courtesy: AP SACS

Figure 19. Seating arrangement

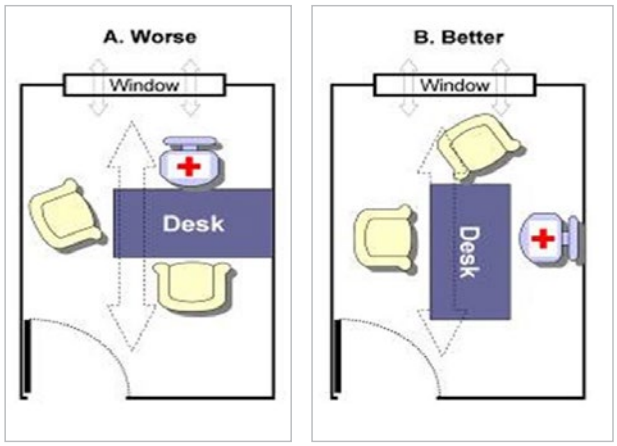


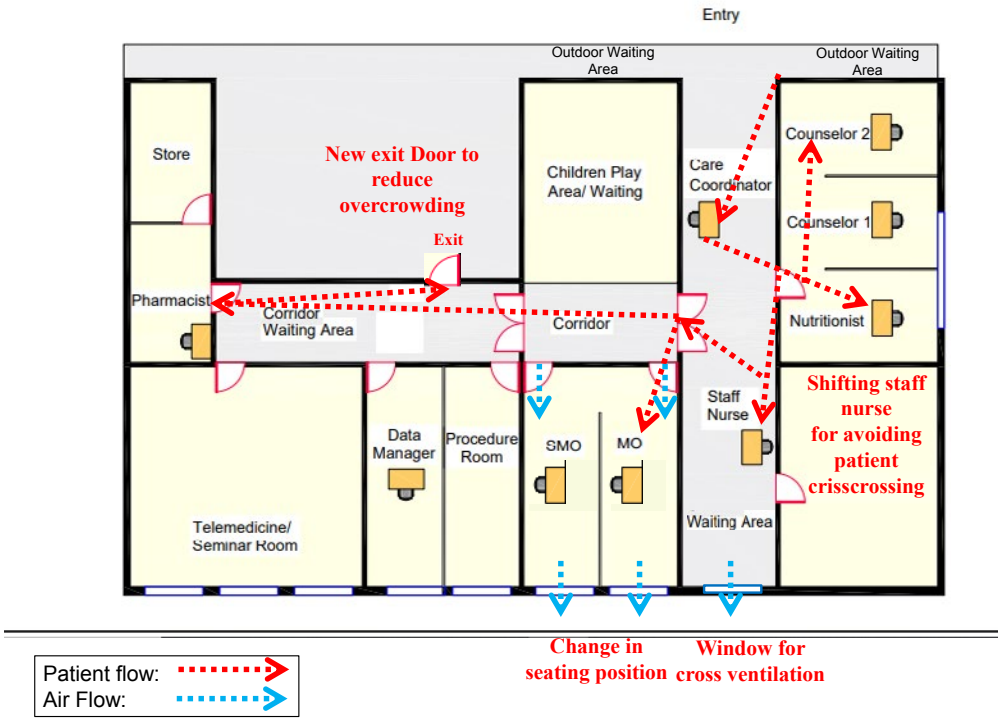
Figure 20. Recommended patient flow at ART centres

Existing Patient Flow

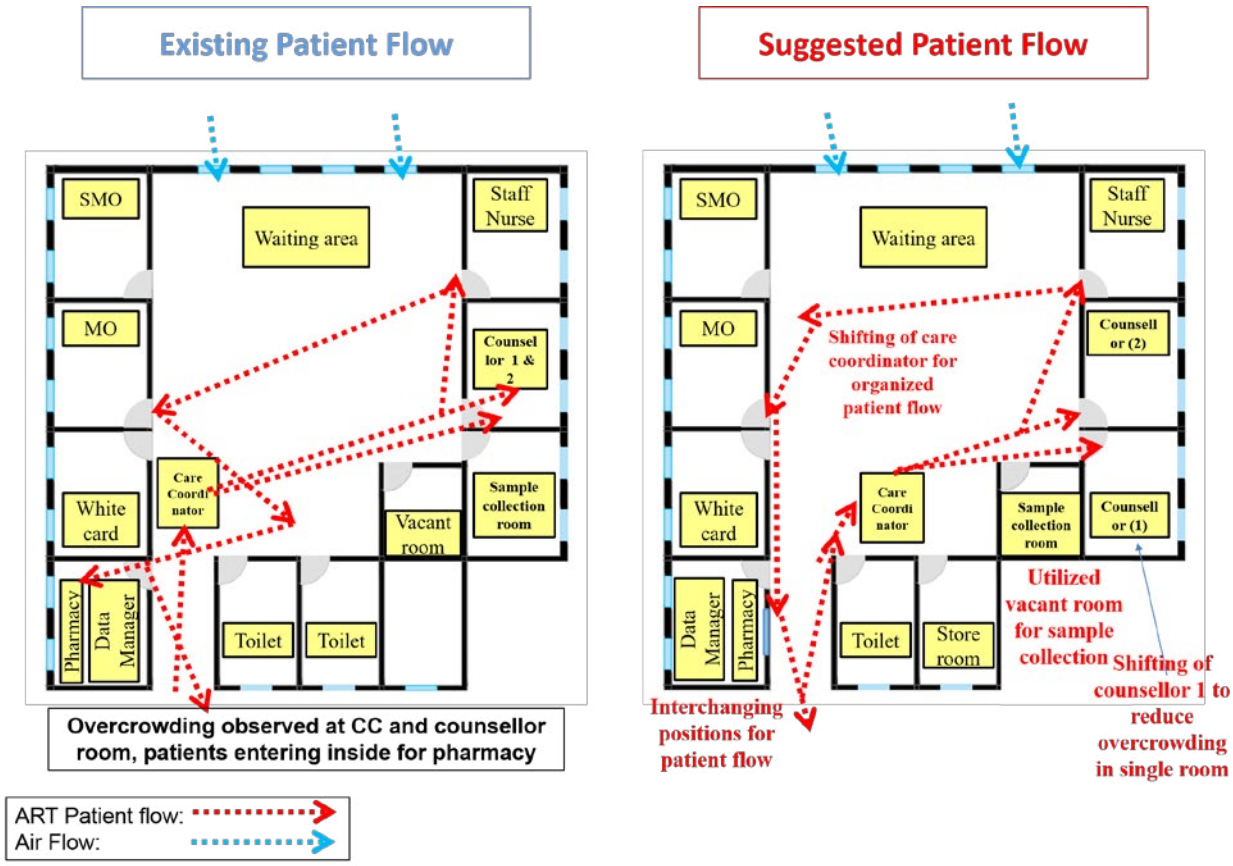
Criss crossing of patients, overcrowding in waiting area, seating arrangement not as per AIC guidelines

Suggested Patient Flow

Patient flow organised, overcrowding and criss crossing of patients reduced, ventilation improved.



Courtesy: SHARE India and MDACS



Triage and fast tracking of patients attending ART centre with respiratory signs and symptoms

Care coordinators or nurses should screen and triage all patients arriving at ART centre as early as possible for any respiratory symptoms. Patients with respiratory symptoms should be educated on cough hygiene, kept in a separate well-ventilated waiting area if possible, and fast-tracked through their visit.

- Education on cough hygiene for persons with respiratory symptoms
- Educate HCWs, patients, family members, and visitors on the importance of covering their cough to help prevent the transmission of airborne infections (both TB and other respiratory infections)
- Instruct patients about covering their mouth and nose with a tissue when coughing and dispose of used tissue in waste containers
- Provide a disposable surgical mask to all patients with respiratory symptoms
- Fast-tracking of patients with respiratory symptoms is critical to reduce the time the patient is in the facility, so to reduce possible contamination of air and spread of infectious respiratory disease to other patients and healthcare providers
- Community care coordinator or nurse of the ART centre shall facilitate the fast-tracking of patients with respiratory symptoms to get them counselled by the counsellors, examined by the doctors and provided with the drugs quickly, without making them wait in the regular queue. Patients with presumptive TB should be referred to the for NAAT testing/appropriate investigation for TB. This will facilitate early identification and treatment of TB patients
- Signboard display of the fast-tracking policy within the ART centre should be visible to avoid confusion among waiting patients

16.2.1.3 Personal Protective Equipment (PPE): Personal protective equipment for example, surgical mask to patients, particulate respirators certified as N-95 should be available as required in high-risk situations, especially DR-TB, and during high-risk aerosol-generating procedures such as bronchoscopy or sputum induction.

16.2.1.4 Health Care worker screening: HCP also need to be periodically screened for tuberculosis as per AIC guidelines of Government of India. HCW should be informed and encouraged to undergo TB diagnostic investigations as well as HIV counselling and testing. HIV positive health workers should also be provided comprehensive package of care which includes ART & TPT. In addition, Health care providers have potential risk of getting occupational exposure to various potential blood borne infections (HIV, HBV and HCV) that occur during performing duties. Therefore, screening for hepatitis to be done irrespective of symptoms. Further, it should be ensured that the ART centre staff are vaccinated for Hepatitis B.

16.3 Post Exposure Prophylaxis (PEP) for HIV:

Post exposure prophylaxis for HIV refers to the comprehensive management instituted to minimize the risk of infection following potential exposure to HIV. This includes first aid, counselling, risk assessment, relevant laboratory investigations based on informed consent of the source and exposed person and depending on the risk assessment, the provision of short term (4 weeks) of antiretroviral drugs, with follow up and support including maintaining confidentiality. PEP aims to inhibit the replication of the initial inoculums of virus and thereby prevent establishment of chronic HIV infection.

Post exposure prophylaxis (PEP) is a standard protocol for preventing chances of getting HIV infection when a health care worker is exposed to a source patient known to be / possibly HIV-infected (i.e., occupational exposure). In cases of sexual assault, PEP should be given to the exposed person as a part of post sexual assault care.

16.3.1 Steps for management of exposed person:

PEP should be initiated as early as possible after exposure that has the potential for HIV transmission, **preferably within 72 hours.**

Important steps which needs to be followed are given below:

Step 1: Management of exposed site (for occupational PEP)

Step 2: Establish eligibility for PEP

Step 3: Counselling for PEP

Step 4: Laboratory evaluation

Step 5: Prescribing PEP

Step 6: Follow-up

Please refer to ART chapter of National Guidelines for HIV care and Treatment 2021, NACO for details.

Step1: Management of exposed site

For skin:

- 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, betadine

For 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

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

Step 2: Establish eligibility for PEP

Eligibility for PEP is determined by:

- Source HIV status: Assessment for eligibility should be based on the HIV status of the source whenever possible and may include consideration of background prevalence and local epidemiological patterns*
- Type and severity of exposure: Exposures that may warrant HIV PEP include:
  - √ Type of body fluids: blood, bloodstained saliva, breast milk, genital secretions and cerebrospinal, amniotic, peritoneal, synovial, pericardial or pleural fluid. While these fluids carry a high risk of HIV infection, this list is not exhaustive. All cases should be assessed clinically, and health workers should make decisions as to whether the actual exposure constitutes a significant risk.
  - √ Types of exposure:
    1. Mucous membrane: sexual exposure; splashes to eye, nose, or oral cavity
    2. Parenteral exposures:
       - an accident with a high calibre needle (>18 G) visibly contaminated with blood
       - a deep wound (haemorrhagic wound and/or very painful); transmission of a significant volume of blood
       - an accident with material that has previously been used intravenously or intra-arterially

Exposures that do not require HIV PEP include:

- When the exposed individual is already HIV positive
- When the source is established to be HIV negative
- Exposures to bodily fluids that do not pose a significant risk, i.e., tears, non-blood-stained saliva, urine, and sweat
- Exposure to intact skin (unless abraded or inflicted with dermatitis)

**Ascertainment of source HIV status may be difficult in some settings. In settings with high background HIV prevalence or where the source is known to be at high risk for HIV infection, all exposure may be considered for post-exposure prophylaxis. PEP initiation should never be delayed due to unavailability of the source's HIV test results.*

Step 3: 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 details of window period, baseline test, drugs that are used, their safety and efficacy and issues related to these drugs during pregnancy and breast-feeding.

He/she should be counselled on safe sexual practices till both baseline and 3 months HIV test are found to be negative.

Psychological support: Many people will 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.

Step 4: Laboratory evaluation

HIV, HBV and HCV testing of exposed person should be done as early as possible. The decision whether to test for HIV or not should be based on the informed consent of the exposed person. A positive HIV status at baseline indicates need for referral to HIV care and treatment.

Step 5: Prescribing PEP

- Timing of PEP. As post-exposure prophylaxis (PEP) for HIV has its greatest effect if begun within 2 hours of exposure, it is essential to act immediately. There is little benefit if >72 hours have lapsed but PEP can still be used if the health care worker presents after 72 hours of exposure. The prophylaxis needs to be continued for 28 days.
- A 28-day prescription of antiretroviral drugs should be provided for HIV post-exposure prophylaxis following initial risk assessment.
- Report exposure immediately to appropriate authority.
- Never delay the start of therapy due to debate over regimen.
- In cases with exposure from person on ART, start available three drug regimens and seek opinion after that.
- In case of highly treatment experienced source, initiate first dose as per guidelines and expert opinion should be sought.

Step 6: Follow-up

Enhanced adherence counselling is recommended for individuals initiating HIV post exposure prophylaxis.

- Follow-up client at 7 days, 14 days, 28 days and 12 weeks after starting PEP.
- Follow-up HIV testing at 4 weeks, if negative, test again at 12 weeks after which test as per risk category.
- Assess for and manage adverse effects due to PEP.

Monitor for acute sero-conversion illness, within 3-6 weeks after exposure. If suspected, refer to treatment services.

Recommended PEP regimen

Exposed person	Preferred regimen for PEP	Alternate regimen (if preferred regimen is not available or contra-indicated)
Adults and adolescents (≥ 10 years old and ≥ 30 kg body weight)	**Tenofovir (300 mg) + Lamivudine (300 mg) + Dolutegravir (50mg)** (one tablet OD)	**Tenofovir (300 mg) + Lamivudine (300 mg)** (FDC – one tablet OD) **+ Lopinavir (200mg)/Ritonavir (50mg)** (two tablets BD) or **Tenofovir (300 mg) + Lamivudine (300 mg) + Efavirenz (600mg)** (one tablet OD)
Children (weight ≥20 Kg and age ≥6 years	**Zidovudine + Lamivudine (dosage as per weight band)** + Dolutegravir (50mg)** (one tablet OD)	*If Hb <9 gm/dl:* **Abacavir + Lamivudine** (dosage as per weight band) **+ Dolutegravir (50mg)** (one tablet OD) or **Zidovudine + Lamivudine + Lopinavir/ Ritonavir** (dosage as per weight band) **
Children (weight <20 Kg or age 6< years)	**Zidovudine + Lamivudine + Lopinavir/ Ritonavir** (dosage as per weight band) **	*If Hb <9 gm/dl:* **Abacavir + Lamivudine + Lopinavir/ Ritonavir** (dosage as per weight band) **

* *If Hb <9 gm/dl*

** *Refer to National Guidelines for HIV care and Treatment 2021 for national pediatric ART dosing schedule*

***DTG can be used in children at least 4 weeks of age AND weighing at least 3 kg, if age appropriate dosing is available

- PEP should be initiated as early as possible after exposure that has the potential for HIV transmission, preferably within 72 hours. PEP for HIV has its greatest effect if initiated within 2 hours of exposure.
- Duration of the PEP is 28 days.
- For an informed consent, exposed persons (clients) should receive appropriate information about what PEP is and the risk and benefits of PEP.
- Adequate counselling must be provided on adherence, follow up protocol, possible adverse effects, safe sexual practices. In case of children, caregiver should be adequately counselled before initiating PEP.
- HIV (after informed consent), HBV and HCV testing of exposed person should be done as early as possible.
- Follow-up client at 7 days, 14 days, 28 days and 12 weeks after starting PEP.

Availability of PEP drugs: PEP drugs are required on an urgent basis after accidental exposure and should be available and accessible round the clock. In all cases, the first dose of PEP should be offered as soon as possible, preferably within 2 hours, once the decision to give PEP is made. The PEP regimen should be made available from ARV drug stocks, in the casualty, OT, labour room, ICU and emergency ward, with proper documentation. A regular check should be made for expiry of drugs with replacement of short expiry drugs.

Documentation: PEP cases should be documented in accidental exposure form (including consent form) and PEP register and reporting of drug consumption should be done in IMS.

CHAPTER 17

DATA MANAGEMENT SYSTEMS

The ART centres have twin objectives of improving health outcomes of PLHIV by providing quality care and contributing towards the larger goal of ending AIDS epidemic in the country. Therefore, having robust data management system at ART centres is critical for patient and programme monitoring. This chapter provides consolidated guidance on data systems for patient and programme monitoring by the National AIDS Control Programme.

The data management systems at ART centres serve two main functions:

a. **Patient monitoring and management:** It enables effective and appropriate management of a patient over time to ensure continuity of care, thereby enhancing health outcomes and quality of life.
b. **Programme monitoring and management:** The data generated at ART centres is used for programme monitoring, including outputs, outcomes, quality and gaps, both in relation to patient management as well as national plan goals and targets.

This data is used by National AIDS Control Programme to:

- Ensure efficient patient management and improve long-term chronic care
- Monitor and report national and global indicators
- Identify gaps in service access and coverage, improve linkages and address priorities along the HIV care continuum
- Take evidence-based policy decisions

17.1 Data Management Systems for Monitoring of ART Services:

A standardized data management system with comprehensive and uniform data collection tools (registers and forms), clearly defined reporting mechanisms (flow of information) and an appropriate storage and retrieval mechanism are necessary to ensure that the required patient and programme information is captured and used consistently and regularly.

17.1.1 Information management system (IMS): NACP has launched IT enabled **information management system**, a case-based recording and reporting system that captures each patient's demographic, clinical, laboratory and pill pick -up information in a longitudinal manner. This information management system of NACP (currently also called SOCH) is referred to as **IMS** in this document. It captures key variables of each patient longitudinally. Primary source of data is the white card. The IMS enables the ART centre staff to generate lists (due list, LFU list, death list etc) and reports (monthly progress report, adherence, drug stock report etc). **All ART centres as well as LAC/LAC plus centres are required to maintain and update information in IMS on daily basis.** NACO plans to transition all reporting to **IMS** in a phased manner.

17.1.2 Recording and reporting tools: Standardized recording and reporting tools used for data collection and supervision have been classified under various sections as discussed below. It is planned to simplify the recording and reporting mechanisms and optimally utilize IMS for reporting and monitoring.

Table 20. Recording and reporting tools to be maintained at ART Centres, SACEPs and LAC/LAC plus

Recording and reporting tools	**Proposed plan** *Continue =To be continued in hard copy till further notification* *Autogenerated from IMS= Recording and reporting tools is to be continued but autogenerated from IMS. Soft copy to maintained** *Integrated with IMS= Integrated into functionality of IMS** *Discontinued= the tool is discontinued/phased out and is not required to be maintained in hard/soft copy*
Care and treatment -records and registers	
1. Patient visit register	Continue
2. HIV Care Register	Continue
3. Patient treatment record (white card)	Continue
4. ART enrolment register	Continue
5. Patient booklet (green booklet)	Continue
6. Daily/ Monthly OI reporting format	Discontinued
7. Death register	Autogenerated from IMS (details to be added to white card)
8. EID register	Discontinued
9. CD4 laboratory register	Autogenerated from IMS (lab module)
10. Viral load lab register	Autogenerated from IMS (lab module)
11 Post exposure prophylaxis register	Autogenerated from IMS
Referral forms	
1. ICTC to ART referral form	Continue
2. TB-HIV (ART) duplicate referral form	Discontinued
3. Exposed infant/child referral form	Discontinued
4. Transfers out form	Integrated with IMS (patient to be given a printout of this form)
5. Accidental exposure form (PEP notification and consent form)	Continue
6. NTEP lab referral form	Continue
Stock Management Registers (Drugs, CD4 Kits & Consumables etc.)	
1. ARV drug stock register	To be autogenerated from IMS (soft copy to maintained)
2. ARV drug dispensing register (adult)	Integrated with IMS
3. ARV drug dispensing register (paediatric)	Integrated with IMS
4. OI drug stock register	To be autogenerated from IMS (soft copy to maintained)
5. OI drug dispensing register	Integrated with IMS
6. Expired drug stock and disposal register	Continue
7. CD4 kits & consumable stock register	To be auto generated from IMS (soft copy to maintained)
8. Fixed assets register	Continue

SACEP related tools	
1. SACEP request and reply Form	To be auto generated from IMS
2. SACEP referral summary (revised format)	To be auto generated from IMS by financial year to be linked with line list of PLHIV with unsuppressed VL) (at all referring ART centres)
3. SACEP register (revised format)	To be auto generated from IMS (at CoE/pCoE & ART plus centre)
4. SACEP meeting format	To be auto generated from IMS (at CoE/pCoE & ART plus centre)
5. Monthly reporting format (third line)	No separate reporting required (third line reporting to be integrated with MPR)
TB-HIV tools	
1. HIV TB line list	Auto generated from IMS (soft copy to be maintained at ART centres and reviewed on monthly basis)
2. HIV TB register	HIV-TB register to be auto generated from IMS
3. TB Treatment card	Continue
LAC/LAC plus reporting tools	
1. Link out /link in form	*Integrated with IMS*
2. Form 4B, 4C	Discontinued. Integrated with IMS
3. MPR of LAC (revised format)	Auto generated from IMS (soft copies to be downloaded by LAC and maintained)
Line Lists	
1. Master line list (with longitudinal data points – revised format)	Auto generated from IMS (with longitudinal data points)
2. PLHIV tracker format	Auto generated from IMS
Programme performance monitoring reports	
ART centre monthly progress report	*Autogenerated from IMS* *To be submitted by ART centres to SACS by 4th of next month. SACS after verification of the data should submit to NACO by 10th of next month*

**Guidance would be provided by SACS for discontinuation of physical records and registers*

Line lists to be auto-generated by IMS: In addition to the tools mentioned in above table, the following line lists shall be auto generated from IMS

1. Daily missed list
2. Missed list of PLHIV who were due on previous day
3. Missed/LFU list
4. List of PLHIV died
5. List of PLHIV transferred in/transferred out
6. PLHIV not initiated on ART with gap analysis
7. Viral load due list

8. Line list of PLHIV with unsuppressed VL (to be linked to step up counselling, repeat VL SACEP referral and action taken)
9. CD4 due list
10. EID confirmatory due list
11. Stable and unstable PLHIV
12. PLHIV on MMD
13. List of PLHIV at LAC/LAC plus
14. Tracker sheet (not initiated on ART, ART MIS/LFU, new PLHIV initiated on ART, PLHIV with adherence <80% or virally unsuppressed and undergoing step up counselling (monthly)
15. HIV-TB cascade with gap analysis (testing and treatment cascade)
16. IPT cascade with gap analysis
17. 3, 6, 12 and 24 month retention cohort
18. Short expiry and expired drugs

17.2 Key Aspects of Data Management for ART services

- Information collected, compiled and reported is complete, correct, consistent, accurate and reliable
- Patient information is stored securely to ensure confidentiality
- Information (patient records, registers and reports) should be easily retrievable
- Use routine data for patient care
- Relevant information can be given as feed back into the programme

17.3 Storage of Records and Registers

As with all medical patient records, correct and appropriate storage in a safe place with restricted access is important to ensure easy retrieval and access by authorized health care workers. ART centres should ensure the following while managing the data:

- **Data confidentiality:** Every establishment keeping the records of HIV-related information of protected persons should adopt data protection measures. The measures should include procedures for protecting information from disclosure, accessing information, security, accountability and liability of persons in the establishment.

  All physical medical records should be kept secured in a locked cabinet with access to authorized staff only, in order to avoid misuse of information. All data should be stored in a password-protected computer with access to authorized staff only. Please refer to NACO Data Confidentiality and Protection guidelines for more details.
- **Records easily retrievable:** ART centre should ensure that records are arranged systematically – serially by registration / ART initiation number. This facilitates quick search of patient treatment records for patient visits as well as identification of patients who have missed appointments or are lost to follow-up. As a good practice, all staff should undertake the exercise to arrange the cards systematically, once every week, preferably on Saturdays.

17.4 Data Flow and Reporting Mechanism

There is pyramidal flow of data from ART centres to NACO. The responsibility of information collection, compilation, reporting, management and analysis rests at three levels:

1. **ART centres** for creation and maintenance of patient records and files, entering data into IMS, and reporting to SACS/NACO through monthly reports. The list of tools and ART staff responsibilities for completion of each tool are given at Annexure 27, however overall responsibility lies with SMO/MO of the centre under supervision of the nodal officer. LAC/LAC plus will also update data in IMS for the linked out PLHIV and generate the monthly reports in prescribed format. ART centres will incorporate this information into final monthly progress report. ART centres should ensure the usage of IMS by all LACs.

2. **State AIDS Control Societies (SACS)** for consolidation of ART centre information. SACS is required to review the data, apply quality checks (completion, correctness, consistency), coordinate with ART centres to rectify any errors or missing information before sharing the data with NACO. SACS is also responsible for data analysis for providing feedback to ART centres and dissemination of information to state-level stakeholders. Data should also be shared with CoE to support mentoring of the ART centres on gaps in patient care.
3. **NACO** does compilation of reports, analysis, evaluation and dissemination of information back to SACS for, planning, procurement and expansion.

17.5 Data Use and Feedback

In order to successfully address challenges in reaching sustained levels of epidemic control, it is critical that programme data should be routinely analyzed and assessed to identify gaps in service access and coverage, linkages and address priorities along the HIV care continuum cascade. Data generated from the analysis should further be used for decision making for efficient patient management, programme management and plan evidence-based immediate solutions to address the gaps and finding missing PLHIV and retaining them in care.

17.5.1 Data use at ART centre level: It is critical for ART centres to use the data being collected for:

- Patient monitoring management and clinical decision making;
- Identifying gaps in treatment cascades and sub-cascades (KP, pregnant women, children, HIV-TB coinfected etc);
- Planning activities to address gaps in cascade and patient specific issues based on data; and
- Making patient management systems more efficient to enhance retention.

SMO/MO of ART centres should organize monthly team meetings with the ART staff after generating the monthly progress report. The purpose of these meetings is to:

- inculcate team culture for data analysis and use of data to address gaps
- cross-check of the data to be submitted to the SACS
- to identify gaps in service access and coverage, improve linkages, retention and VL load suppression
- to review performance trends for key indicators using IMS dashboards and output reports for performance analysis

Key indicators to be reviewed:

- ART initiation: Number and proportion of PLHIV initiated on ART among registered in FY
- LFU, MIS 2, MIS 3, opted out and deaths out of those initiated on ART in financial year
- New LFU, opted out and deaths during the month
- VL coverage and suppression
- Proportion of on ART PLHIV who are stable and on MMD/LAC
- Step up counselling and SACEP referral for unsuppressed PLHIV, action taken on SACEP recommendation
- Drug stock

- The minutes of meeting should be documented and followed up in next monthly meeting
- **Score card:** Score card provides feedback to ART centres on a quarterly basis regarding their performance on key indicators related to linkage, retention and priorities related to retention cascade. All indicators of score card to be distributed amongst ART staff for close monitoring and performance improvement. Please refer to Annexure 28 for score card.

17.5.2 Data use at SACS level: It is important that data collected is analysed at the state level to identify gaps in service access and coverage, linkages and address priorities along the HIV care continuum cascade in the state and by districts and by ART centres. At SACS level, data should be analysed to:

- measure the progress made towards achieving the identified targets and goals and should be used for further planning and to make mid-course corrections.
- provide feedback to the ART centre for improvement through positive reinforcement.
- plan for supportive supervision, guidance and mentoring of ART centres 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 programme implementation plans (PIPs) and annual action plans (AAP) based on data and evidence.
- state officials of all divisions should plan monthly meetings after receiving data from ART centres to analyse the gaps and address the issues.

17.5.3 Data use at NACO level: Data collected is analyzed at the national level to identify gaps in service access and coverage, linkages and address priorities along the HIV care continuum cascade. At national level data should be used to:

- measure the progress made towards achieving the identified targets and goals and should be used for further planning and to make mid-course corrections
- provide feedback to states and ART centres
- monitor and mentoring states/ART centres based on performance
- prepare annual plans, procurement of drugs and commodities, and expansion
- understand and address gaps in patient management to improve long-term chronic care
- monitor and report national and global indicators
- inform evidence-based policy decisions in a timely manner

17.6 Data Quality Assurance

Accuracy of data is essential in ensuring that programmes are implemented correctly and are monitored appropriately to assess outcomes and potential impact. Accurate programme data also ensures that decisions based on such data are evidence-based.

ART centre should follow routine data quality assurance (DQA) procedures to verify the accuracy and completeness of reported data on at least a quarterly basis. This exercise should be led by nodal officer of the ART centre and with support of SMO/MO in-charge and data manager. The purpose of these data review meetings is to assess data quality, review data with ART staff and assess findings, highlighting and documenting data discrepancies; and decide appropriate action. Signed reports should be maintained in file for records and shared with SACS. Routine data quality assurance activities should be joined by SACS/ DAPCU/TE/RC in person or virtually. Please refer to **Annexure 29** for DQA format.

As part of DQA, the following data verification process should be practiced:

- Review all registers for data completeness
- Crosschecking (comparing) monthly reported results with patient records (white card) and IMS
  - Compare the total number of patients ever registered with the number in the HIV care register and IMS
  - Compare the total number of patients ever started on ART with the number in the enrolment register and IMS.
  - Compare total PLHIV initiated during the last quarter with the number in the ART enrolment register and IMS during last quarter
  - Select 20 patient records randomly from IMS based on ART enrolment number
    - Review white card and IMS for completeness and updated entries
    - Cross check the status of PLHIV (on ART, LFU, died, opted out, stopped treatment) with white card

- Cross check the important variables (ART regimen, last date of pill pick up, VL result adherence, address and phone number) with white card
- Review IMS and white card for completeness and updated entries

- Based on the results of data verification, the nodal officer of ART centre should ensure rectification of errors and report shared with SACS.

17.7 Guidance for Retention/ Disposal of Records

i. Records to be maintained and kept in safe custody at all times (Category 1):

- Patient treatment record (white card) of all PLHIV except in category 2; expired drug stock and disposal register; fixed assets register are to be maintained in hard copy and kept in safe custody at all times.
- MLL, ART MPR, LAC MPR, monthly reporting format (second/third line), death register are to be maintained in soft copy and kept in safe custody

ii. Records to be maintained for a minimum period of 5 years from the day of last entry in the record (Category 2):

- Patient treatment record (white card) of PLHIV who are reported died/ opted out/ stopped treatment/ transferred out (more than 5 years); and PLHIV declared as permanent LFU (as per program guidance) are to be maintained for minimum period of 5 years from the day of last entry in the record, after which these can be disposed off.
- HIV care register and ART enrolment register can be disposed if information from these records is entered in MLL/IMS or digitised, after a minimum period of 5 years from the day of generation of the record.
- SACEP register, HIV-TB register, laboratory registers (CD4 & viral load), stock registers (ARV drugs, OI drug, CD4 kits & consumable), PEP register, accidental exposure form can be disposed after 5 years.

iii. Records to be maintained for a minimum period of 1 years from the day of last entry in the record (Category 3): Patient visit register and drug dispensing registers (ARV and OI drugs).

Notes:

- *The medico-legal reports/records should be preserved for a period of at least 10 years or till the disposal of case by the court. The records should be in the custody of the nodal officer or in the record room of hospitals.*
- *Those records which are part of white card (annexures like SACEP request and reply form, link out /link in form, transfers out form, lab reports etc.) shall follow the white card retention policy as mentioned above.*
- *All other records not mentioned in above categories and integrated into IMS or discontinued under the national program as per the **table no. 20** can be disposed.*
- *For disposal of any record, three members committee under the chairmanship of Nodal Officer of the ART centre shall classify/verify the records and ensure disposal as per the guidelines.*
- Before disposal of any record, centre should document details (name/quantity/period) of the record in 'fixed asset register' with date of disposal.

17.8 Reporting by Private Sector

Accurate estimation and effective planning by the NACP depends primarily on the number of PLHIV both in the private and public sector. To encourage reporting by the private sector, NACO has designed a simple quarterly reporting format for the sites that provide treatment services in the private sector and the number of patients accessing ART and VL services. Reporting format is provided in Annexure 30.

CHAPTER 18

PROGRAMME MANAGEMENT, MONITORING AND MENTORING MECHANISMS

18.1 Responsibility of the CST Division at SACS

The Joint Director (JD)-CST is the focal person for care support and treatment services in the state. If the post of JD (CST) is not sanctioned or vacant, the Project Director should identify a senior officer, preferably, Additional. Project Director as a nodal officer for the effective supervision and monitoring of the implementation of CST services in the state. Project Directors of SACS should take all steps to sensitize the Principals, Deans and Medical Superintendents of the medical institutions in their states on CST related activities and support referral from the hospital for other services. The SACS will oversee the coordination of ART services at the implementation level through a team approach and coordination with community.

Responsibilities of JD (CST)/Officer in charge for CST

Joint Director is overall responsible for planning, implementing and monitoring HIV care support and treatment related activities in the state.

1 All administrative and file work related to the CST division in the state including facilitating staff appointment, salary, appraisals and office orders to CST field staff (ART centre, LAC plus, CoE)

2 Compile monthly progress reports and share with NACO before 10th of every month

3 Site level supervision, mentoring and monitoring of ART centres (all centres to be visited once in 3 months by officials from CST division) and submit report indicating critical gaps in quality ART service delivery, action to be taken with timeline to PD/APD SACS and to CST division NACO

4 Ensure timely submission of the complete and correct MPR and other reports by the ART centres to NACO and SACS

5 Review the updation and utilization of information management system (IMS) by the ART centres and the drug stock entries by SACS in IMS

6 Identify sites for establishing new ART centres and decentralized ART distribution sites as per NACO criteria

7 Identify ART centres for upgradation to ART Plus centre as per NACO criteria

8 Coordinate with Principals/Deans/Medical Superintendent/Directors/CDMO of hospitals within the state for facilitating quality and stigma free ART service delivery in the state

9 Coordinate with NACO in the planning and implementation of ART services

10 Coordinate and review the ART services with active participation of NGO and PLHIV network

11 Collate, compile and share ART information with NACO

12 Facilitate sensitization trainings by the ART centres for the hospital staff, resident doctors, interns, nursing students, medical students etc. for quality and stigma free HIV care and ART service delivery by the hospital and ART centre, biomedical waste management and post-exposure prophylaxis

13 Monitor the CD4 and viral load testing coverage and supply of kits
14 Monitor supply and utilization of ARV drugs, relocation and coordination with NACO to avert any drug stock outs
15 Coordinate with the other divisions of the SACS for ensuring maximal linkages with ICTC, PPTCT, HIV-TB and the lab services
16 Monitor procurement, supply and availability of OI drugs and PEP drugs
17 Review of functioning of the CSC and ensure ART and CSC conduct ART-CSC coordination meeting
18 Facilitate to conduct state level CSC meetings
19 Establish system for continuous quality improvement at all ART centres
20 Closely monitor ART centres for performance in key indicators and take immediate steps for improvement of low performing centres.
21 Review the performance of ART centres using the NACO score card and standard review format and provide feedback with assigned responsibilities and timeline to the ART centres to mitigate gap
22 Conduct regular State Grievances Redressal Committee (SGRC) meetings and ensure for the resolution of all the pending grievances of PLHIV
23 Facilitate training activities of different categories of health care providers for the ART centres with the concerned CoE
24 Provide feedback on policy implementation to NACO on a regular basis
25 Monitor and review of the utilization of VL results by the ART centre staff
26 Ensure seamless functioning of SACEP at the ART plus centres and CoE/pCoE

18.2 Responsibility of the Regional Coordinator / Technical Expert CST

NACO has additionally appointed Regional Coordinators/Technical Experts to support planning, implementation, monitoring and supportive supervision of CST services. Regional coordinators are directly contracted by NACO while technical experts are contracted by the technical support units (TSU) at SACS. The key job responsibility is site level monitoring and mentoring of ART centre staff through extensive travel. They are required to submit all the reports to NACO/SACS. They are not replacement for JD or the other staff of the CST division at SACS. The RCs work directly under the supervision of CST division of NACO and the Project Director at SACS, while the technical expert is under administrative control of TL TSU (SACS) and provide technical support to CST division at SACS. The role of RC/TE is primarily for technical support, mentoring/ monitoring of facilities and to undertake field visits rather than routine administrative work at SACS.

Job Responsibilities of RCs/Technical Experts are to:

1. Ensure implementation of CST services as per prescribed operational guidelines for CoE, pCoE, ART plus centres, ART centres, LAC/LAC Plus, DSD sites and CSC
2. Undertake regular visits to the ART centres, Laboratories of CD4/viral load testing for monitoring, supportive supervision and mentoring
3. Assess feasibility of new ART centres, LAC, DSD sites
4. Coordinate with Principals/Deans of medical colleges and Superintendents/Director/CDMO of district hospitals/other hospitals for coordination of ART services with other departments in the institution
5. Ensure implementation of ART services with high quality and good clinical practices
6. Ensure that PLHIV are neither discriminated nor denied admission/care in the hospital
7. Strengthen linkage between the ART centres, ICTC, PPTCT, EID, NTEP and CSC in the state
8. Support SACS in developing targets with timelines, determine resource requirements and review ART centres performance at state level.
9. Assist SACS in training, supervision and establishment of follow up systems for ART patients in the public and private sector

10. Review functioning of CSC on regular basis to ensure adherence to NACO guidelines
11. Provide e-feedback on the drug stock at the ART centres and drug forecast based on the ART centre monthly reports.
12. Analyze the reports from the ART centres and provide feedback to SACS and the ART centres.
13. Assist JD CST in conducting of regular State Grievances Redressal Committee (SGRC) meetings
14. Assist JD CST to establish system for continuous quality improvement at all ART centres.
15. Assist JD CST to closely monitor ART centres for performance in key indicators and in taking immediate steps for Improvement of low performing centres
16. Coordinate training activities of different categories of health care providers for the ART centres with the concerned CoE.
17. Support SACS/ART centres in forecasting/calculating ARV and OI drug requirements.
18. To provide a regular update to NACO on the ART programme in the region and assist the SACS and NACO in analysis of data and publications
19. Participate in periodic review meetings at NACO
20. Ensure all the ART centres share ART monthly progress of report with SACS by 4th of every month
21. Actively participate in the SACEP meetings in the region/state

18.3 Role of District AIDS Prevention Control Society (DAPCU)

The District Programme officer(DPO)-HIV is the overall in charge of HIV Programme in the district.

1. ART/LAC functioning should be part of the District AIDS Prevention Control Committee meeting which is headed by District Collector
2. S/he should support the functioning of ART centres, particularly coordinating for LFU tracking, drug stock management, data management systems
3. S/he should also conduct regular supportive supervision of LAC in the district and provide feedback to the SACS
4. S/he should also facilitate coordination & linkages of LAC with health systems in the districts
5. S/he should also facilitate coordination & linkages of PLHIV within NACP facilities in the districts.
6. The DPO-HIV should ensure for regularly conducting various coordination committee meetings in district (ICTC-ART centre coordination, ART-CSC coordination, HIV-NTEP coordination etc.) and for mitigating the gaps in any HIV related service delivery in the district.
7. The DAPCU and DPO-HIV should also supervise functioning of CSC in the district, particularly with respect to ART-CSC coordination and LFU tracking
8. DAPCU should coordinate for tracking and tracing of MIS/LFU cases and inter-district coordination

18.4 Role of Centres of Excellence and Paediatric Centres of Excellence

CoE shall monitor and mentor the ART centres linked to them on both programmatic and clinical aspects. The CoE should be able to plan, organize and carry out all mentoring activities. A core group of mentors of CoE will be identified and trained. This team of mentors will comprise of Programme Director, Deputy Programme Director, faculty, ART SMO/MO, Research Fellow – Clinical, Data Analyst. Mentoring will be for ART Plus centres and ART centres, LAC, LAC plus, CSC linked to the CoE and for the trainees from the same institute and other facilities. The role of the CoE and the Clinical Expert Panel includes supporting and strengthening performance of the linked ART centres and other facilities and mentoring for corrective measures taken to strengthen the programme. ART programme indicators will be used to determine and monitor the ART centre performance.

Programmatic mentoring / supportive supervision will be done by a team which would include staff from the institution, CoE, NACO, SACS. CoE staff will make onsite visits to the ART centres and provide supportive supervision and programmatic support. The mentoring will be done through email and telephone also. CoE will

also take the responsibility of updating/orienting the facility level staff on the recent revisions in the guidelines during their visits.

Planning of mentoring visits should be made in consultation with officials of SACS and the CoE to ensure supportive supervision provided during routine programme monitoring visits by RCs and SACS officials is not duplicated. Mentoring visits should be viewed as an opportunity to provide technical assistance and guidance. Mentors and mentees identified should be individualized to the institution and based on the needs of the institution/CoE. Frequency, timing and duration of mentoring visits will be defined by the CoE. However, a minimum number of onsite visits need to be determined but may be modified according to the needs identified. The Programme Director CoE/pCoE should also serve as a regional mentor which would add to the quality of mentoring provided within the programme. For more details on mentoring by CoE, plaese refer to Section 12.1.7 a

18.5 Role of ART Centres in Program Management

Programmatic functions of ART centres are enlisted in Section 1.1.2. List of routine programmatic activities to be conducted by ART centres are provided under 'Activity calendar' at Annexure 31. Roles and responsibilities of nodal officer and staff at ART centre with respect to program management are detailed in Section 13.4.

18.6 Monitoring and Supervision formats to be used by SACS/ RC/TE/DAPCU

Apart from all the M&E tools described in previous chapter, other formats required for monitoring and supervision are:

1) ART supportive supervision visit format (Annexure 32)
2) Score card (Annexure 28)
3) LAC supportive supervision visit format (Annexure 12)
4) Format for assessment of CSC (refer to CSC guidelines)
5) Standard format for review meeting

Feasibility or readiness assessment checklists:

1) ART feasibility visit format (Annexure 16)
2) ART preparedness format (Annexure17)
3) LAC feasibility assessment format (Annexure 8)
4) LAC plus feasibility assessment format for ART initiation (Annexure 9)
5) ART plus feasibility assessment checklist (Annexure 21)
6) Third line feasibility assessment format for ART plus centres (Annexure 22)

CHAPTER 19

CONTINUOUS QUALITY IMPROVEMENT

Every public health programme needs to be reviewed and monitored periodically to assess the progress, identify gaps and re-align plans. Continuous quality improvement (CQI) for ART services involves systematic and continuous activities that are implemented for improving quality of care with resultant measurable impact on patient outcomes and goals of national programme. CQI involves activities that are aimed to monitor, assess, and improve quality of ART services. The activities are cyclical so that programme continues to seek higher levels of performance to optimize care for the patients, while striving for continuous improvement.

19.1 Objectives

Continuous quality improvement (CQI) for ART services aims at ensuring provision of quality (comprehensive, patient-centred, timely, effective, efficient and stigma free) care resulting in optimal patient outcomes. The purpose of continuous quality improvement is to enhance health care by identifying problems, implementing and monitoring corrective action and assessing its effectiveness. An essential element of quality improvement is the focused monitoring of high-risk, high-volume or problem-prone aspects of ART services. ART centres which are identified to have challenges or the aspects of ART services which need focus are prioritized. General areas of CQI include access to care, the intake process, retention in care and patient outcomes.

19.2 Key Approaches for Continuous Quality Improvement (CQI)

Key approaches recommended for continuous quality improvement (CQI) of CST services under national programme are:

i. Mentoring

ii. Monitoring

Mentoring serves as an extension of training to increase the knowledge, perfect the skills, improve the attitudes and strengthen the motivation of involved health personnel. The mentoring in context of ART comprises both, on **clinical and programmatic** aspects and is for all facilities (CoE, ART Plus, ART, LAC, LAC plus, CSC etc.). Clinical mentoring entails training and consultation on complex cases; supports and enhances diagnostic, patient management and decision-making skills; case-based learning through discussion of complicated cases/patients referred to SACEP. Programme mentoring involves supporting and strengthening the problem solving and decision-making skills; enhances data utilization to identify gaps and solutions; supports implementing and monitoring corrective actions; and addresses issues of quality assurance of programme activities. This includes supportive supervision on training, staffing, performance against key indicators, records review for completeness and consistency, availability of guidelines, proper timely referral, team meeting and liaison with community.

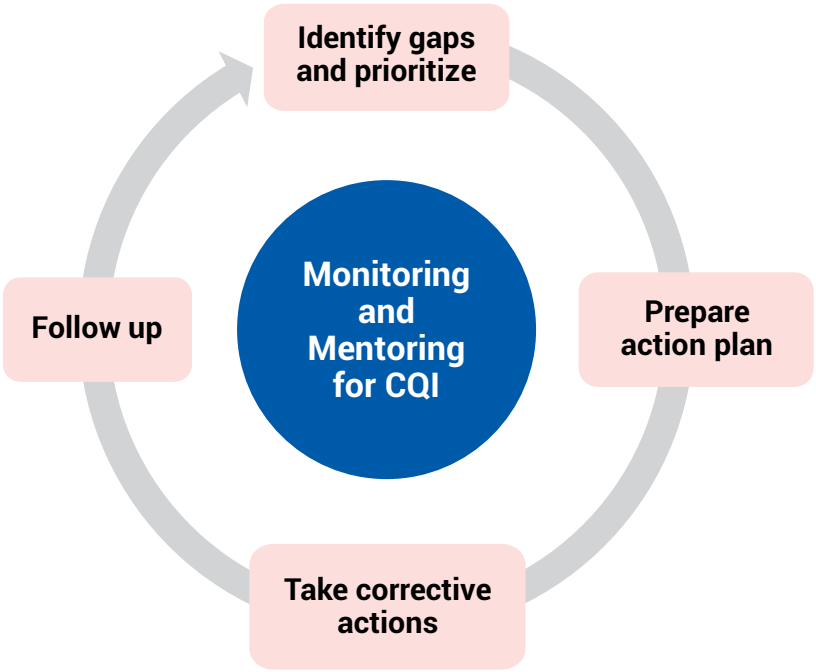
Mentoring is completed by **monitoring,** which entails the tracking of performance of ART services to ascertain that activities are accomplished both in terms of patient and programme outcomes. Monitoring utilizes information that is routinely collected in the programme to track progress towards intended outcomes.

Depending on the observations/result of the routinely collected data, mentoring should be planned for where the staff are provided help to improve their own work performance continuously.

19.3 Continuous monitoring and mentoring cycle

Framework for continuous quality improvement, along with steps and the role of mentoring and monitoring, is described in Figure 21.

Figure 21. Framework for continuous quality improvement (CQI) for ART services



The process for developing and implementing a quality improvement plan incorporates the following:

i. Identification of gaps and prioritization: Gaps may be identified through any of these sources - performance against key programme indicators (score card), monthly progress report, dashboard indicators under complaints from community and providers, quality of care, supportive supervisory/mentoring visits, monthly/ quarterly review or performance against annual plan.

Data is reviewed for performance and/or outcomes. The following may be considered during the process of selecting sites/areas for improvement in ART services:

- What are the patients' issues and concerns?
- What are the staff's issues and concerns?
- What are the priorities for national programme?

The issues with the greatest impact on PLHIV and national programme are identified.

Sites/issues identified for improvement should have one or more of the following characteristics:

- Poor performance against key programme indicators using score card (linkage, retention, VL suppression, uptake of DSD). Details regarding key indicators and use of score card are provided at Annexure 28
- Implementation of new/revised guidelines
- Problem-prone: high frequency, longstanding, multiple unsuccessful attempts to resolve in the past
- High volume, affecting a large number of patients
- High risk, placing patients at risk for poor outcomes
- Based on patient satisfaction or grievances

ii. Development of action plan: A specific work plan is developed that will lead to improvement in performance and/or outcomes, as per template given under Table 21

- Desired improvements are spelled out

- Through analysis of the data, barriers/opportunities to improvement are identified in consultation with the ART centres and considering the patient grievances
- Targets and timeline for improvement are set
- Indicators are then selected (i.e., it is determined what will be measured and how it will be measured)
- A team approach is adopted and staff organized to accomplish the work, while assigning responsibility to individual staff for key processes

iii. Take corrective actions: Action plan is executed in a time bound manner. Support the team through regular mentoring and communication (informal, staff meeting, periodic review). Data may be gathered at regular intervals on an ongoing basis for continuous assessment of performance and execution of the plan

iv. Follow-up: Based on the analysis, a decision is made regarding the next step:

a. Continue the process as is with the same indicators/data monitoring
b. Continue the process with modifications (i.e., implement additional interventions to remove identified barriers)
c. Add new monitors/quality indicators
d. Stop monitoring

New goals are developed or current targets are maintained. A new work plan is developed

Table 21. Template for action plan and follow up

Identified problems	Root causes of problem	Interventions to address the root causes	Indicator (process/ outcome)	Monitoring frequency (daily/ weekly/ monthly)	Expected outcome	Timeline	Responsible person	Expected outcome/Aim met?	Remarks
								Date ..... Yes ☐ No ☐	
								Date ..... Yes ☐ No ☐	

19.4 Standard Operating Procedures

Mentoring and monitoring should be done by JD CST, CST in charge at SACS, RC/TE, CoE, pCoE or any other person who have the necessary expertise in the area. The CoE/pCoE have a defined role in mentoring their linked centres and more details can be assessed through the CoE scheme.

19.4.1 Modes of mentoring and monitoring

- On-site mentoring and monitoring
- Distance mentoring and monitoring through virtual meetings with sites, telemedicine, NDLS/RDLS, case-based learning, email, phone call etc.
- The blended mentoring and monitoring which is a mix of on-site and online events should be utilized to continuous quality improvement

19.4.2 Opportunities for monitoring and mentoring

i. Site visits
ii. Virtual meeting with ART centre
iii. ART review meetings
iv. SACEP meeting

i. Monitoring and mentoring through ART centre visits: SACS CST division, RC/Consultant must undertake supportive supervision site visits to the ART centres and monitor the centre performance based on the monitoring tools and the supervisory checklist. Programme officers at SACS should prepare a quarterly calendar for site visits.

Preparatory work before visit

a. Prioritising sites/ issues for monitoring and mentoring: Identification of ART centres for visit may be based on the following parameters:
   - Sites with poor performance against key programme indicators (linkage, retention, VL suppression, uptake of DSD) using score card/dashboard.
   - Sites with poor performance against AAP targets. Performance against process indicators and achievements to be assessed
   - High volume, affecting a large number of patients
   - Problem-prone sites: sites with frequent and longstanding issues
   - Sites with high risk problems, placing patients at risk for poor outcomes
   - Based on patient satisfaction or grievances. Any outstanding issues or complaints from community

b. Programme data on key indicators such as linkage loss, retention and VL suppression and for AAP targets to be analysed using IMS and MPR for facility visit

c. Collect information from other divisions on cross cutting issues

e. Inform ART centres and DAPCU regarding visit to keep ready the information required against performance, linkage loss, retention or other issues identified

d. Joint visits in coordination with other division for cross cutting issues

e. Plan to attend monthly DAPCU review meetings

During the visit

It is carried out in a respectful and non-authoritarian way with a focus on using monitoring and mentoring visits as an opportunity to solve the issues and improve knowledge and skills of health staff. SACS CST division, RC/ Consultant must undertake supportive supervision site visits and monitor the centre performance based on standard supervisory checklist and tools. The supervisor must encourage an open, two-way communication, and building team approaches that facilitate problem-solving.

- in depth review to analyse the performance against key indicators, process indicators, quality indicators and patient flow
- Review of data management & data analysis done by ART centre
- Assessment to be done as per the supervisory check list. During the visits, the JD/RC / CoE should use the ART centre visit format for proper documentation (Annexure 32)
- For describing the problem, try to answer the following questions:
  - Where does the problem occur?
  - With whom does the problem occur?
  - When and how often does the problem occur?
  - When and how did the problem start occurring?
- To identify and implement solutions try to answer the following questions. The specific solution depends upon the cause(s) of the problem. Solutions you select should:
  - remove (or reduce) the specific cause(s)
  - be reasonable (affordable and realistic)
  - not create other problems
- Preparation of action plan for identified gaps/issues in standard template (Table 21)
- Mentoring of site staff for implementation of action plan

- Implement solutions immediately, whenever possible. For example, immediately provide supervised practice of a task incorrectly performed.
- Visit to link ART centres should also be undertaken
- Debriefing of head of the institution, nodal officer, DAPCU officials at the end of the visit. Before leaving the centre, explain to the nodal officer any problems you found and solutions you implemented/action plan. If any help is needed in solving a problem, discuss it with the officers / authority concerned.

Post visit

a. Preparation & submission of report within one week

b. Feedback to ART centre on the visit within two days of approval of tour report of the visit, along with recommended action, timeline & person responsible

c. Regular mentoring and periodic follow up (based on timeline and frequency decided) with the ART centres on recommended actions

ii. Monitoring and Mentoring through ART Review meetings

All states should ensure that regular review meetings of ART centres within the state are held once in every three months. These meetings can be done physically or virtually. The JD CST / Official in-charge of CST at SACS with support from the Regional Coordinator/Technical Expert shall ensure proper organization of meeting, documentation and follow up action on the issues raised during the meeting. The concerned CoE should also be involved in the meeting and meeting should be held at CoE as far as possible. This meeting should be done as per the following guidelines:

Preparing for review meeting

- The latest available score card to be assessed before review meeting to get an idea about the performance of all centres related to various indicators
- Desk review of data and performance analysis with available information from reports at SACS level to be done beforehand. By this exercise SACS may identify 3 best performing and 3 poor performing centres in state for all the key performance indicators
- Previous meeting minutes and action taken reports received so far should be screened to understand any centre specific long pending issues
- Standardised template should be shared with ART centres 15 days in advance for submission before meeting

During the meeting

- All centres should make presentations as per the template
- Cross-check the validity of data well-before the presentation and approval from your nodal officer on the contents. Focus only on operational and functional issues
- The Nodal officer and one SMO/MO must attend, and the Nodal officer should deliver the presentation
- During the review, the ART centres should bring HIV care and ART enrolment register (not the current one) and white cards of five pre-ART and on ART patients each (both more than one year old) selected randomly by RC/TE before the meeting. They should also bring "daily due" list/VL due list/last month's tracker format given to CSC/DAPCU.
- RC/TE to get the slides from all centres well in advance and guide the centres on proper compilation of data and presentation
- Feedback on key indicators based on quarterly score card should be shared with the centres and corrective actions should be planned for low performance indicators
- Based on score card, SACS level analysis, the best performing centres to be appreciated while poor performing centres to be provided opportunity to learn from others and provided with solution for the potential barriers identified during the meeting for poor performance on a particular indicator
- Centre wise action plan (template given) should be prepared to improve the performance for key indicators. The responsibility may be assigned for the time bound activity to be carried out as per recommendations of the review panel and ART centres should be mentored for the improvement in performance for a specific indicator

Follow up after the review meeting:

The minutes of the meeting is to be shared with all ART centres, COE and NACO by the JD CST/CST in charge within 1 week of the meeting, with due approval from APD/PD SACS.

Action taken report based on recommendation within the timeline must be shared by the ART centres. ART centres should be provided mentoring and follow up support for corrective action.

iii. Monitoring and mentoring by CoE/pCoE:

As per CoE / pCoE scheme, CoE should plan, organize and carry out mentoring activities, both programmatic and clinical mentoring. A core group of mentors need to be identified and trained for mentoring. This team of mentors will comprise of Programme Director, Deputy Programme Director, Faculty, ART SMO/MO, Research Fellow-Clinical, Data Analyst. Mentoring shall be for ART Plus centres, ART centres, LAC, LAC plus, CSC linked to the CoE and for the trainees from the same institute and other facilities. They will mentor centres through on site as well as distance monitoring mechanisms.

iv. Monitoring and mentoring during SACEP:

SACEP meetings provide experiential learning to all the attached ART centres on patient preparedness, adherence counselling, clinical management practices being followed by the referring centres. The review of the patient treatment records, and clinical review of the patients provides an insight into how good or poor is the patient management at the referring centre. Based on these findings programme officers (JD-CST/DD/RC/TE) can mentor referring ART centres and the same could also be incorporated in the SACEP feedback.

19.4.3 Monitoring and supervision formats

Apart from all the M&E tools described in Section 18, other formats required for monitoring and supervision are:

1) ART supportive supervision visit format (Annexure 32)
2) Score card (Annexure 28)
3) LAC supportive supervision visit format (Annexure 12)
4) Format for assessment of CSC (refer to CSC guidelines)
5) Standard format for review meeting

19.5 Star Rating of ART Centres

With the overall objective of ensuring continuous quality improvement for universal access to comprehensive, equitable, stigma-free, quality care, support and treatment services to all PLHIV, NACO has proposed to introduce the star rating systems for ART centres. The purpose of this rating is:

- Acknowledge the well performing ART centres
- Motivate all ART centres to initiate steps to improve the quality of implementation
- Ensure sustainable quality services
- Enhance the capacity of the ART centres in understanding strength, weaknesses and gaps
- Develop at least one ART center in each state as model/standard ART (Learning sites)

Rating criteria: Scoring of ART centres shall be done based on performance against the key indicators (to be selected based on program priorities from time to time) during four quarter of the financial year.

Overall score for four quarters of financial year	Star Rating
>90	5-star rating
80-90	4-star rating
70-80	3-star rating

CHAPTER 20

PROCUREMENT AND SUPPLY CHAIN MANAGEMENT OF ARV AND OI DRUGS

20.1 Procurement and Supply Chain Management of ARV Drugs

20.1.1 Overview of Procurement and Supply Chain Management of ARV Drugs

Procurement of ARV drugs are done centrally by NACO based on anticipated requirement of drugs. Supply chain management of ARV Drugs follows a hub and spoke model. ARV drugs allocated to the state are supplied to the SACS which act as the hubs for further distribution of the required quantity of drugs to ART centres. Currently, the ARV drugs are supplied to the respective CMSS warehouse from where CMSS supplies to SACS warehouse as per consignee list and delivery schedule provided by NACO at the time of indenting. The JD (CST)/officer in charge for CST at SACS is the focal point for SCM at SACS. The staff from Procurement & Supply Chain Management unit at SACS shall be engaged in the logistics & record maintenance.

In addition to the major ARV drugs which are procured and supplied by NACO, SACS/CoE are authorized to procure ARV for exceptional cases (such as drug adverse effects/drug interactions requiring single or exceptional drugs for management). The budget for such drugs is allocated in AAP based on the requirement in the state. (Refer to Section 21.2 for budget details)

Table 22. Recommended inventory levels for ARV drugs

	State level	ART centre	LAC
Minimum level of stock	12 months of stock	3 months of stock	2 months of stock
Maximum level of stock	18 months of stock	6 months of stock	3 months of stock

20.1.2 Roles and Responsibilities with regards to procurement and supply chain management of ARV drugs

Responsibilities of NACO

- Responsible for forecasting the state-wise need, indenting and procuring ARV drugs centrally and coordinate with procurement agent and suppliers to facilitate availability of ARV drugs at SACS
- Provide timely information to SACS about the delivery schedules and quantities so that SACS can plan for storage and distribution accordingly
- Support SACS by providing indicative annual quantity required by each ART centre/CoE/ART plus centres to help SACS in further distribution of ARV drugs to facilities
- NACO will also facilitate interstate relocation in case of low stocks, near expiry drugs or during natural calamities and conflict situations

Responsibilities of SACS

- Appoint a nodal person in charge of supply chain management
- Ensure proper receipt and storage of drugs

- Arrange adequate space for safe storage of drugs at SACS level in the state
- Supply the drugs to ART centres as per requirement in two- three instalments in line with the drug supplies
- Maintain accurate records for all drugs received from suppliers/other states and distributed to ART centres in IMS
- Monitor and analyse the stock positions at ART centre for smooth supply chain management
- Ensure continuity and uninterrupted drug supplies at ART centre/LAC plus/LAC level
- Prevent drug expiry by timely relocations within the state and if needed facilitate outside the state relocations with official directives from NACO
- Prevent stock outs by need based relocations
- Guard the drugs against misuse/pilferage/rodents/damage etc
- Quarterly physical verification and reconciliation of stocks at SACS and ART centre level
- Timely submission of monthly ARV stock report to NACO
- Comply with NACO for requests on redistribution of drug stocks to other states

Responsibility of ART centres

- Ensure proper receipt and storage of drugs
- Arrange space for safe storage of drugs
- Transfer of ARV drugs to LAC as per requirement
- Maintain accurate records for all drugs received/sent from/to SACS/other ART centres/LAC /LAC plus centres and drugs dispensed to patients as per guidelines
- Ensure updation of IMS
- Monitor and analyse the stock positions at ART centre and LAC
- Ensure continuity of drug availability at ART centre
- Prevent drug expiry/stock outs at ART centre and LAC by timely reporting to SACS
- Guard the drugs against misuse/pilferage/rodents/damage etc
- Quarterly physical verification and reconciliation of stocks
- Timely submission of monthly ARV stock report to SACS

Table 23. Responsibility matrix for ARV drugs

Activities/ Responsibilities	Responsibility Matrix for ARV Drugs								
	NACO Level				SACS Level			ART/LAC	
	DDG -NACO	DD - NACO	DS, US Procurement	US Procurement	PD/ APD SACS	JD CST/ DD/ AD	Store in-charge	Nodal Officer/ Medical Officer	Pharmacist
Forecasting	A	R	C	C	C	C	C	C	C
Procurement	C	C	A	R	I	I	I	I	I
Indenting	A	R	C	C	A	A	R	A	R
Receiving	I	I	I	I	A	A	R	A	R
Inventory Management	I	I	I	I	A	A	R	A	R
Issue	I	I	I	I	A	A	R	A	R
Legend	R Responsible		A Accountable		C Consulted		I Informed		

20.1.3 Standard operating procedures for SCM of ARV drugs at SACS level

20.1.3.1 Regarding receipt of drugs

- Cross verify at the time of receiving the drugs that the exact quantity is received against the allocated quantity and confirm the same to procurement division of NACO/supplier/procurement agency (deviation, if any, should be highlighted for further actions)

- Acknowledge the receipt after actual counting of drugs
- Provide CRC to procurement agent & procurement division of NACO
- Mention receipt of quantity if received less or in seal broken condition.
- Stack drugs should be based on expiry dates FEFO procedures **(first expiry/first out)**
- Maintain accurate record for all drugs received from suppliers/other states in IMS
- Refer to the revised guidelines sent from time to time by NACO.

20.1.3.2 Drug Storage at state warehouse

- Arrange cartons with arrows pointing up and with identification labels, expiry dates and manufacturing dates clearly visible
- Store drugs and other supplies to facilitate FEFO (first expiry/first out) procedures
- Stack cartons at least 10cm (4 in) off the floor, 30cm (1ft) away from the walls and other stacks and no more than 2.5m (8ft) high
- Separate damaged and expired drugs and supplies from usable supplies
- Remove these damaged drugs from inventory immediately and dispose them off using established procedures for disposal of drugs. SACS will be accountable for expiry of drugs in the state and will have to provide justification for the same
- Keep fire safety equipment available, accessible and functional

20.1.3.3 Distribution of drugs to ART centres

- Mechanism for drug transport/courier needs to be developed (currently this is done in coordination with the agency identified by NACO)
- Drugs are to be distributed to ART centres, based on their requirement in two-three instalments annually
- Distribution of ARV drugs at ART centres should be made in such a manner that a minimum three months of buffer stock is available at any given time at the ART centre and LAC/LAC plus (immediate action is to be taken if drugs are available for less than three months)
- Efforts should be made to keep nearly 20% of the received stock at SACS warehouse as buffer quantity at any given time, if feasible
- Existing stocks at ART centres are to be taken care while making allocation to ART centres
- Accurate records are to be maintained for all drugs distributed to ART centres
- Periodical physical count of stocks should be done
- Stocks should always be distributed based on **First Expiry First Out (FEFO)**

20.1.3.4 Record keeping

- **IMS:** All entries pertaining to inflow and outflow of ARV drugs should be updated in IMS on a real-time basis by the store officer. The JD (CST)/officer in charge of CST at SACS should ensure updation in IMS.
- **State drug stock register:** Soft copies to be maintained at SACS warehouse. These would be autogenerated from IMS if IMS is updated on daily basis.
- **Drug distribution register:** This is used by the SACS warehouse to account for the ARV drugs distributed to the various ART centres or sent to other states on daily basis. Soft copies to be maintained at SACS warehouse. These could be autogenerated from IMS, if IMS is updated on daily basis. This is important
  a) it provides consumption rate
  b) it helps to avoid stock outs
  c) it helps to avoid expiry
- **Reporting:** Monthly report on ARV stocks is to be sent to NACO along with compiled MPR of ART centres by 7th of every month
- **Stock reconciliation:** This is used to determine the discrepancies between the actual stock and the reported stock. Periodically physical count of stocks should be done and quarterly report to be maintained and shared with NACO in the prescribed format (Annexure 33)
- **Goods received note:** Store officer must make this note acknowledging receipt of stock from the transportation agency and supplier. This is to certify that the goods have been received duly inspected in good condition in accordance with the conditions of the contract and amendment if any.

- **Final acceptance certificate:** Store officer must prepare this note along with the goods received note. The consignee must prepare four copies of the GRN and FAC-one for the warehouse, and the remaining three for NACO, procurement agent and the supplier
- **Pickling list:** This is made by store officer after the stock has been dispatched to the various ART centres. It keeps account of the stock that has been distributed.

20.1.3.5 Interstate relocations

Any additional quantities of drugs required should be intimated to CST division of NACO. NACO will arrange for inter-state relocations, if feasible. Similarly, in case of excess stocks at SACS level, NACO should be informed for any inter-state relocations if possible.

20.1.4 Standard operating procedures for SCM of ARV drugs at ART centres

20.1.4.1 Regarding receipt of drugs

- Cross verify at the time of receiving the drugs that the exact amount is received against the allocated quantity and confirm the same to SACS
- Deviation if any should be highlighted for further actions
- Acknowledging the receipt after actual counting of drugs
- Mention receipt of quantity if received less or in seal broken condition
- Accurate records for all drugs received from SACS / other ART centres should be maintained
- Refer to the revised guidelines sent from time to time by NACO

20.1.4.2 Drug storage

- Arrange cartons with arrows pointing up and with identification labels, expiry dates and manufacturing dates clearly visible
- Store drugs and other supplies to facilitate FEFO (First-to-expire, First-out) procedures
- Stack cartons at least 10cm (4 in) off the floor, 30cm (1ft) away from the walls and other stacks and no more than 2.5m (8ft) high
- Separate damaged and expired drugs and supplies from usable supplies
- Remove them from inventory immediately and dispose them off using established procedures for disposal of drugs.
- ART centre will be accountable for expiry of drugs in the centre and will have to provide justification for the same.

20.1.4.3 Drug dispensing to patients

- Drugs are to be dispensed to patients as per the prescription of the SMO/MO
- Proper instructions should be given to patients while dispensing the medicines
- Accurate records are to be maintained for all drugs dispensed to the patients in IMS
- Drugs should always be dispensed based on first expiry/first out

20.1.4.4 Usage of near-expiry of drugs

- Drugs expiring in a particular month can be used till last date of the month
- If drugs are issued for one month to PLHIV, it should have at least 45 days left for expiry from date of issue by ART centre. e.g., a drug with an expiry in August 2021 can be used till 31st August 2021. Hence, this can theoretically be issued to patients with one month remaining in expiry i.e. before 31st of July 2021
- Similar precautions to be taken while dispensing ARVs for MMD so that PLHIV uses the drug before the expiry period
- The SACS should not issue ARV drugs having expiry date <60 days

The list of short expiry drugs and quantity which cannot be consumed within the time period specified should be intimated to SACS and regional coordinator at least before 3 months of expiry.

20.1.4.5 Drug stock management, record keeping and reporting

- All entries pertaining to drugs received and dispensed should be updated in **IMS on a real-time basis** by the pharmacist. The SMO/MO in charge should ensure updation in IMS.
- **Drug stock register and drug dispensing register:** This is used by the pharmacist to input the inflow and outflow of stock. This is to be maintained on daily basis. This would be autogenerated from IMS, if IMS is updated on daily basis.
- **Monthly report:** Monthly report on ARV stocks is to be sent to SACS by 7th of every month as part of the MPR.
- **Stock reconciliation:** This is used to determine the discrepancies between the actual stock and the reported stock. Periodical physical count of stocks should be done and quarterly report to be maintained (Annexure 33) and shared with SACS.
- Minimum three months stock should be available at any given time at the ART centre and the Link ART centre. SACS should be immediately informed if any of the ART drug is available for less than 3 months.
- Any excess stock beyond the consumption of ART centre should be reported to SACS for timely relocation.

20.1.4.6 Transfer of ARV drugs to LAC/LAC plus

- Ideally at least 3 months stock should be available for PLHIV at LAC/LAC plus at any point of time.
- Stock requirement should be calculated every month, based on number of PLHIV on ART (considering MMD patient) and stock balance reported in IMS/MPR by pharmacist/staff nurse of LAC/LAC Plus.

Calculation of quantity of ARV drugs*:

- **For LAC:** Number of PLHIV on ART at LAC X 3 months + one month buffer stock -stock in hand at LAC
- **For LAC Plus:** In addition to above, LAC plus will also receive drugs for ART initiation in new PLHIV

Average no of PLHIV/ month X 3+ one month buffer stock

*** PLHIV already on MMD or expected to be on MMD to be considered**

- Stock should be transferred based on actual stock available at NACO & space available at LAC in consultation with SACS Officials. Drugs with longest expiry should be supplied to LAC as far as possible.
- ARV drugs stocks shall be sent by the nodal ART centre to the LAC through courier/ postal service/ care coordinator or any other staff of nodal ART centre /LAC.
- Drug stock reporting by Nodal ART centre: The Nodal ART centre shall not deduct the total quantity of drugs transferred to Link ART centre in the monthly report sent to NACO. Only the drugs actually dispensed to the patient at the LAC /LAC plus during the month as reported in IMS/MPR of LAC are to be factored as consumption.

20.1.4.7 Procedure for disposal for expired drugs

All attempts should be made that ARV dugs do not expire. However, in case expiry of ARV drugs has happened despite the best efforts to prevent it, expired drugs should be disposed at the centre itself following the procedure adopted in hospital for other drugs that expire in the hospital. Empty bottles/expired drugs should be disposed to prevent recirculation. The procedure for disposal for expired drugs is as below,

- Forming a committee of two- three persons including nodal officer of the ART centre,
- Listing out the drugs expired along with batch no. and quantity expired (with date of expiry)
- Separating the tablets from bottle
- Destroying the tablets in incinerator / by dissolving in water and then disposing it if the incinerator is not available.
- Removing the labels from the bottles (may be dipped in water for some time to separate out the labels)
- The empty bottles should be disposed off in the municipal waste.
- The quantity of expired drugs to be reduced from the balances and reported in the monthly report.
- Details for the same is to be emailed to SACS and NACO and reported in IMS.

For details, please refer to NACO Procurement and Supply Chain SOPs

20.2 Drugs for Prophylaxis/Prevention and Management of Opportunistic Infections

Drugs for prophylaxis/prevention and management of opportunistic infections should be available at all the ART centres. The common drugs that are required for the management of OI's should be made available from the health institution/facility. It is important that timely indent of such drugs based on the requirement of OI should be given to health institution/facility or NHM so that adequate provision can be made to include the quantities required by ART centres. DAPCU/SACS/RC/TE should support ART centres in calculating their requirements. The drugs, which are routinely not available or not procured by hospitals or health systems, should be procured by SACS/ART centres.

SACS should also make efforts to get all drugs required for prophylaxis/prevention and management of OI infections as well ARV drugs included in the **"State List of Essential Medicines"**. Please refer to Annexure 34 for list of drugs commonly required for prophylaxis/prevention and management of OI.

CHAPTER 21
FINANCIAL MANAGEMENT

21.1 Guidance for Financial Management

Funds required for running an ART centre are provided to each ART centre and are to be utilized as per guidelines describe below.

21.1.1 Bank account

ART centre should open a separate bank account for management of funds. in the name of 'ART centre - XXXX (name of the institution)' to be operated jointly by 2 - 3 faculty members of the institution including nodal officer of ART centre. This is essential for proper and timely utilization of funds made available to ART centre. Payment should be made by cheque except for small contingent expenses. A cash book will be maintained by ART centre to meet petty cash expenses. For this purpose, the nodal officer may draw imprest money not exceeding Rs. 5000 at a time.

21.1.2 Audit of accounts

SACS will get accounts of each ART centre audited. **Statement of expenditure and utilization certificate** for the preceding financial year of each ART centre should be submitted to SACS. Further release of grants would be subject to submission of these documents.

21.1.3 Guidelines for expenditure

ART centre would incur expenditure as per norms given hereunder:

- Staff salary
- Contingency and operational cost per year (telephone, internet broadband, stationery, printer cartridge, postal charge, local travel etc.)
- Non-recurring one-time grant (computer & accessories, TV & DVD, furniture, almirah, storage racks)
- Non-recurring one-time grant for refurbishment of the centre
- Annual recurring grant for standard precautions (universal work precautions)

The salary of staff will start at the lowest range and then performance-based incentive can be given yearly as per NACO norms revised from time to time. The salaries of all the staff members shall be sent directly by the SACS to the bank account of staff members by e-transfer. The salary shall be paid as per the latest NACO office memorandum regarding the remuneration pattern.

The operational costs and funds for contingency and standard precautions (universal work precautions) shall be sent by SACS to the ART centres. The guidelines for expenditure are subject to change from time to time. The SACS/ART centres should follow the latest instructions from NACO in this regard.

21.2 Pattern of Assistance for CST Services

Funds for implementation of CST activities are allocated in the Annual Action Plan (AAP) of state based on the following pattern of assistance.

S.No	Particulars	Cost head	Unit cost	Remarks
1	ART centres	Operational Cost (recurring cost)	Rs 1.5 lakhs per ART centre per yearRs 50,000 per FI-ART centre	Telephone/internet bills, stationary, printer cartridge, local travel of staff for meetings, drug transportation and contingency etc.
		standard precautions (universal work precautions)	Rs 50,000 per ART centres per year	Commodities for universal work precautions
		HR cost	As per actuals	In line with the HR norm
		Non-recurring grant for new ART centres (renovation, furnishing and equipment)	Rs 4.5 lakh per new ART centre	2.5 lakhs for refurbishment and 2 lakhs for procurement of equipment and furniture. For minor renovations and furniture for the FI-ART upgraded to ART centres, Rs 3 lakh for refurbishment and equipment / furniture
2	Link ART Centre (Applicable only for LAC/LAC plus in public health systems)	Non -recurring grant for new LAC	INR 15000 (one-time cost)	For establishment of Link ART centres (infrastructure development and equipment)
		Operational cost (recurring cost)	INR 37,000 per LAC/year	Operational expenses, stationary, TA/DA, contingency etc.
		HR (for LAC plus only)	As per actuals	In line with the HR norm
3	Centres of Excellence	Operational cost	INR 18,00,000/CoE/year	Infrastructure maintenance, research, travel, mentoring and contingency etc.
		HR cost	As per actuals	In line with the HR norm
4	Paediatric Centres of Excellence	Operational cost	INR15,00,000/pCoE/year	Infrastructure maintenance, research, travel, mentoring and contingency etc.
		HR cost	As per actuals	In line with the HR norm
5	VL testing	VL HR	As per actual	LT at VL lab
		Sample transport	Rs 1 lakh/ART centre for low load (<1500 PLHIV on ART) Rs 1.5lakh/ART centre for medium load (1500 – 3000 PLHIV on ART) Rs 2 lakh /ART centre for high load (>3000 PLHIV on ART)	For transportation of VL sample from ART Centres to the linked VL labs Cost may be higher in ART centres located in difficult terrains
6	CD4 labs	Infrastructure and installation of new CD4 lab to be established	Provision of onetime non-recurring grant of 1 lakh is there for establishment of new CD4 labs.	
		Operational cost CD4 machine	INR 25,000-50,000 depending on type of machine	

7	SACS	Supportive supervision	Based on requirement	
		Printing	Based on requirement	For printing of registers, white card, green book etc.
		OI management	Based on requirement	Procurement of OI drugs and diagnostics
		ARV for exceptional cases	Based on requirement	Procurement of ARV drugs in exceptional cases
		RC-TA/DA	Based on requirement	For TA/DA of RC
		Private sector collaborative activities	Based on requirement/ number of expected private sector sites	For monitoring, meetings, training and collaborative activities with private sector
		Refurbishment of existing centres	Based on requirement	Refurbishment/furniture/ equipment

* Details of commodities to be procured from funds for universal precautions is given at **Annexure 35**

Note: overall pattern of assistance and unit cost is revised from time to time in line with national directive

The details mentioned above are indicative and appropriation / reallocation of funds from one head to another or from one ART centre to another, based on need, can be done with approval of Project Director SACS.

CHAPTER 22

THE HIV AND AIDS (PREVENTION AND CONTROL) ACT, 2017

The HIV and AIDS (Prevention and Control) Act, 2017 is a progressive legislation safeguarding human rights, legal rights and reinforcing constitutional rights for people living with HIV (PLHIV). The Act has come into force from 10th September 2018. The act envisages an enabling environment at workplace, education setting, health setting etc for people infected and affected with HIV and AIDS.

Major features of the Act are

- Address stigma & discrimination
- Create an enabling environment for enhancing access to services
- Safeguard rights of PLHIV & those affected by HIV
- Provide free diagnostic facilities and ART to PLHIV.
- Promote safe workplace in healthcare settings to prevent occupational exposure
- Strengthen system of grievance redressal

Informed Consent

The Act states that no HIV test shall be undertaken or performed upon any person; or no positive person shall be subject to medical treatment, medical interventions or research, without the informed consent. Here the term informed consent includes pre-test and post-test counselling to the person being tested or such person's representative.

In the Act the term 'informed consent' is defined as 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, such information 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.

However, the Act also contains provisions where informed consent for conducting an HIV test shall not be required—when a court determines by an order; for procuring, processing, distribution or use of a human body; for epidemiological or surveillance purposes and for screening purposes in any licensed blood bank.

Disclosure of HIV status

As per the Act, no person shall be compelled to disclose HIV status except by an order of the court that the disclosure of such information is necessary. Also, no person shall disclose or be compelled to disclose the HIV status or any other private information of other person imparted in confidence. The Act also includes areas where informed consent for disclosure is not required where the disclosure is made—

a. By a healthcare provider to another healthcare provider who is involved in the care of such person, when such disclosure is necessary to provide care or treatment to that person;

b. By an order of a court that the disclosure of such information is necessary in the interest of justice;

c. In suits or legal proceedings between persons, where the disclosure of such information is necessary;

d. If it relates to statistical or other information of a person that could not reasonably be expected to lead to the identification of that person;

e. To the officers of the Central Government or the State Government or State AIDS Control Society of the concerned State Government for the purposes of monitoring, evaluation or supervision.

Disclosure of HIV positive status to partner: The Act states that no healthcare provider, except a physician or a counsellor, shall disclose the HIV-positive status of a person to his or her partner. A healthcare provider, who is a physician or counsellor, may disclose the HIV positive status of a person under his direct care to his or 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.

The Act also provides that disclosure to the partner shall be made in person after counselling and that a healthcare provider shall have no obligation to identify or locate the partner of an HIV-positive person.

Confidentiality of data: Every establishment keeping the records of HIV-related information of protected persons shall adopt data protection measures. The measures shall include procedures for protecting information from disclosure, accessing information, security, accountability and liability of persons in the establishment.

Provisioning of ART: The Act provides for measures for providing, as far as possible, diagnostic facilities relating to HIV or AIDS, antiretroviral therapy and opportunistic infection management to people living with HIV or AIDS.

Safe working environment under establishments:

The Act provides for every establishment, engaged in the healthcare services and / or where there is a significant risk of occupational exposure to HIV, shall provide for:

a. Universal precautions to all persons working in such establishment who may be occupationally exposed to HIV.

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.

d. Inform and educate all persons working in the establishment of the availability of universal precautions and post exposure prophylaxis.

ANNEXURES

Annexure 1
ART preparedness counselling checklist/form

ART Preparedness Counselling Checklist/Form

Pre-ART No: _____ ART No: _____

Mobile/Phone number verified: ☐ Yes ☐ No

Complete Address documented on White Card: ☐ Yes ☐ No

STEP 1: Education about HIV and ART:

☐ PLHIV acceptance of HIV positive status ☐ What is HIV? ☐ Routes of HIV transmission

☐ Positive living ☐ Meaning of viral load (U=U)

ART Awareness: *The following basic information about ART has been provided:*

☐ What is ART? ☐ ART is a lifelong treatment ☐ Benefits of ART ☐ Importance of adherence (>95%)

STEP 2: Identify patient's motivation to stay alive and healthy

What is the most important thing for you in life? ☐ Family ☐ Career ☐ Studies ☐ Getting married

☐ Other .....

STEP 3: Identification of caregiver

☐ Caregiver identified-Family member/ Friends/ Others/ None

☐ Have you disclosed your status to the care giver

☐ Caregiver counselled on adherence and follow-up visits

☐ Any other family/personal issues .....

STEP 4 and 5: Identify the potential barriers to adherence/retention and strategies to overcome

☐ Adherence to ART is important to avoid development of drug resistance

☐ Strict adherence required (>95%)

Potential Barriers:

☐ Beliefs/Myths	☐ Physical illness	☐ Substance use	☐ Depression
☐ Pill burden	☐ Social functions	☐ Fear of Disclosure	☐ Lack of knowledge about ART
☐ Financial/travel issues	☐ Feeling healthy	☐ Forgetfulness	☐ Adverse effects
☐ Child behaviour/refusing	☐ Timing	☐ Caregiver	☐ Drug stock out
☐ Long wait	☐ Stigma	☐ Others _____	

Interventions:

Services

☐ Counselling (individual)	☐ Counselling (group)	☐ Peer support	☐ Treatment buddy
☐ Link to Govt. schemes/NGOs	☐ Home visits by ORWs	☐ Need based Referrals _____	

Reminder Tools

☐ Written instructions	☐ Phone calls	☐ SMS	☐ ICT based tools
☐ Alarms	☐ Calendar	☐ TV shows	

☐ Other _____

STEP 6: Devise a treatment plan that suits the patient the best

Timing ☐ Morning ☐ Afternoon ☐ Evening Dosage ☐ OD ☐ BD

Storage of ARV drugs ☐ Safe place (.....)

☐ Always carry additional pills with you always when you go out/travel

☐ If you miss a dose, you should take as soon as you remember

☐ Are you on any other medication? ☐ Spacing with food or other medications

☐ Adverse effects of ART ☐ Visit/Contact ART centre if any new symptoms develop (Adverse drug reaction/IRIS)

Any other family member on ART ☐ Yes ☐ No. If yes, specify..... ☐ Don't share ARV drugs

STEP 7: Plan for the next appointment

☐ Next due date to visit _ _ / _ _ / _ _ _ _

First follow up visit after ART initiation

Date of Visit: _____/_____/_____ ART adherence of previous visit/month? .....

☐ Review and recap the patient's understanding about previous session/ visit

Patient's ART adherence is ☐ >95%, PLHIV motivated to maintain the same

☐ <95%, specify reason.....

Strategies discussed in previous visit were implemented ☐ Yes ☐ No; if not, mention reasons..... .....

.....

☐ Any new issue identified in this visit; specify .....

☐ Strategies discussed to overcome this new issue; specify .....

☐ Explain if patient take the treatment well, s/he will be eligible for longer treatment supply and easier collection systems

Treatment Plan

☐ Timing of drug intake ☐ Reminder strategy ☐ Next due date to visit .....

Second follow up visit after ART initiation

Date of Visit: _____/_____/_____ ART adherence of previous visit/month? .....

☐ Review and recap the patient's understanding about previous session/ visit

Patient's ART adherence is ☐ >95%, PLHIV motivated to maintain the same

☐ <95%, specify reason.....

Strategies discussed in previous visit were implemented ☐ Yes ☐ No; if not, mention reasons..... .....

.....

☐ Any new issue identified in this visit; specify.....

☐ Strategies discussed to overcome this new issue; specify.....

Treatment Plan

☐ Timing of drug intake ☐ Reminder strategy ☐ Next due date to visit ARTC is .....

Third follow up visit after ART initiation

Date of Visit: _____/_____/_____ ART adherence of previous visit/month? .....

☐ Review and recap the patient's understanding about previous session/ visit

Patient's ART adherence is ☐ >95%, PLHIV motivated to maintain the same

☐ <95%, specify reason.....

Strategies discussed in previous visit were implemented ☐ Yes ☐ No; if not, mention reasons..... .....

.....

☐ Any new issue identified in this visit; specify.....

☐ Strategies discussed to overcome this new issue; specify.....

☐ Restate goals of viral load suppression and treatment pathway ahead if patient is doing fine and adherent

Treatment Plan

☐ Timing of drug intake ☐ Reminder strategy ☐ Next due date to visit .....

Annexure 2
Consent form for patients registering in HIV care and initiating ART

I, (name)....., (address) ..... consent to share all information pertaining to me/my minor child's health and HIV status with the service providers who will be part of the management of my/my child's health condition.

And

I AGREE to receive antiretroviral therapy and other HIV related services provided under the national programme.

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

- That the ART will be started at the earliest after readiness assessment and as per the decision of the doctor. I shall attend the ART centre as per appointment for timely initiation of ART and regular follow-up.
- I agree to receive care/treatment as per national guidelines.
- That ART requires 100 % adherence to drugs, and I shall abide by the same.
- That I understand the adverse effects of ART.
- That I shall not stop the drugs on my own and will return to the centre if there is any problem. In case I stop the drugs on my own accord/do not adhere to the regimen, I shall not hold the health care staff of the ART centre responsible for any complication arising out of the same.
- In case, I am/my minor child is on ART from outside on a different regimen, I agree to receive the drugs/ regimen provided under the national programme.
- In case, I/my minor child want to take ART from other centre or go to other city for livelihood or other reasons, I will inform my ART centre and get a "transfer out" letter before leaving.
- That I may access/update/correct the information which is collected under the programme by visiting concerned NACP facility.
- That all personal information provided will be kept confidential under the programme.
- That receiving ART also involves shared confidentiality with ART staff and other service providers who will be involved in care, support and treatment (such as LAC/ CSC/ positive network/ CBO/ NGO etc.) who may support my/my child's treatment, retention and other welfare measures through phone call/ other modes of communications, outreach and home-based care activities at home.

.....

Signature of witness
(Doctor/nurse/counsellor)

.....

Signature of patient with date /
Signature of caregiver with date

Annexure 3
Index testing services at ART centre

I. What is index testing?

It is an approach of voluntary case-finding focusing on eliciting the spouse/sexual and/or needle sharing partners and biological children of consenting HIV-positive individuals and offering them HIV counselling testing services (HCTS). Index testing should be offered at TI sites, ICTC as well as ART centres/CSC.

II. Who should be offered index testing services at ART centre?

1. **Family testing**
   a. Spouse with unknown status
   b. All biological children (age based on latest HIV testing guidelines of NACO) if the:
      - Mother is HIV positive OR
      - Father is HIV positive AND reports the child's mother is HIV positive, deceased, or her status is unknown
   c. Biological siblings and parents (if the index case is a child)
2. **Partner testing** for all sexual or injecting drug partners from the past year, irrespective of consistent condom use/ clean needle use.

III. When should index testing services to be offered at ART centre?

a. Discuss about partner/family testing services and benefits during first visit at ART centre.
b. Partner/contact elicitation and testing is a dynamic event and should be offered continuously
   1. At first visit to ART centre and in subsequent visits as per need
   2. At least annually as a part of HIV treatment services
   3. For PLHIV returning to care after treatment interruption
   4. For PLHIV with an unsuppressed viral load
   5. After a change in relationship status

IV. Who should offer index testing services at ART centre/CSC?

Elicitation can be done by a trained counsellor or staff nurse at ART centre. In the absence of counsellor or staff nurse, care coordinator can also do elicitation. Follow up at field level shall be done by staff at CSC. At the CSC, the peer counsellor or outreach worker can do elicitation. All the staff should receive training on how to conduct index testing services before offering services.

V. What are the Principles of index testing services?

- The WHO 5 Cs (Consent, Confidentiality, Counselling, Correct test result and Connection to treatment services) are principles that apply to all HCTS including Index Testing services.
- There are eight core principles of Index testing services: Client-centred and focused, confidential, voluntary and non-coercive, free of cost, non-judgmental, culturally/linguistically appropriate, accessible and available to all, comprehensive and integrative.

VI. How to provide index testing services?

There are 10 steps for implementing index testing services:

Step 1- Introduce Index testing services to the index client during visit at ART centre. Inform the index client that his/her information will be kept confidential

Step 2- Offer Index testing as a voluntary service to all newly registered clients or those with high viral load or with unknown HIV status of family members or after a change in relationship status

Step 3- If client accepts index partner testing, then obtain informed consent to inquire about their partner(s) and biological child(ren)

Step 4- Obtain a list of sexual and needle sharing partners and biological children with unknown HIV status

Step 5- Conduct an intimate partner violence (IPV) assessment for each named partner

Step 6- Determine the preferred method of partner notification or child testing for each named partner/child (see below).

Step 7- Contact all named partner and biological children with unknown status using preferred approach

Step 8 - Record outcomes of partner notification and family testing

Step 9- Provide appropriate services for children and partner(s) based on HIV status

Step 10- Follow-up with client to assess for any adverse events associated with Index testing

VII. Approaches for providing index testing services

a. Client referral (Passive): Index client takes responsibility for encouraging/bringing partners/children to seek HIV counselling and testing services

b. Assisted partner notification (Active): Provider/counsellor (as per details given in para IV) assists the index client to notify partner/family about HCTS through two different approaches:

   i. Provider referral- Provider/counsellor contacts clients partners and offers voluntary HCTS services with client consent and confidentiality

   ii. Dual referral- Provider/counsellor sits with the Index client while they disclose their status. HCTS voluntary services are offered

Note: All providers conducting index testing must be trained on index testing procedures including Intimate Partner Violence (IPV), strict adherence to 5C's (consent, confidentiality, counselling, correct test results, and connection to prevention/treatment), IPV risk assessment SOP in place, IPV screening conducted for each contact elicited, with referral options to necessary and relevant services, secure environment to store patient information and a site level adverse event monitoring and reporting system.

Annexure 4
List of previous day missed PLHIV for phone follow up

ART centre Name	HIV care No.	ART No	Name of Patient	Complete Address	Phone Number	Date of call attempt-1	Date of call attempt-2	Date of call attempt-3	Outcome of call *	If Outcome of call =4; Prompt for Date of Visit to ART centre	If Outcome of call =5; Reasons for not willing to come	Remarks

*1-No Phone number; 2-Number not valid/Wrong Number; 3-Phone not reachable/Phone not Answered; 4- Agreed to come to ART centre; 5-Not willing to come/Opted out; 6-Answered by others; 7-Migrated -Spoke with Patient; 8-Migrated Spoke with others; 9-Died; 10-Others Specify

Annexure 5
Line list of PLHIV with unsuppressed viral load/SACEP referral summary

(to be auto generated from IMS and maintained at all ART centres in soft copy)

Sr. No.	ART Reg. No.	Name	Age	Sex	Date of VL test	VL Count	Adherence (<95%, >95%)	Step up Counselling Session1 (date)	Step up Counselling Session 1 (adherence)	Step up Counselling Session 2 (date)	Step up Counselling Session 2 (adherence)	Step up Counselling Session 3 (date)	Step up Counselling Session 3 (adherence)	Step up Counselling Completed (Yes/No)	Date of repeat viral load test	Viral load count	Date of e-referral to SACEP (if unsuppressed as per second VL)	Date of review by SACEP	SACEP recommendation# (1. Switch to second line/ third line 2. Continue same treatment) 3. Refer to COE/4. Step up Counselling	Date of start of second/third line ART
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

Annexure 6
Step-up adherence counselling form

ART No: ..... ART Regimen: ..... Date of ART initiation .....
Date of viral load: ..... Viral load result: ..... Due date for next VL .....

Session-1

Name of counsellor: ..... Date: ..... ART adherence (last 3 months)- 1..... 2 ..... 3.....

		Yes/No	Comments
Does patient have adequate knowledge about	ART adherence & risks of poor adherence		
	VL results		
	ART drug dosage (No. of pills and timing)		
Support system	Name and relation of the caregiver		
	Address and phone no. of caregiver		








Barriers:

- ☐ Forgot ☐ Beliefs/Myths ☐ Lack of knowledge about ART ☐ Adverse effects
- ☐ Physical illness ☐ Substance use ☐ Depression ☐ Pill burden
- ☐ Social functions ☐ Feeling healthy ☐ Child behavior/refusing ☐ Timing
- ☐ Fear of disclosure ☐ Caregiver ☐ Financial/travel issues ☐ Drug stock out
- ☐ Long wait ☐ Stigma ☐ Other_____

Interventions:

Services

- ☐ Counselling (individual) ☐ Counselling (group) ☐ Peer support
- ☐ Treatment buddy ☐ Link to Govt. schemes/NGOs ☐ Home visits by ORWs
- ☐ Need based referrals_____

Tools

- ☐ Written instructions ☐ Phone calls ☐ SMS
- ☐ ICT based tools ☐ Alarms ☐ Calendar
- ☐ TV shows ☐ Other ____

Remind that goal is to achieve suppressed VL

Adherence plan:..... .....

Next due date to visit ART centre is ..... Counsellor's sign

Session-2

Name of counsellor:..... Date:..... ART adherence of previous month:.....

		Yes/No	Comments
Follow-up of session 1	Appreciate if adherence>95% and motivate him to maintain the same		
	Were strategies discussed in session-1 implemented? If not, Why?		




Barriers:

- ☐ Forgot ☐ Beliefs/Myths ☐ Lack of knowledge about ART ☐ Adverse effects
- ☐ Physical illness ☐ Substance use ☐ Depression ☐ Pill burden
- ☐ Social functions ☐ Feeling healthy ☐ Child behavior/refusing ☐ Timing
- ☐ Fear of disclosure ☐ Caregiver ☐ Financial/travel issues ☐ Drug stock out
- ☐ Long wait ☐ Stigma ☐ Other_____

Interventions:

Services

- ☐ Counselling (individual)
- ☐ Counselling (group)
- ☐ Peer support
- ☐ Treatment buddy
- ☐ Link to Govt. schemes/NGOs
- ☐ Home visits by ORWs
- ☐ Need based referrals _____

Tools

- ☐ Written instructions
- ☐ Phone calls
- ☐ SMS
- ☐ ICT based tools
- ☐ Alarms
- ☐ Calendar
- ☐ TV shows
- ☐ Other _____

Remind that goal is to achieve suppressed VL

Adherence plan: ....

Next due date to visit ART centre is ..... counsellor's sign

Session-3

Name of counsellor:..... Date:..... ART adherence of previous month:.....

		Yes/No	Comments
Follow-up of session 2	Appreciate if adherence>95% and motivate him to maintain the same		
	Were strategies discussed in Session-1 implemented? If not, Why?		

Barriers:

- ☐ Forgot
- ☐ Beliefs/Myths
- ☐ Lack of knowledge about ART
- ☐ Adverse effects
- ☐ Physical illness
- ☐ Substance use
- ☐ Depression
- ☐ Pill burden
- ☐ Social functions
- ☐ Feeling healthy
- ☐ Child behavior/refusing
- ☐ Timing
- ☐ Fear of disclosure
- ☐ Caregiver
- ☐ Financial/travel issues
- ☐ Drug stock out
- ☐ Long wait
- ☐ Stigma
- ☐ Other_____

Interventions:

Services

- ☐ Counselling (individual)
- ☐ Counselling (group)
- ☐ Peer support
- ☐ Treatment buddy
- ☐ Link to Govt. schemes/NGOs
- ☐ Home visits by ORWs
- ☐ Need based referrals _____

Tools

- ☐ Written instructions
- ☐ Phone calls
- ☐ SMS
- ☐ ICT based tools
- ☐ Alarms
- ☐ Calendar
- ☐ TV shows
- ☐ Other _____

Remind that goal is to achieve suppressed VL

Adherence plan:..... .....

Next due date to visit ART centre is ..... counselor's sign

Repeat Viral Load

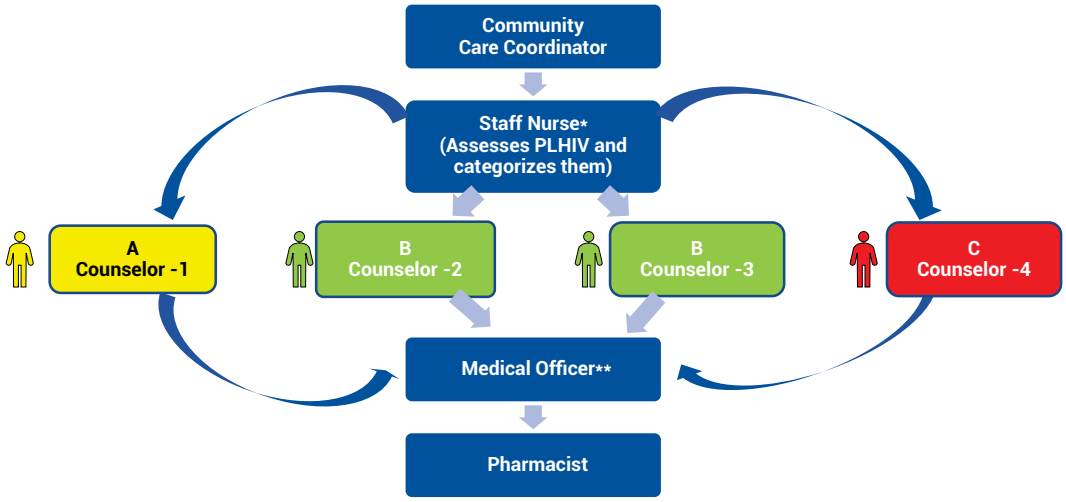
Date of repeat viral load test :..... Viral load result.....

If VL<1000 copies/ml	☐ Appreciate ☐ Reminder for next due date to visit ART centre ☐ Reminder for next VL testing date .....
If VL≥1000 copies/ml	☐ SACEP procedure explained ☐ SACEP e-referral/referral initiated ☐ SACEP recommendations implemented

Annexure 7
Patient flow charts depending on available staff at the ART centre

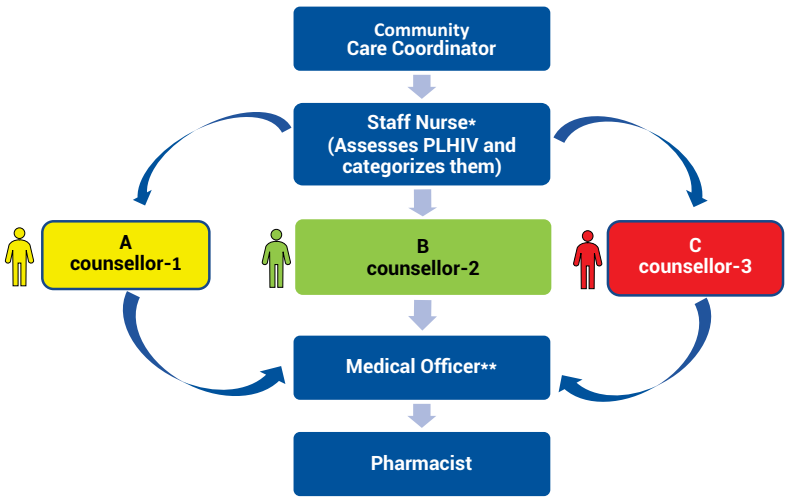
The following are examples of certain patient flowcharts that can be implemented in the ART centres depending on the availability of the staff at the centre.

Flow of PLHIV at ART centre where 4 counsellors are present



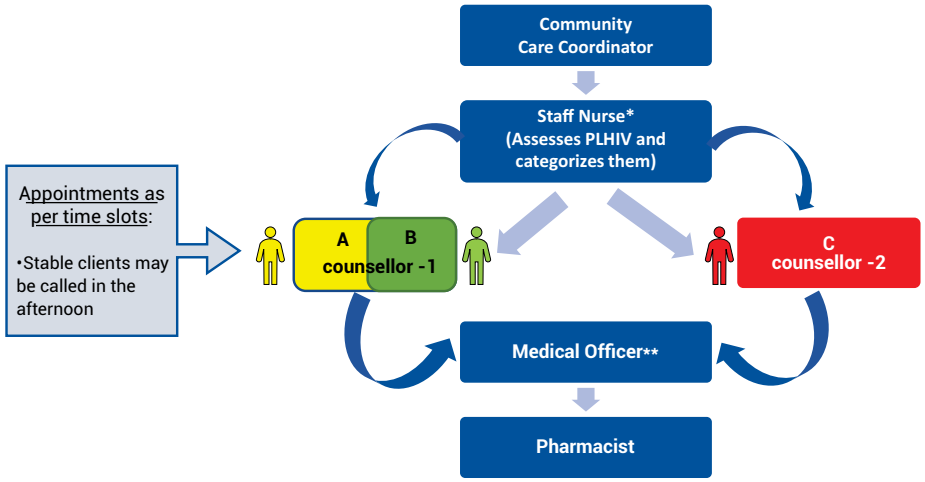
* Additional Staff Nurse ,if available, must be assigned all HIV-TB related activities
** Depending on their availability, medical officers must also be assigned specific patient categories

Flow of PLHIV at ART centre where 3 counsellors are present



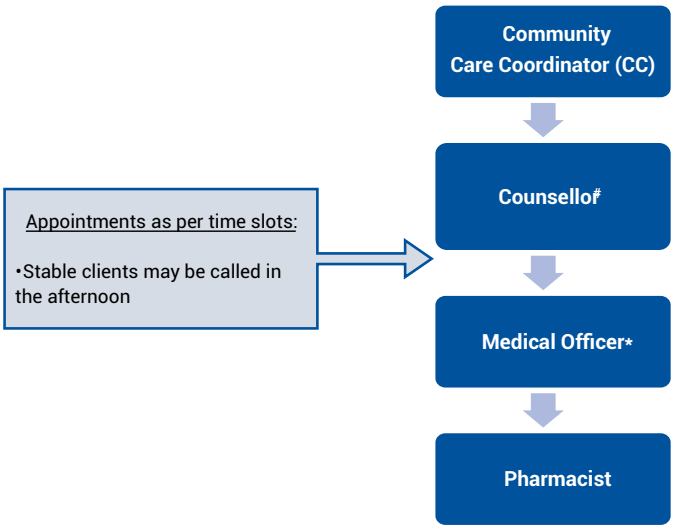
* Additional Staff Nurse ,if available, must be assigned all HIV-TB related activities
** Depending on their availability, medical officers must also be assigned specific patient categories

Flow of PLHIV at ART centre where 2 counsellors are present



* Additional Staff Nurse, if available, must be assigned all HIV-TB related activities
** Depending on their availability, medical officers must also be assigned specific patient categories

Flow of PLHIV at ART centre where 1 counsellor is present



Staff Nurse, if available, must be assigned for triaging of PLHIV and HIV-TB related activities
* Depending on their availability, medical officers must also be assigned specific patient categories
# The counsellor must ensure the delivery of patient-centric packages as per the patient need

Annexure 8
Feasibility assessment checklist for setting up a link ART centre

Check List for setting Link ART Centre (In ICTC setting)		
1	Name of the District and State:	
2	Type of facility:	PHC / CHC / AH / DH /CSC / TI-NGO / Prison / CBO Others (specify).....
3	Name of the Facility-in-Charge	
4	Names of the proposed LAC in charge	
5	Are the facility staff sensitized about LAC (Y/N)	
(At least 30 min interaction with the hospital staff (MS, LAC in charge, Nurse, Pharmacist, Counsellor) about the concept of LAC)		
6	Facility phone number with code	
7	Complete postal address with pin code:	
8	Name of the nodal ART centre	
9	No. of HIV positives detected in the ICTC in last 5 years	
10	Mention the catchment area of the proposed LAC	
11	No. of HIV positives detected in the ICTCs of the catchment area in last 5 years.	
12	No. of PLHIV registered under HIV care from the catchment area at nodal ART centre	
13	No. of PLHIV Alive & on ART from the catchment area at Nodal ART centre	
14	**Commitment**	
a	Is the head of the facility committed towards the National AIDS Control Programme?	
b	Is the hospital administration committed?	
c	Are the identified LAC in charge/doctors committed?	
d	LAC staff nurse identified	
e	LAC pharmacist identified	
15	**Space and Infrastructure**	
a	Is there an ICTC functioning in the hospital?	
	If yes, then	
b	How many rooms does the ICTC have?	
c	Counsellor in place	
d	Name of the counsellor and contact number	
e	Counsellor trained	

f	Computer Available (Y/N)	
g	Telephone Available (Y/N)	
h	Internet available (Y/N)	
i	Space available for counselling (Y/N)	
j	Space available for drug storage (Y/N)	
k	NTEP services available	
16	**Human Resources** (In hospital or linkages)	
a	Specialists available	
b	Physician	
c	Pediatrician	
d	Obstetrician	
e	Chest physician	
f	Dermato venerologist	
g	Others (mention)	
17	**Lab investigations** (applicable for health care facilities)	
a	Haemogram	
b	RFT	
c	LFT	
d	CXR	
e	Sputum for AFB/CBNAAT/TrueNAAT	
f	Others (Mention)	
18	**General Information regarding the facility**	
a	No. of doctors available	
b	No. of beds available	
c	No. of positive deliveries conducted in the last year	
d	Drugs available at the hospital pharmacy	
1	Assessment done by	
2	Date of assessment	
3	Recommended for LAC (Y/N)	
If not mention reasons:		

Signature of the visiting team

Annexure 9
LAC plus: feasibility assessment checklist for approval of ART initiation

Date of feasibility visit: _____

Name of members of feasibility visit team:

1: _____ 2: _____

3: _____ 4: _____

I. GENERAL INFORMATION

1 Name of the district: _____ 2 Name of the hospital: _____

3 Type of hospital: _____ 4 Name of the Medical Superintendent: _____

5 Hospital phone number with code: _____

6 Complete postal address with pin code: _____

II. BACKGROUND INFORMATION

7 Give the catchment areas of the proposed site for LAC Plus _____

8 No. of LAC in the district/catchment area _____

III. Organization & Infrastructure

Institutional Commitment

9	Is the Director committed towards National IDS Control Programme?	YES_____	NO_____
10	Is the hospital administration committed?	YES_____	NO_____
11	Has the nodal officer been identified and is committed?	YES_____	NO_____
	ICTC Functioning		
12	Is there an ICTC functioning in the hospital?	YES_____	NO_____
13	How many rooms does the ICTC have?		
14	Counsellor in place		
15	No. of HIV testing and positives detected in the last 5 years		

S.No	Year	ANC	% Positivity	Non-ANC	% Positivity
1					
2					
3					
4					
5					

	LAC Functioning		
16	Is there a LAC Plus/LAC functioning in the hospital?	YES_____	NO_____
17	How many rooms does the LAC have?		
18	Is the facility staff (LAC MO, staff nurse, Pharmacist) committed towards LAC?	YES_____	NO_____
19	No of patients on ART at LAC plus/LAC		
	General Information regarding the Hospital		
20	No. of doctors available		
21	No. of beds available		
22	No. of positive deliveries conducted in the last year		
23	Drugs available at the hospital pharmacy		
24	Is NTEP functional?	YES_____	NO_____
25	Human resources		
a	Total specialists available?	YES_____	NO_____

b	Physician	YES_____	NO_____
c	Paediatrician	YES_____	NO_____
d	Obstetrician	YES_____	NO_____
e	Chest Physician	YES_____	NO_____
f	Dermato-venreologist	YES_____	NO_____
g	Microbiologist/Pathologist	YES_____	NO_____
h	Others (mention)	YES_____	NO_____
IV. Space Identified for LAC Plus			
26	Location of the LAC plus		
27	Linkages with medicine and OPD specialties		
28	Is adequate space available		
V. Medical Officer and team			
29	Has medical officers been identified and willing to take up responsibility?		
30	Has an alternate medical officer been identified?		
VI. Lab Investigations			
a	Hemogram	YES_____	NO_____
b	RFT	YES_____	NO_____
c	LFT	YES_____	NO_____
d	Blood Sugar	YES_____	NO_____
g	Pregnancy test	YES_____	NO_____
h	CXR	YES_____	NO_____
i	Ultrasound	YES_____	NO_____
j	CBNAAT/TrueNAT	YES_____	NO_____
k	Urine examination	YES_____	NO_____
l	VDRL	YES_____	NO_____
m	PAP smear/VIA	YES_____	NO_____
n	Others (mention)	YES_____	NO_____

Summary:

1. Background: _____
2. Organization and infrastructure: _____
3. Space for the LAC plus: _____
4. Human resources: _____
5. NGO linkages: _____
6. Lab investigations: _____
7. Conclusion: _____

Issues	Suggested Follow up

Recommendation: **1. Recommended to upgrade for ART Initiation**

2. Not recommended for ART initiation (mention reasons)

Signature of the feasibility visit team:

1. _____ 2. _____

3. _____. 4. _____

Annexure 10
LAC/LAC plus monthly reporting format
(excel sheet provided separately)

LAC- Monthly Reporting Format

1. General Information						
1.1	Name of Nodal ART centre (As per NACO MPR)					
1.2	Code of Nodal ART centre (As per NACO MPR)					
1.3	Location (As per NACO MPR)	District			State	
1.4	Name of LAC					
1.5	Address of LAC					
1.6	Location	District			State	
1.7	Reporting period	Month			Year	

2. Contact details for LAC			
2.1	Name of LAC In charge		
2.2	Phone number		Email ID _____
2.3	Name of the staff making this report		
2.4	Designation of the staff making this report		
2.5	Phone number		Email ID _____

3. Treatment Status of PLHIV On ART							
		Adults			Children		Total
		Male	Female	TS/TG	Male	Female	
3.1	Number of PLHIV on ART "linked out" to LAC by nodal ART centre (at the beginning of this month)						
3.2	Number of PLHIV on ART "linked out" to LAC by nodal ART centre during this month						
3.3	Cumulative number of PLHIV on ART ever linked out to LAC by nodal ART centre (at the end of this month) = 3.1+ 3.2						
3.4	Number of PLHIV linked in (referred to) to nodal centre this month						
3.5	Cumulative number of PLHIV who were retained back at (at the beginning of this month)						
3.6	Number of PLHIV whose status is lost to follow-up (LFU) (at the end of the month)						
3.7	Cumulative number of PLHIV who died at LAC (at the end of this month)						
3.8	Number of PLHIV whose status is in MIS (at the end of the month)						
3.9	Total number of PLHIV alive and on ART (OT) (at the end of this month = 3.3 - (3.5+3.6+3.7))						

4. Treatment adherence							
4.1	Of all patients who are on treatment this month (3.9) the number who have been assessed for adherence						
4.2	Of 4.1, this month and who have been assessed for adherence, how many had 95% adherence or better						
5. TB Screening							
5.1	Number of PLHIV attending LAC during the month						
5.2	Out of the 5.1, number of PLHIV who underwent (4S) screening						
5.3	Out of the 5.2, number of PLHIV with presumptive TB (those with one or more symptom(s) present)						
5.4	Out of the 5.3, number of PLHIV with presumptive TB, referred to NAC for further investigations						

6. Regimen used during the month		
	Regimen	**No. of patients Alive On ART in this Regimen**
6.1	Tenofovir + Lamivudine + Dolutegravir (TLD)	
6.2	Abacavir + Lamivudine + Dolutegravir (ALD)	
6.3	Tenofovir + Lamivudine + Efavirenz (TLE))	
6.4	Others ( )	
6.5	Total (Should be equal to 3.9) (It will be red highlight if not matching with 3.9)	

7. Drug Stock at LAC						
	Regimen -->	**TLD**	**ALD**	**TLE**	**Other ( )**	
7.1	Opening stock					
7.2	Stock received from nodal ART centre (during the month)					
7.3	Stock sent back to nodal ART centre (during the month)					
7.4	Reusable stock returned (by patient or families) (during the month)					
7.5	Stock consumption during the month					
7.6	Stock expired during the month					
7.7	Stock remaining on last day of the month after physical count					
7.8	Approx. number of months for which stock is sufficient					
7.9	Earliest date of expiry of drugs (DD-MM-YYYY)					
Check -->	Check (if red highlighted, there is mismatch in calculation between 6.1 and 6.7)					

LAC plus - Monthly Reporting Format

1. General Information						
1.1	Name of nodal ART centre (As per NACO MPR)					
1.2	Code of nodal ART centre (As per NACO MPR)					
1.3	Location (As per NACO MPR)	District		State		
1.4	Name of LAC Plus					
1.5	Address of LAC Plus					
1.6	Location	District		State		
1.7	Reporting period	Month		Year		

Contact details for LAC			
1.8	Name of LAC Plus In charge		
1.9	Phone number		Email ID _____
1.10	Name of the staff making this report		
1.11	Designation of the staff making this report		
1.12	Phone number		Email ID _____

2. Status of PLHIV Registered in HIV Care

		Adults			Children		Total
		Male	Female	TS/TG	Male	Female	
2.1	Number of PLHIV registered in HIV care at the beginning of this month at LAC Plus (Same as 2.3 of previous month)						
2.2	Number of new PLHIV registered in HIV care at LAC Plus (Pre ART) during the month						
2.3	Cumulative number of PLHIV, registered in HIV care at LAC Plus at the end of this month						
2.4	Of the 2.3, number of PLHIV eligible for ART initiation at LAC Plus at the end of this month						
2.5	Of the 2.4 number of PLHIV initiated on ART at LAC Plus at the end of this month						
2.6	Cumulative number of PLHIV initiated on ART centre at LAC plus at the end of this month						
3.1	Number of PLHIV on ART "linked out" to LAC Plus by NAC (at the beginning of this month) (Same as 3.4 of previous month)						
3.2	Number of PLHIV on ART "linked out" to LAC Plus by NAC during this month						
3.4	Cumulative number of PLHIV on ART ever linked out to LAC Plus by NAC (at the end of this month) = 2.6 + 3.1+ 3.2						
3.4a	Cumulative number of PLHIV on ART ever linked out to LAC Plus by NAC and initiated by LAC Plus (at the end of this month) = 2.6 + 3.4						
3.5	Number of PLHIV linked in (referred to) to nodal centre this month						
3.6	Cumulative number of PLHIV who were retained back at NAC (at the beginning of this month)						
3.7	Number of PLHIV whose status is lost to follow-up (LFU) (at the end of the month)						
3.8	Cumulative number of PLHIV who died at LAC Plus (at the end of this month)						
3.9	Number of PLHIV whose status is MIS (at the end of the month)						
3.10	Total number of PLHIV alive and on ART (OT) (at the end of this month = 3.4a - (3.6+3.7+3.8))						

4. Treatment adherence							
4.1	Of all patients who are on treatment this month (3.9) the number who have been assessed for adherence (refer guideline)						
4.2	Of 4.1, this month and who have been assessed for adherence, how many had 95% adherence or better (refer guideline)						
5. TB Screening							
5.1	Number of PLHIV attending LAC Plus during the month						
5.2	Out of the 5.1, number of PLHIV who underwent (4S) screening						
5.3	Out of the 5.2, number of PLHIV with presumptive TB (those with one or more symptom(s) present)						
5.4	Out of the 5.3, number of PLHIV with presumptive TB, referred to NAC for further investigations						

6. Regimen used during the month		
	Regimen	**No. of patients Alive On ART in this Regimen**
6.1	Tenofovir + Lamivudine+ Dolutegravir (TLD)	
6.2	Abacavir + Lamivudine+ Dolutegravir (ALD)	
6.3	Tenofovir + Lamivudine+ Efavirenz (TLE))	
6.4	**Others ( )**	
6.4	Total (Should be equal to 3.9)	

7. Drug Stock at LAC						
	Regimen -->	**TLD**	**ALD**	**TLE**	**Other ( )**	
7.1	Opening stock					
7.2	Stock received from NAC (During the month)					
7.3	Stock sent back to NAC (During the month)					
7.4	Reusable stock returned (by patient or families) (During the month)					
7.5	Stock consumption during the month					
7.6	Stock expired during the month					
7.7	Stock remaining on last day of the month after physical count					
7.8	Approx. number of months for which stock is sufficient					
7.9	Earliest date of expiry of drugs (DD-MM-YYYY)					
Check -->	Check (if red highlighted, there is mismatch in calculation between 6.1 and 6.7)					

Annexure 11
Schedule for Hands-on training at ART centres for LAC/LAC plus Staff

Day-1

Time	Topics	Resource Person
09.00 to 09.10 am	Registration of participants	
09.10 to 09.20 am	Introduction	
09.20 to 09.30 am	Brief Agenda of the training	RC/TE/ SACS CST officials/DAPCU
09.30 to 11.00 am	LAC/LAC plus concept, SOPs, roles & responsibilities of LAC/LAC plus staff	RC/TE/SACS CST officials/DAPCU
11.00 am to 1.30 pm	Hands-on training of the staff (LAC/LAC plus staff shall sit beside their respective ART staff to understand the flow of patients and roles/ responsibilities)	
1.30 to 2.15 pm	Lunch	
2.15 to 3.30 pm	Pharmacology of ART with adverse effects and drug interactions, display of ART and OI medicines & discussion of paediatric dosage schedule, standard precautions & PEP	Nodal officer/SMO/MO/RC/TE
2.15 to 3.30 pm	Monitoring and evaluation tools of LAC/LAC plus (registers, white cards, monthly report of LAC/LAC plus and follow up & linkage mechanism), mechanism of drug transfer	RC/SACS CST officials/Data Manager of nodal ART centre

Day-2

Time	Topics	Resource Person
09.00 to 09.30 am	Recap of day-1	
09.30 am to 01.00 pm	LAC/ LAC plus staff shall work at the ART centre to examine/fill the formats /counsel/dispense drugs for on ART patients (as if the LAC has started)	
1.00 to 1.30 pm	Lunch	
1.30 to 3.00 pm	Linkage mechanisms between Nodal ART centre & LAC (communication format, reporting, sample transport, drug transport, coordination between ART & LAC staff)	Nodal officer/SMO/MO/ RC
3.00 to 4.00 pm	Overview of ART initiation, preparedness counselling and issues of drug adherence	SMO/MO/ counsellor of nodal ART centre
4.00 to 04.30 pm	Queries, closing remarks and feedback from the participants (TA/DA payment)	

Annexure 12
Checklist for supportive supervision visit of LAC/LAC plus

(This checklist is to be used by the designated supervisory team in conjunction with the ARV treatment unit staff during their visit to a LAC. The aim is to see the quality of services offered their conformity to national guidelines, to identify problems and take corrective actions.)

Name of LAC: _____

Contact details of LAC: _____ Email ID: _____

Name of Nodal ART Centre

Date of visit _____

Name of Supervisor _____

Name of LAC In charge _____

No. of patients registered in HIV care (LAC Plus) _____

No. of patients on ART _____

I Institutional commitment & functioning of ART centre				**Remarks**
1.	Is there high commitment to the national ART programme (this shall be indicated by involvement of the institution in the ART)?	☐ Yes	☐ No	
2.	Is proper space and infrastructure available at LAC?	☐ Yes	☐ No	
3.	Are there proper signage for the LAC?	☐ Yes	☐ No	
4.	Is internet, computer with printer, available at LAC?	☐ Yes	☐ No	
5.	Is the LAC staff identified as per NACO guidelines (LAC in charge, LAC medical officers, lab technician, counsellor, pharmacist, nurse)?	☐ Yes	☐ No	
6.	Has the LAC medical officer undergone NACO training?	☐ Yes	☐ No	
7.	Has orientation/ hands on training of LAC staff been carried out as per NACO guidelines?	☐ Yes	☐ No	
8.	Does LAC function every day?	☐ Yes	☐ No	
9.	Is the IEC material displayed in Link ART centre?	☐ Yes	☐ No	
10.	Are the LAC services well organized: shall be indicated by the channel of movement of the patient to access services as required (clinical, lab, drugs, counselling)?	☐ Yes	☐ No	
11.	Is the SOP for the functioning of the LAC is being followed as per operational guidelines? (specifies roles and responsibilities, patient flow, etc)?	☐ Yes	☐ No	
12.	Is there adequate coordination of the LAC with other departments of the institution?	☐ Yes	☐ No	
13.	Are the indoor admissions /referral done for OI treatment (when required)?	☐ Yes	☐ No	
14.	Are general hygiene and Infection control practices in place?	☐ Yes	☐ No	

II Recording & Reporting				
15.	Are the NACO specified patients and programme monitoring records being maintained?	☐ Yes	☐ No	
i.	HIV care register *	☐ Yes	☐ No	
ii.	ART enrolment register	☐ Yes	☐ No	
iii.	Drug stock register	☐ Yes	☐ No	
iv.	Drug dispensing register	☐ Yes	☐ No	
v.	Patient treatment record (white card)	☐ Yes	☐ No	
vi.	Green book	☐ Yes	☐ No	
16.	Is confidentiality of records maintained?	☐ Yes	☐ No	
17.	Are the records properly stored?	☐ Yes	☐ No	
18.	Are the patient treatment records up to date?	☐ Yes	☐ No	
19.	Are periodic communications sent to nodal ART centre?	☐ Yes	☐ No	
20.	Is data entered in IMS on real-time basis	☐ Yes	☐ No	
21.	Is the LAC monthly report sent to nodal centre at the end of each month?	☐ Yes	☐ No	
ART initiation* (for LAC plus only)				
22.	Is the blood collection for CD4 regularly been done every 6 months for all registered patients?	☐ Yes	☐ No	
23.	Is CD4 testing done every 6 months for all registered patients?	☐ Yes	☐ No	
24.	Is Pre-ART CD4 due listing being maintained and followed?	☐ Yes	☐ No	
25.	Is there a mechanism in place to track back patients with borderline CD4 results?	☐ Yes	☐ No	
26.	Are all patients eligible for ART referred to Nodal ART centre?	☐ Yes	☐ No	
27.	Are all PLHIV screened for TB symptoms?	☐ Yes	☐ No	
ART services				
28.	Are the national guidelines for ART being followed?	☐ Yes	☐ No	
29.	Is adherence issue being given due importance (adherence counselling, pill count)?	☐ Yes	☐ No	
30.	Is the daily missed list of patients maintained and followed up?	☐ Yes	☐ No	
31.	Are the patient referred back to nodal ART centre at 6 months for routine monitoring & CD4 testing	☐ Yes	☐ No	
32.	Are the patients screened for adverse effects or OI and referred to nodal ART centre?	☐ Yes	☐ No	
III Drug stocks				
33.	Is the drug dispensation record up to date?	☐ Yes	☐ No	
34.	Are there adequate drugs for the next 3 months (stock position)?	☐ Yes	☐ No	
35.	Are the drugs stored as per the specifications?	☐ Yes	☐ No	
36.	Is the "First Expiry First Out" principle followed?	☐ Yes	☐ No	
37.	Does the regimen wise consumption of drugs match with the number of patients on ART?	☐ Yes	☐ No	

IV Laboratory Services Availability				
i.	HIV testing	☐ Yes	☐ No	
ii.	Sample collection for enumeration of CD4 cells	☐ Yes	☐ No	
iii.	CBC and other routines biochemistry investigations	☐ Yes	☐ No	
iv.	LFT	☐ Yes	☐ No	
v.	Blood sugar	☐ Yes	☐ No	
iv.	Lipid profile	☐ Yes	☐ No	
vii.	S. Creatinine	☐ Yes	☐ No	
viii.	CXR	☐ Yes	☐ No	
ix.	TB diagnostics	☐ Yes	☐ No	
38.	Are baseline tests being done for all the patients? (for LAC plus only)	☐ Yes	☐ No	
39.	Any of the above testing is charged?	☐ Yes	☐ No	
V Referral & Linkages				
40.	Are there referrals from the ICTC to the LAC? (Write the number in last 3 month). Compare with total positives detected at ICTC in same period.	☐ Yes	☐ No	
41.	Are HIV / TB linkages maintained? (check line list register & monthly report)	☐ Yes	☐ No	
42.	Is there effective communication between LAC & nodal ART centre?	☐ Yes	☐ No	
43.	Are a proper MIS/LFU tracking mechanism in place?	☐ Yes	☐ No	
44.	Does the ART centre have any mentoring of LACs?	☐ Yes	☐ No	
Other Information				
45.	Are the PEP drugs available in casualty, ICU & labour room?	☐ Yes	☐ No	
46.	Are the universal work precautions followed?	☐ Yes	☐ No	
47.	Are measures for airborne infection control in place?	☐ Yes	☐ No	

*Applicable for LAC plus

Key observations and recommendations:

Date: .....

Signature and name .....

Annexure 13
RRF- Request and reply form for review by SACEP at CoE/pCoE/ ART plus centre

Date:

Name of the referring ART centre _____

Centre of Excellence /ART plus centre _____

Name:	
ART No:	
Age	
Sex:	
Weight	
Reason for referral:	☐ **Suspected First Line Failure** ☐ **Suspected Second Line Failure** ☐ **adverse effects to ARV drugs** ☐ **Others (specify) .....**
Documents attached	☐ **All clinical records** ☐ **All lab reports** ☐ **Photo documentation of adverse effects**
Summary of Clinical History (describe in brief major events since ART initiation)	
Current clinical staging of patient	
Any current coinfection/opportunistic Infection/comorbidity	☐ Yes ☐ No
concomitant drugs (if any) If yes, mention date of initiation and Treatment details)	ATT: ☐ Yes ☐ No TPT: ☐ Yes ☐ No CPT: ☐ Yes ☐ No HBV/HCV treatment: ☐ Yes ☐ No Any other (specify)
Type and grade of adverse effects (if any)	

Complete ART history **(ART drugs started on with time duration for each ART drug regimen)**

S. NO	Period (Dates from to)	ART Regimen	Duration (in Years & Months)	Reason for change of regimen

Serial Viral Load

Viral load test: Date..... Result .....Copies/mL.

Viral load test: Date..... Result .....Copies/mL.

Viral load test: Date..... Result .....Copies/mL.

Viral load test: Date..... Result .....Copies/mL.

C. Serial CD4 test with dates (last CD4 done within 1 month)

Baseline CD4 count: Date ..... Result .....

CD4 count: Date ..... Result .....

CD4 count: Date ..... Result .....

CD4 count: Date ..... Result .....

CD4 count: Date ..... Result .....

F. Treatment adherence percentage for each of the last three months (Give exact %):

1 …… % 2. …… % 3. …… %

G. Latest Lab Investigations

Investigation	Date	Result
1. Haemoglobin	.....	.....
2. Sr. Creatinine	.....	.....
3. Sr. ALT (SGPT)	.....	.....
4. Blood Sugar	.....	.....
5.	.....	.....

Reply from SACEP at CoE / PCoE / ART plus centre to Referring ART centre (After SACEP review)

Date.....

ART centre..... ART Reg no.....

SACEP Reg. no: .....

SACEP recommendations: ☐ Continue same treatment

☐ Repeat PVL after ..... months

☐ Switch to ..... (regimen) with dosage .....

☐ Substitute with ..... (regimen) dosage .....

Others (specify).....

.....

Advice/Instructions: .....

.....

Reply from Referring ART centre to CoE/CoE/ART plus centre after SACEP approval

Action taken with date: .....

.....

Annexure 14
Guidance for counselling for disclosure of HIV status to children and adolescents

Criteria for disclosure

- Children > 5 years old and caregivers involved
- Partial disclosure (6 -9 years) & full disclosure (10-12 yeras)
- It is recommended to do the disclosure progressively from 6 years age and tell them about their HIV status when they are between 10 and 12 year old.

Guiding Principles

- Disclosure should follow a planned process. There are levels of disclosure over time.
- Disclosure of HIV status is continuous and progressive process. Child should be prepared gradually to accept the full and complete knowledge of having HIV infection.
- Be respectful of the child's needs and feelings.
- Be led by the child in terms of the amount of information they require.
- Use age-appropriate language in line with education and emotional readiness.
- Use images or drawings to help children understand the explanations during counselling
- Be honest. If you do not know the answer to the child's questions, say so.
- **It is important that the disclosure be done by the caregiver, the role of the counsellor is to support this process. If the caregiver really cannot do it, then the counsellor can help to do it in the presence of the caregiver.**
- **A child aged 12 years and older may be fully disclosed through the disclosure stepwise process.**

	Step-1 (only with Caregiver)	Step-2 (with child and caregiver)*
Partial Disclosure (6-9 years old)	1. Ask what the caregiver has told the child so far about the reason for coming to the clinic and taking treatment. 2. **Explain that partial disclosure is** like a journey with many stops. At each stop, we will explain a little more to the child. At the end of the journey, when it is the right time for the child, the child will understand HIV and the treatment the child is taking. • HIV will NOT be named at this stage. 3. **Explain the advantages of disclosure:** • Usually, children who know their status take their medicine better because they understand why they have to go to the clinic and take treatment.	1. **The visit to the clinic** • Ask the child: What do you do when you come to the clinic? Help the child to talk about clinical check-ups, treatment and blood tests. 2. **The body and the blood system and soldiers inside the blood – the immune system** • Explain that we all have blood that travels all around inside the body which circulates through arteries and veins. • Explain that inside the blood we all have small soldiers that protect us from becoming sick. They fight against different types of germs that cause diseases. 3. **A sleeping germ - Explain that sometimes a strong germ enters the body. The body soldiers are not strong enough to fight against the special germ. This germ cannot be killed by medicine, but it can be put to sleep.** 4. **When the sleeping germ multiplies, the soldiers will not be enough to fight disease anymore.** • if we do not fight the sleeping germ, the body will become very weak and more germs will enter the body and cause diseases. Then we get sick very easily

	• Children may have fears that are worse than the real thing. 4. **Explain the timing for disclosure:** • You can take opportunities to talk to your child about HIV, for example when they have to go to the clinic or have blood tests. • Follow the lead of the child. When children ask questions, find ways to respond with adapted explanations as per their age without lying 5. **Assess barriers to disclosure:** • How do you feel about giving information to the child on their condition today without naming HIV? • What are your fears about disclosing child's status one day? *Multiple sessions may be required until caregiver is ready for partial disclosure*	5. **Treatment to fight the sleeping germ** • Explain that there is very good news. There is a medicine that contains special warriors. These warriors are very, very strong and they fight the sleeping germ and keep it asleep. When the germ is asleep, it makes the soldiers in the blood happy. They can then multiply and protect our body against other germs that cause diseases. 6. **The importance of taking treatment every day to keep the sleeping germs asleep** • Explain that to make sure that the sleeping germs stay asleep and keep us well, the child must take their medicines called "Good Night Medicine" every day around the same time. They are called "good night medicine" because they keep the 'sleeping' germ asleep. • Remind the child that in case they forget to take medication, they should take it as soon as they remember. 7. **Explain to the child that they have the sleeping germ and reassure them that they do not need to be afraid because the "Good night Medicine" is very good at keeping the germ asleep.** 8. **Repeat Session-2 steps at every visit to make sure the child understands**

	Step -1 (only with Caregiver)	**Step-2 (with child and caregiver)***
Full Disclosure (10-12 years old)#	1. **Introduction and assessment of readiness for full disclosure** • How is the child doing since the last session? • Did the child ask questions? • Did you disclose to the child his or her HIV status? • Explain that, if the caregiver has not disclosed and is willing to do so, we can help to talk about the child's HIV status to the child today. • If the caregiver expresses reluctance to disclose, let them express their fears. Support them in finding solutions and remind them about the advantages of disclosure. 2. **Propose specific help to the caregiver for disclosure:** • Propose role plays to practice disclosure and discuss how to answer difficult questions. • Prepare the caregiver for the emotional response of the child such as crying or shouting.	1. **Assess what the child remembers from the previous session on partial disclosure** • Explain the importance of taking treatment every day to keep the sleeping germ asleep and make the soldiers of the body stronger 2. **If the caregiver is ready to disclose to the child, support disclosure to the child:** • Ask the child: Do you know the name of the sleeping germ that you have in your body? • Propose that the caregiver tells the child. If it is difficult, support the caregiver to tell the child that the sleeping germ is called HIV. Let the child talk and ask question and give the child time to absorb the new information. 3. **Assess feelings and support** • Some children may feel sad or angry; others will be shocked when they hear they have HIV. • How do you feel about this news? It is normal to experience such feelings and you can express whatever you want. 4. **Ways of transmission** • Explain HIV can be transmitted when a mother who has HIV is pregnant and transmits the virus to her baby during pregnancy, giving birth or during breastfeeding. HIV can also be transmitted when people have sex without using a condom or by sharing sharp materials that were in contact with HIV infected blood.

	• It is important for the caregiver to accept the reaction of the child, whatever it is. • Recommend the caregiver to be supportive to the child and respect his/her emotions. • Speak with the caregivers about the distinction between telling all and telling what is necessary for the child's understanding. 3. Discuss disclosure and secrecy • Ask with whom the child could speak about HIV. • Explain that disclosure inside the family can increase support to the child. It is important that the child feels supported in taking treatment. It is up to the caregiver and the child to decide whom it is good to tell. The caregiver should ensure that the child is not stigmatized by family members. 4. Assess barriers to disclosure: • What are your fears about disclosing the HIV status to the child? 5. Reassure about the benefits of disclosure and propose to support the caregivers in disclosing to the child.	• As you can see there are many ways a person can get infected with HIV; the important thing is that you know you have the virus in your body and you can take your medication every day, so that the HIV stays asleep and does not attack your soldiers and does not make you sick. • HIV cannot be transmitted by playing, hugging, kissing, sharing forks, glasses or taking a bath with someone who has HIV. 5. Who to tell: • Ask the child and the caregiver if there is anyone else that they can share their experiences with and get support from a close family member, teacher or the nurse. 6. Encourage adherence to keep HIV asleep in the body • Identify and address most common barriers to adherence. • Assist the child to develop an individualized adherence plan and set clear treatment milestones such as school holidays. • Provide comprehensive support for HIV positive adolescents who are pregnant and breastfeeding on ART or co-infected with TB.

If the child is asking question and seems ready, the full disclosure may be started before 10 years age. By the age of 12, children living with HIV may be fully disclosed.

ART centre staff should encourage, support and guide the care giver of disclosure through step 1. If the caregiver desires/ requests, disclosure may be done together (by the caregiver along with the support of the MO/counsellor). Parents should be encouraged to disclose the status along with the support of the counsellors.

Annexure 15
Referral form

Date of referral: ____/_____/_____

Reg. No.: _____

Referring facility: _____ Referred to: _____ Reasons for referral: _____ Name of the Patient: _____ Age/ Gender: _____ Signature & Name of the referring Doctor
Feedback Department and Hospital: _____ Recommendations: _____ Signature & Name of the Doctor

Annexure 16
ART feasibility assessment visit format (initial visit)

Date of feasibility visit: ..... Name of members of feasibility visit team: .....

I. General Information					
1.	Name of the district	2. Name of the hospital			
3.	Type of hospital	4. Name of the Medical Superintendent			
5.	Hospital phone number with code	6. Postal address with pin code			
II. Background Information					
7	Give the catchment area of the proposed site for ART centre				
8	No. of Positives detected during last five years in the district/ catchment area	**Sr No**	**Year**	**ANC**	**%Positivity**	**Non-ANC**	**% Positivity**
		1					
		2					
		3					
		4					
		5					
9	Percentage of ICTC Seropositivity in	(a.) General Clients					
		(b.) Pregnant Women.....					
10	No. of LAC in the district/catchment area						
11	No. of patients on ART in the LAC in the district/ catchment area	Name of the LAC			No. of patients on ART		
12	Does the district already have ART centre? If yes, give names and number of patients registered in HIV care and on ART?	Name of the ART Centre			No. of patients on ART		
13	Distance of the proposed site from nearest existing ART centre						
III. Organization & Infrastructure							
	Institutional Commitment						
14	Is the Head of the Institution committed towards the National AIDS Control Programme?	☐ Yes	☐ No				
15	Is the hospital administration committed?	☐ Yes	☐ No				
16	Has the Nodal officer been identified and is committed?	☐ Yes	☐ No				
17	Is the institution willing to provide baseline investigation and common OI drugs?	☐ Yes	☐ No				
	LAC Functioning						
18	Is there a LAC Plus/LAC functioning in the Hospital?	☐ Yes	☐ No				
19	No. of patients on ART at LAC Plus/LAC	☐ Yes	☐ No				
	General Information regarding the hospital						
20	No. of doctors available	☐ Yes	☐ No				
21	No of beds available	☐ Yes	☐ No				
22	No of positive deliveries conducted in the last year	☐ Yes	☐ No				
23	Are common OI drugs available at the hospital pharmacy	☐ Yes	☐ No				
24	Is NTEP functional in hospital	☐ Yes	☐ No				
25	Human resources	☐ Yes	☐ No				
a	Total specialists available	☐ Yes	☐ No				
b	Physician	☐ Yes	☐ No				

c	Paediatrician	☐ Yes	☐ No
d	Obstetrician	☐ Yes	☐ No
e	Chest physician	☐ Yes	☐ No
f	Dermato-venreologist	☐ Yes	☐ No
g	Microbiologist/Pathologist	☐ Yes	☐ No
h	Others (Mention)	☐ Yes	☐ No
IV. Space Identified for ART centre			
26	Location of the proposed ART centre	☐ Yes	☐ No
27	Total area of the proposed site	☐ Yes	☐ No
28	Linkages with ICTC	☐ Yes	☐ No
29	Linkages with Medicine OPD & other Specialites	☐ Yes	☐ No
30	No of rooms/cabins planned	☐ Yes	☐ No
a	Doctors	☐ Yes	☐ No
b	Counsellors	☐ Yes	☐ No
c	Data operators	☐ Yes	☐ No
d	Drug storage & pharmacist	☐ Yes	☐ No
e	Lab technician	☐ Yes	☐ No
V. Nodal Officer and ART Team			
31	Has the Nodal officer been identified and is committed? (Give name)	☐ Yes	☐ No
32	Has the ART Team been identified? (Give name)	☐ Yes	☐ No
VI. Lab and radiological investigations (ready to provide free of cost)			
a	Hemogram	☐ Yes	☐ No
b	RFT	☐ Yes	☐ No
c	LFT	☐ Yes	☐ No
d	Blood sugar	☐ Yes	☐ No
e	Lipid profile	☐ Yes	☐ No
f	Pregnancy test	☐ Yes	☐ No
g	CXR	☐ Yes	☐ No
h	Ultrasound	☐ Yes	☐ No
i	CBNAAT/TrueNAT	☐ Yes	☐ No
j	Urine examination	☐ Yes	☐ No
k	VDRL	☐ Yes	☐ No
l	PAP Smear/visual inspection with acetic acid (VIA)	☐ Yes	☐ No
m	Others (mention)	☐ Yes	☐ No

Issues:	Suggested Follow up Action:

I ..... (Head of the Institution) of ..... agree to provide essential support for ART centres in accordance to the guidelines.

Signature of the Medical Superintendent/CDMO .....

Summary:

1. Background: .....
2. Organization and infrastructure: .....
3. Space for the ART centre: .....
4. Human resources: .....
5. NGO linkages: .....
6. Lab investigations: .....

Conclusion:

Recommendation : Recommended to set up ART centre

: Not recommended (specify reasons for same)

Signature of the feasibility visit team: 1 ..... 2. .....

Annexure 17
Format for readiness assessment for initiating services at new ART centre

Name of the Hospital: .....

Name of the ART centre in-charge: .....

Date of appraisal/visit: .....

Name and designation of the visiting persons: .....

Indicator	Readiness status		Remarks
Head of the health care facility/ART in charge committed to provide ART care and support	☐ Yes	☐ No	
ART unit strategically located in medicine OPD	☐ Yes	☐ No	
Bank account opened	☐ Yes	☐ No	
Space and infrastructure	☐ Yes	☐ No	
Has the space refurbishment done for ART centre	☐ Yes	☐ No	
Medical examination rooms – 2 Nos.	☐ Yes	☐ No	
Counselling cabins – 2 Nos.	☐ Yes	☐ No	
Patient waiting area	☐ Yes	☐ No	
Medical records, drug & supplies room	☐ Yes	☐ No	
Blood and specimen collection room	☐ Yes	☐ No	
Furniture & equipment for ART centre	☐ Yes	☐ No	
Computer and printer	☐ Yes	☐ No	
Phone & internet	☐ Yes	☐ No	
IMS linkage	☐ Yes	☐ No	
HR and training	☐ Yes	☐ No	
Nodal Officer in-charge ART centre in place and trained	☐ Yes	☐ No	
Ten member ART team for referrals trained	☐ Yes	☐ No	
Trained laboratory personnel (microbiologists & biochemists) available in the health care facility	☐ Yes	☐ No	
ART SMO recruited and trained	☐ Yes	☐ No	
ART counsellor recruited and trained	☐ Yes	☐ No	
Data manager recruited and trained	☐ Yes	☐ No	
Staff nurse keeper recruited and trained	☐ Yes	☐ No	
ART pharmacist recruited and trained	☐ Yes	☐ No	
Lab technician recruited and trained	☐ Yes	☐ No	

Care coordinator recruited	☐ Yes	☐ No	
Availability of drugs	☐ Yes	☐ No	
Adequate stock of first line drugs available	☐ Yes	☐ No	
Adequate drugs for opportunistic infections available	☐ Yes	☐ No	
Partnerships	☐ Yes	☐ No	
PLHIV networks contacted and involved	☐ Yes	☐ No	
NGOs contacted and involved	☐ Yes	☐ No	
Private providers contacted and involved	☐ Yes	☐ No	
Other support groups contacted and involved	☐ Yes	☐ No	
Documents Available			
Recording and reporting available as per guidelines	☐ Yes	☐ No	
National Operational Guidelines for ART Services	☐ Yes	☐ No	
National Guidelines for HIV care and Treatment 2021	☐ Yes	☐ No	
Laboratory Services Available			
Microbiology lab with adequate space and technical expertise to perform the following tests	☐ Yes	☐ No	
HIV testing	☐ Yes	☐ No	
Enumeration of CD4 cells	☐ Yes	☐ No	
Is facility to perform the following investigations available? CBC and other routines investigations (LFT, RFT, blood sugar, lipid profile, pregnancy test, X-ray, urine routine, USG, pap smear/VIA)	☐ Yes	☐ No	

Have the discrepancies identified during appraisal visit rectified.....?

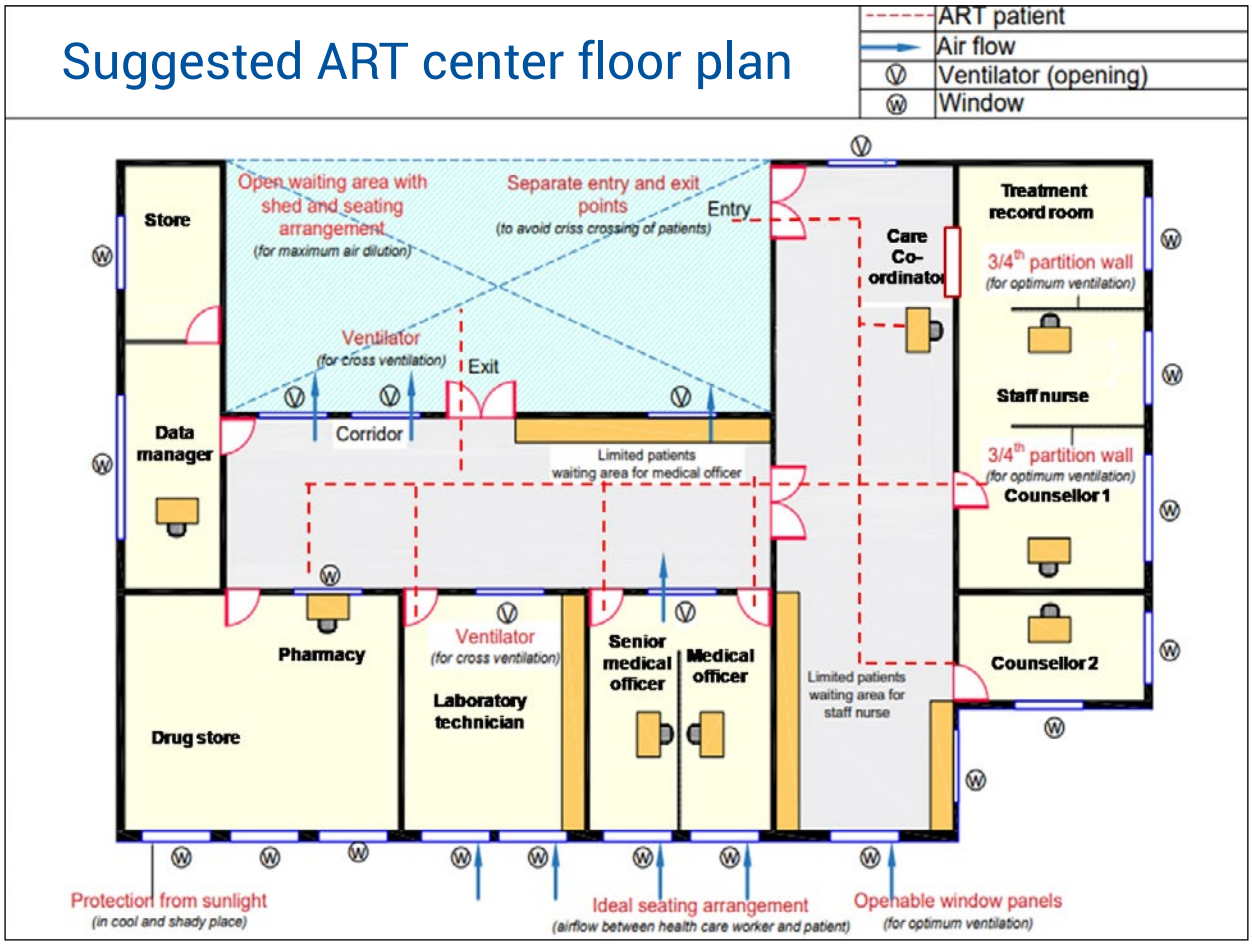
Overall Preparedness : Recommended for starting ART service delivery

: Not recommended

Signature of the visiting official/team:

1. _____ 2. _____

Annexure 18
Suggested ART centre floor plans



Annexure 19
Technical specification for hardware devices

i. Facility based Desktop

S.No.	Specifications	Details
1	Configuration	Intel i5
2	CPU	Intel®Core™i5-9500Processor with Intel®UHDGraphics630 (9 MB Intel® Smart Cache, up to 4.4 GHz with Intel turbo boost technology, 6 core,6 threads)
3	Chip set	Int el Q370
4	Bus Architecture	4 PCI (PCI/PCI Express)
5	Memory	8 GB DDR4 -2666 SDRAM
6	Hard Disk Drive	1TB hard Disk as secondary SDD.
7	SSD Drive	Additional SSD Drive 360 GB as primary drive
8	Monitor	Up to 56 CM (22 inch) or larger LED/TFT Digital Color Monitor, TCO-05 certified, Display input type: 1 VGA, 1 HDMI
9	Keyboard	104 Keys
10	Mouse	Optical with USB interface
11	Bays	3 Nos or above
12	Ports	USB 3.0-2, USB 2.0-1, headphone-1, microphone-1, audio in-1, audio out-1, DVI-1, Single link -1, RJ 45-2, Display port -1,2;2 PS/2
13	Cabinet	Small form factor, Built-indevices-Speakers, microphones
14	DVD ROM Drive	8X or better
15	Networking Facility	Data link protocol-Ethernet, Fast Ethernet, Gigabit Ethernet Ethernet controllers- Intel I219-LM Features- Remote wakeup, PXE support, Intel Active Management Technology
16	Operating System	Windows 10 Professional 64- bit edition with Media, Documentation and Certificate of Authenticity
17	OS Certificates	Windows 10 OS Certifications
18	Power Management	Screen Blanking, hard disk and system idle mode in power on set up password, power supply, SMPS surge protection
19	Pre-loaded Software	Office 365, latest version of antivirus with five years license
20	Environmental Standards	Energy Star Certified
21	Warranty	3 years onsite warranty

ii. Web Cam Specifications

S.No.	Specifications	Details
I.	Resolution	720p/30fps
2.	Focus	Fixed
3.	Lens	Standard
4.	Field of View	60°
5.	Voltage	240 Volts
6.	Microphone	Mono, Built -in with noise reduction
7.	Warranty	One Year

iii. Speaker

S.No.	Specifications	Details
1.	System Configuration	2.0 System
2.	Connector Type	USB + 3.5 mm Audio Jack
3.	Volume Level Control	Yes
4.	Power Output	Min0.8WattRMSperChannel
5.	Frequency response	100Hz-1SKHz
6.	Connectivity	Wired
7.	Warranty	One Year

iv. Printer

The Committee recommended the following technical specifications.

S.No.	Specifications	Details
1	Printing Method	Laser
2	Type	Multi -functional (copy, print, scan)
3	Display	2 line LCD text
4	Printing output	Monochrome
5	Max Print Resolution	1200*1200 dpi
6	Duty Cycle	800 pages per month A4
7	Print Speed	20 ppm or higher
8	Duplex Print	Automatic
9	Scan and Copy	
9.1	Bit depth color	8 bit
9.2	Scan area size	216*297 mm
9.3	Scan method	Contact Image Sensor (CIS)
9.4	Optical Scanning Resolution	600 * 600 dpi & hardware up to 4800X4800 DPI
9.5	Scan Type	Automatic Document Feeder (ADF)
9.6	Copy resolution	400* 600 dpi
10	Operating Temp/ Humidity range	15° c -32° c/ 10%-80% RH
11	Connectivity	USB Supp ort - USB 2.0/ 3.0 and wireless Support along with RJ 45 Support
12	Paper Handling	150 sheet Input Trey, Standard Cassette

v. Specifications of the OFFLINE UPS of 1KVA with 60 Minutes Backup

Description	Specification
Certifications	ISO 9001:2008 and 14001 Certified OEM
Technology	True Offline UPS with Double Conversion technology Rectifier &Inverter both be IGBT based
Power Rating	1000VA/800W
Input Voltage &Range	160-280 VAC @100% load
Input Freq. Range	45Hz ~ 55 Hz
Input Power Factor	>=0.95
Output Voltage Range	220 / 230 / 240 VAC ±3%
0/p Voltage Distortion	< 6% (Non-linear load) < 3% (linear load)
Output Frequency	47.5~52.5Hz

Output Power Factor	0.8
Output Crest Factor	3:1
Transient Response	Less or equal to 3% for 100% nonlinear load (Battery mode)
Battery Type	Sealed maintenance free valve regulated lead acid
Backup	60 Min with supplied Desktop and Webcam
Protection	Internal/External Transient Voltage Surge Suppress orati/pof UPS OR Inbuilt Galvanic Isolation Transformer along with monitoring LED
Audible Noise	<45 dB@ 1 Meter
Operating Temp. & Humidity	20-90%RH @0-40u C (Non-condensing)
CD/LED Display	UPS Status, Load Level, Battery Level, 1/ p O/p voltage, Discharge Timer and Fault Conditions Management
Warranty Service	UPS two Year warranty and Battery two years.

v. Specifications of the Router

Description	Specification
Data Rate	802.11a/b/g/n/ac
Operating frequency	2.4GHZ/5GHz
Transmit/Receive	MIMO Technology
Memory	25MB Flash and 512MB RAM.
Network Standard	IEEE802.11a, IEEE802.11b, IEEE802.11g, IEEE802.11n, IEEE802.11ac, IPv4, IPv6
Encryption	64-bit WEP, 12-bit WEP, WPA2-PSK, WPA-PSK, WPA-Enter prose, WPA2 - Enter prise, WPS support
Processor	1.4 GHz dual-core processor
Operation Mode	"Wireless router mode Access point mode"
Power Supply	"AC Input: 110V~240V (50~60Hz) DC Output: 19 V with max. 2.37 A current"
Internet Connection type	Automatic IP, Static IP, PPPoE (MPPE supported), PPTP, L2TP, minimum 4 LAN port, DHCP services should be available in the router

Annexure 20
List of CoE and pCoE along with linkage plan

Sl. No	Name	State linked with CoE & pCoE
A	**Center of Excellence (CoE)**	
1	Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh	Punjab, Chandigarh, Himachal Pradesh, Jammu & Kashmir, Ladakh, Haryana
2	Maulana Azad Medical College (MAMC), New Delhi	Delhi, Haryana, Madhya Pradesh, Uttarakhand
3	Institute of Medical Sciences, Banaras Hindu University, Varanasi	Uttar Pradesh, Uttarakhand, Madhya Pradesh, Bihar
4	Regional Institute of Medical Sciences (RIMS), Imphal	Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Tripura, Nagaland
5	BairamjiJijibhai Medical College (BJMC), Ahmedabad	Gujarat, Rajasthan, Dadra and Nagar Haveli and Daman and Diu
6	School of Tropical Medicine (STM), Kolkata	West Bengal, Jharkhand, Chhattisgarh, Odisha, Bihar, Assam, Sikkim
7	Sir J.J. Hospital, Mumbai	Goa, Maharashtra, Mumbai, Madhya Pradesh
8	Government Gandhi General Hospital , Secunderabad, Hyderabad	Telangana
9	Siddhartha Medical College, New GGH, Vijayawada (Krishna)	Andhra Pradesh
10	Bowring and Lady Curzon Hospital, Bangalore	Karnataka
11	Government Hospital of Thoracic Medicine (GHTM), Tambaram, Chennai	Tamil Nadu, Pondicherry, Kerala, Andaman & Nicobar, Lakshadweep
B	***Paediatric* Centre of Excellence (pCoE)**	
1	Kalawati Saran Children's Hospital Lady Hardinge Medical College, Delhi	Delhi, Haryana, Madhya Pradesh, Uttarakhand, Rajasthan
2	Jawaharlal Nehru Hospital (JN), Imphal	Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Tripura, Nagaland
3	Kolkata Medical College & Hospital(MCH), Kolkata	West Bengal, Jharkhand, Chhattisgarh, Odisha, Bihar, Assam, Sikkim
4	Lokmanya Tilak Municipal General Hospital (Sion), Mumbai	Goa, Maharashtra, Mumbai, Madhya Pradesh, Gujarat, Daman and Diu, Dadra Nagar & Haveli
5	Niloufer Children's Hospital, Hyderabad,	Telangana, Andhra Pradesh
6	Indira Gandhi Institute of Child Health (IGICH), Bangalore	Karnataka, Kerala
7	Institute of Child Health (ICH), Chennai	Tamil Nadu, Puducherry, Andaman& Nicobar

Annexure 21
Feasibility assessment for upgradation of ART centres into ART plus

Date of feasibility assessment:

Name of members of feasibility visit team:

<table>
<tr><td colspan="3">I. General Information</td></tr>
<tr><td>1.</td><td>Name of the district</td><td></td></tr>
<tr><td>2.</td><td>Name of the hospital</td><td></td></tr>
<tr><td>3.</td><td>Type of hospital (medical college/district hospital)</td><td></td></tr>
<tr><td>4.</td><td>Name of the nodal officer of ART centre</td><td></td></tr>
<tr><td>5.</td><td>Hospital phone number with code</td><td></td></tr>
<tr><td>6.</td><td>Postal address with pin code</td><td></td></tr>
<tr><td colspan="3">II. Relevant Information</td></tr>
<tr><td>7.</td><td>PLHIV on ART</td><td></td></tr>
<tr><td>8.</td><td>List of proposed sites that would be attached for SACEP referral</td><td><table><tr><td>S.No</td><td>ART centres</td><td>PLHIV on ART</td></tr><tr><td>1</td><td></td><td></td></tr><tr><td>2</td><td></td><td></td></tr><tr><td>3</td><td></td><td></td></tr><tr><td>4</td><td></td><td></td></tr><tr><td>5</td><td></td><td></td></tr></table></td></tr>
<tr><td>9.</td><td>Does the district already have ART Plus Centre?</td><td><table><tr><td>Name of the ART plus centre</td><td>No of patients on ART</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>10.</td><td>Distance of the proposed site from nearest existing ART plus centre</td><td></td></tr>
<tr><td>11.</td><td>Is the hospital administration committed towards the National AIDS Control Programme?</td><td></td></tr>
<tr><td>12.</td><td>Is the nodal officer involved in day to functioning of ART centre and clinical management of PLHIV?</td><td></td></tr>
<tr><td>13.</td><td>Is there coordination between the ART centre and the other departments of the hospital?</td><td></td></tr>
<tr><td>14.</td><td>Is the institution providing laboratory/radiological investigations and common OI drugs free of cost to all PLHIV?</td><td></td></tr>
<tr><td>15.</td><td>Are there any difficulties faced by the PLHIV for admission and surgeries in the hospital OPD or the IPD?</td><td></td></tr>
<tr><td>16.</td><td>Is the ART centre having staff as per NACO guidelines (SMO/ MO/ Staff Nurse/ Counsellors /Lab Technician/ Pharmacist/ Data Manger/ Community care coordinator)?</td><td></td></tr>
<tr><td>17.</td><td>Are the ART centre staff trained as per NACO guidelines (Hands on training/Induction training/refresher training)?</td><td></td></tr>
<tr><td>18.</td><td>Is NTEP functional in hospital?</td><td></td></tr>
</table>

19.	Is the nodal officer willing to take up the responsibility of ART plus centre?	
20.	Have the SACEP members (experts / faculty) from the Institution identified?	
21.	Are the identified SACEP members willing to undergo NACO training on management of treatment failure/severe adverse effects?	
22.	Names of identified SACEP members with designation	
23.	Has the counsellor to support SACEP meeting identified?	
24.	Proposed SACEP Day	
25.	Space to conduct SACEP meeting available?	
26.	Others (mention)	
27.	Issues	Suggested follow up action

Recommendation: 1. Recommended for ART plus centre.....

2. Not Recommended (If not reasons for same).....

Signatures of the feasibility assessment team: 1..... 2.....

Annexure 22
Checklist to authorise select ART plus centres to do prescription of third line ART

I. General Information		
1.	Name of the district	
2.	Name of the hospital	
3.	Type of hospital (medical college/district hospital)	
4.	Name of the nodal officer of ART plus centre	
5.	Hospital phone number with code	
6.	Postal address with pin code	
II. Relevant Information		
7.	PLHIV on ART	
8.	For how long the the centres functioning as ART plus	S.No / ART centres / PLHIV on ART 1 2 3 4 5
9.	List of ART centres that are attached for SACEP referral	
10.	How far is the existing third line SACEP facility located?	
11.	Is the hospital administration committed towards the National AIDS Control Programme?	
12.	Is the nodal officer involved in day to functioning of ART centre and clinical management of PLHIV?	
13.	Is the ART plus centre conducting regular SACEP as planned?	
14.	Does SACEP review and send recommendations to referring centres in a timely manner?	
15.	Do the nodal officer and other identified SACEP members regularly participate in SACEP meetings?	
16.	Is there a good coordination between the ART centre and the other departments of the hospital?	
17.	Does ART plus centre have optimal coordination with CoE	
18.	Is the institution providing laboratory/radiological investigations and common OI drugs free of cost to all PLHIV?	
19.	Is the ART centre having staff as per NACO guidelines (SMO/MO/staff nurse/counsellors /lab technician/ pharmacist/data manager/care coordinator)?	
20.	Are the ART centre staff trained as per NACO guidelines	
21.	Comments of CoE/SACS	
22.	Issues:	Suggested follow up action:

Recommendation : Recommended for prescribing Third line ART

: Not recommended (specify reasons)

Signature of the feasibility assessment team: 1.....2.....

Annexure 23
NACO performance management and development system (PMDS) for ART centre staff

Name of ART centre: .....

Name of the staff and designation: .....

Date of joining: .....

Performance period: .....

A. Performance Review

I. Common for all staff

S.No.	Parameters	A.1 Self Review					A.2 Supervisor's Assessment				
		1	2	3	4	5	1	2	3	4	5
I. For all staff members											
1	Punctuality to work										
2	Attendance										
3	Team player										
4	Drive in achieving goals and objectives										
5	Interpersonal/communication skills										
6	Cross department works/collaboration										
7	Overall knowledge (appropriate to the function)										
8	Overall care skills (appropriate to the function)										
Total (I)											

II. For individual staff members

1. Senior Medical Officer (SMO) /Medical Officer (MO)		A.1 Self Review					A.2 Supervisor's Assessment				
S.No.	**Parameters (10)**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
1	Overall leadership / supervision of the medical and administrative functions of the centre (for MO-in the absence/unavailability of SMO)										
2	Team management skills – delegation of duties, cohesion of team members, conflict management, coordination of various functions of team members										
3	Implementation of and adherence to the national technical and operational guidelines on ART										
4	Clinical examination of patients, advise for diagnostics, proper prescriptions, and referrals to other departments										
5	Management of complicated clinical cases										
6	Ensuring the maintenance of accurate and updated records, and timely reporting to NACO/ SACS										
7	Monitoring the consumption of ARV/OI drugs, other medicines, CD4 kits and consumables and giving alerts to the concerned authorities										

8	Coordination / referral / linkage systems with SACS / CSC / Other agencies working in the field of HIV/AIDS										
9	Monitoring and mentoring the Link ART centres attached to the centre										
10	Referral of suspected treatment failure cases to SACEP										
Total (II)											

3. Staff Nurse		**A.1 Self Review**					**A.2 Supervisor's Assessment**				
S.No.	**Parameters (10)**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
1	Adherence to the national guidelines and protocols on ART										
2	Performance of baseline and nutritional assessment of the patients										
3	Assessment of PLHIV for advanced HIV disease										
4	Provision of need-based nursing care and support to the patients										
5	Triaging of PLHIV for patient centric care										
6	Coordination and tracking of referrals made within the hospital through linkages with other departments and inpatient wards										
7	Ensuring implementation of standard precautions, biomedical waste management and infection control measure in the centre										
8	Carrying out of activities related to HIV-TB care and coordination										
9	Updating and maintenance of the records and registers as per guidelines										
10	Multitasking as per requirement										
Total (II)											

4. Pharmacist		**A.1 Self Review**					**A.2 Supervisor's Assessment**				
S.No.	**Parameters (10)**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
1	Adherence to the national guidelines and protocols for good pharmacy practices										
2	Proper maintenance of the pharmacy										
3	Proper dispensing of ARV and OI drugs as per FEFO principle										
4	Drug adherence and treatment education skills										
5	Advice to patients about possible drug adverse effects										
6	Updating and maintenance of drug stock and dispensing records and IMS										
7	Informing the authority about low stocks, near expiry or excess stocks										
8	Coordination with NTEP for ATT and TPT										
9	Ensuring regular supply of ARV drugs to the attached LACs										
10	Multitasking as per requirement										
Total (II)											

5. Lab Technician		A.1 Self Review					A.2 Supervisor's Assessment				
S.No.	Parameters (8)	1	2	3	4	5	1	2	3	4	5
1	Adherence to the national guidelines and protocols related to laboratory services										
2	Collection of specimen for CD4 counts, testing at the Dept. of Microbiology and obtaining the reports (Transportation of samples to linked lab for testing and collection of reports, if CD4 not available)										
3	Assistance in the performance of VL testing										
4	Monitoring the stock of CD4 kits and consumables and updating the authority about excess/shortage										
5	Preparation and submission of monthly CD4 report to the ART centre										
6	Preparation of 'Due List' for CD4 testing and VL testing										
7	Maintenance of recording and reporting tools for laboratory										
8	Multitasking as per requirement										
Total (II)											

6. Data Manager		A.1 Self Review					A.2 Supervisor's Assessment				
S.No.	Parameters (8)	1	2	3	4	5	1	2	3	4	5
1	Updating and maintenance of the records and registers as per guidelines										
2	Entry of data in IMS										
3	Preparation and submission of monthly reports prescribed by NACO/ SACS										
4	Preparation and submission of cohort reports										
5	Data analysis and feedback on issues										
6	Maintenance of the accounts of ART centre										
7	Maintenance of HR file, communication file and attendance register										
8	Multitasking as per requirement										
Total (II)											

7. Care Coordinator		A.1 Self Review					A.2 Supervisor's Assessment				
S.No.	Parameters (6)	1	2	3	4	5	1	2	3	4	5
1	Assistance to PLHIV in OPD and IP including newly registered cases										
2	Performance of the role as peer educator										
3	Follow up of LFU/MIS cases over phone as per due list										
4	Coordination with linked CSC/LAC										
5	Dissemination of information to PLHIV on various benefit schemes of the govt./other										
6	Multitasking as per requirement or due to manpower shortage										
Total (II)											

	Calculation of Total Score	Self Review	Supervisor's Assessment
1	Average score of Total (I) i.e. sum total (I) divided by 8		
2	Average score of Total (II) i.e. sum total (II) divided by number of parameters (in brackets)		
Average score point (1 + 2) rounded off to nearest one number			

(Discuss with staff member, if there is major discrepancy between the scores)

B. Key to performance grading

1. Poor	2. Needs improvement	3. Satisfactory	4. Good	5. Excellent

C. PMDS supervisors

1. SMO/MO	-	1st Level: Nodal Officer	2nd Level: HoD, Medicine
2. Paramedical/Other Staff	-	1st Level: SMO/MO	2nd Level: Nodal Officer

D. Overall evaluation of team member's performance by first level supervisor

(to be completed by supervisor)

1. Overall assessment: may include attitude to work, competencies such as creativity and innovation, flexibility, problem solving abilities, team work, persistence towards achieving goals, interpersonal skills, communication skills, working relationship, facilitative roles in cross departmental and NGO/network coordination/collaboration, etc.

2. The overall performance of the team member (tick box)
   - ☐ 4) Exceeds expectations
   - ☐ 3) Meets all expectations
   - ☐ 2) Meets most expectations
   - ☐ 1) Falls below expectations

3. Recommendation for contract renewal / salary increment for team member as per NACO guidelines
   In view of the performance evaluation I have made above, I recommend
   - ☐ Granting of contract renewal / salary increment
   - ☐ Extension for three months for reasons stated above and a final review one month before the end of this period
   - ☐ Contract not renewed

Date: Supervisor's Name: Signature:

E. Second-level supervisor evaluation (HoD, Dept. of Medicine)

- ☐ I approve the recommendation of the first-level supervisor in Section E
- ☐ I disagree with the recommendation of the first-level supervisor in Section E

Comments/decisions: (additional pages may be attached)

Date: Supervisor's Name: Signature:

F. Staff member's comments (Only if assessment is below Grade – 3) (To be returned to first level supervisor within one week)

I have seen this performance evaluation (Tick appropriate box)

- ☐ I have no comments to add
- ☐ I have the following comments to add (additional pages may be attached)

Date: Name of staff:

Annexure 24
Undertaking by private medical colleges for operationalization of antiretroviral therapy (ART) centres

Certificate / Undertaking given by _____
_____(Name and address of the Private Medical College) in reference to National AIDS Control Organisation's letter no: _____ dated _____.

1. We undertake that our Institute namely _____agrees to abide by the Roles of Private Medical College as laid down in the above mentioned letter.
2. We certify that our Institute shall provide Infrastructure and Human Resource for ART Center as per the Operational Guidelines for ART services issued by NACO.
3. We certify that our Institute shall provide all health services related to provision of ART and treatment of opportunistic infection, free of cost to patients who require treatment.
4. We certify that all the rules and regulations would be followed and the prescribed documents will be maintained as per the Operational Guidelines for ART services.
5. We certify that our Institute is not engaged in any corrupt practice.
6. We undertake that the antiretroviral drugs (ARVs) made available by State AIDS Control Society under the National AIDS Control Programme for ART centres shall not be used for any purpose other than for People Living with HIV (PLHIV) registered in our ART center.
7. In-case of dispensing ARVs to PLHIV from other ART centre State/Country, the institute would seek approval on case to case basis from SACS/NACO.
8. Any violation of this shall be ground for unilateral discontinuation of ART centre by State AIDS Control Society with one-month notice.
9. We shall follow the provisions under HIV/AIDS Prevention and Control Act 2017 and on any ground, no PLHIV shall face stigma and discrimination at our institute.
10. We undertake that our Institute shall follow National AIDS Control Programme's "Guidelines on confidentiality of data of protected persons under HIV/AIDS Prevention and Control Act 2017.
11. We shall respect the autonomy and privacy of the patients, obtain written informed consent from the patients before initiating ART, and maintain confidentiality of the patients.
12. We shall regularly report to SACS/NACO in prescribed formats.

Signed & sealed for and on behalf of _____

Annexure 25
Memorandum of understanding for ART centres under public/ private partnership

Agreement between

State/District AIDS Control Society

&

_____ XXYYZZ (Name of the NGO/Private Sector Organization/PSU)

This Agreement is made on _____ day of _____(month)_____(year) between the Project Director of the _____ SACS/DACS _____ (address of SACS/DACS office) under the aegis of National AIDS Control Organisation(NACO), Ministry of Health and Family Welfare, Government of India (hereinafter referred to as "SACS").

AND

_____XXYYZZ (hereinafter referred to as "XYZ"), a Corporate Organization/NGO/PSU/ Private Hospital bearing registration number- and having its registered office at - acting through _____AABBCC, the authorised signatory, hereinafter referred to as "ABC", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assignees or legal representatives.

WHEREAS SACS is providing first line Antiretroviral Treatment (hereinafter referred to as ART) to People Living with HIV/AIDS (hereinafter referred to as PLHIV) in the state/district/union territory through designated public hospitals as per the guidelines issued by NACO from time to time;

AND WHEREAS SACS coordinates the aforementioned provision of ART at designated public hospitals by guiding the distribution and rational use of antiretroviral drugs;

AND WHEREAS SACS (under the aegis of NACO), desirous of extending the provision of ART to more PLHIV in collaboration with not-for-profit non-governmental organizations and other private sector organizations.

AND WHEREAS _____ XXYYZZ (hereinafter referred to as "XYZ"), is a NGO/ Corporate Organization/ Private Hospital registered under the Companies Registration Act/or is an PSU. It has established a centre to extend HIV/AIDS related treatment, care and other services to its employees living with HIV/AIDS and to extend these services to PLHIV in the nearby areas as a part of their corporate social responsibility;

AND WHEREAS the parties hereto had set up a collaborative ART project since _____ (month & year) and hereby reduce the terms of the agreement to writing.

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART SERVICES

The purpose of the present Agreement is to establish/continue the collaborative ART services between SACS (under the aegis of NACO) and XYZ that had been a model for high quality provision of ART and associated healthcare and medical management of PLHIV in _____ (Name of the site), India.

II. RESPONSIBILITIES OF SACS

1) SACS shall provide support for training/refresher trainings of personnel of XYZ involved in the collaborative ART services.
2) SACS shall share regular updates on National ART guidelines from time to time to the Nodal officers of XYZ

3) SACS and XYZ shall form a committee comprising of representatives from SACS, members designated by NACO, CEO / Director of XYZ/ Designated representative of XYZ, which shall supervise the provision of ART services.

4) SACS will provide ARV drugs for ART on receipt of a requisition/s from XYZ and certificate of utilization of drugs in the prescribed format.

5) Provide CD4 testing and Viral load testing for people living with HIV through linkages with existing laboratories under NACP.

III. RESPONSIBILITIES OF XYZ

1) XYZ had set up a centre at _____ (Name of the site) and has appointed (ABC)_____, as the official contact for the collaborative ART services.

2) XYZ represents that it provides various health services to PLHIV, a description of which is set out at Schedule III to the present Agreement.

3) XYZ undertakes that it will comply with all the laws in-force in India, at the time of signing the MoU, in operationalizing the PPP ART centre as done earlier. XYZ has obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.

4) XYZ strictly follows the National ART guidelines (drug regimens as well as physical standards) issued by NACO from time to time, follow the terms of reference for staff including qualifications as specified by NACO and has ensured that mechanisms needed for good treatment adherence are in place.

5) XYZ shall respect the autonomy and privacy of the patients, and obtain written informed consent from the patients before initiating ART treatment, and maintain confidentiality of the patients on the principle of shared confidentiality. Ensure compliances of provisions made in HIV/AIDS Prevention and Control Act-2017.

6) XYZ shall provide data protection systems to ensure that the confidential records of the patients are computerized and are protected so that they are not accessible to any unauthorized person.

7) XYZ shall provide a copy of all medical records to the patients on their request.

8) XYZ shall provide all health services related to the provision of ART and treatment of Opportunistic Infections (OI), including those listed in Schedule III, as per norms decided by the committee constituted by SACS and XYZ (Ref. II-3). The ARV drugs used for PLHIV will be supplied by NACO/SACS to (name of ART centre site). The ARVs will be provided free of cost to the patients and can charge subsidised rate for OI drugs and other routine investigations as per the decisions by the committee constituted by SACS and XYZ. XYZ shall not deny services to any person living with HIV on any ground.

9) PEP medicine should be provided free of cost in case of accidental exposure, as decided by the physician in-charge of the ART centre as per NACO ART Guidelines.

10) XYZ shall maintain all the registers and reporting formats as per NACO ART guidelines. They will send reports of all adverse drug reactions to NACO/SACS.

11) XYZ shall use standard NACO Monitoring and Evaluation tools.

12) XYZ shall provide standard, regular monthly reports of patient numbers and relevant details for the previous month to SACS by the 4th of each month in prescribed MPR formats in accordance with the guidelines laid down by NACO from time to time. NACO will be free to use the data sent to them in an anonymous manner.

13) XYZ shall follow National AIDS Control Programme's "Data Management Guidelines 2020" (for data collection, protection and sharing).

14) XYZ shall provide details of the ART team at their centre along with the names and technical qualifications, in case of any change, to SACS from time to time.

15) XYZ shall entirely bear the costs related to the staff's salary and the cost related to the infrastructure. XYZ represents that it has enough funds to run the programme for the next three / five years. XYZ will permit SACS to inspect its documents relating to the balance sheets, profit and loss accounts, grants and

donors, financial and other documents so that SACS can verify the representation of sustainability of the collaborative ART project.

16) The concerned SACS will provide ARV drugs for ART on receipt of a requisition/s from XYZ and certificate of utilization of drugs in the prescribed format.

17) XYZ shall make provision for CD4 and Viral Load sample transportation to the NACO designated labs. If the institute has own CD4/VL testing facilities, which can be utilized after approval from NACO/SACS.

18) XYZ has to establish a network with NGOs involved in HIV care and support as well as with the State Network of People Living with HIV/AIDS in the area for increasing access to treatment and for follow-up support.

19) The designated representatives of XYZ shall continue to attend the coordination meetings with SACS at their own cost.

20) XYZ shall not permit research or clinical trial, whether relating to the allopathic system of medicine or any alternate system of medicine or any combination thereof, at the designated ART centre, except with the approval of the Drugs Controller General of India(DCGI) for conducting such clinical trial. Further, in the event of an approved clinical trial, the XYZ will ensure that ethical protocols are complied with.

21) Use of any data obtained by XYZ during the course of its collaborative ART services shall be in an anonymous manner such that the identity of the patients enrolled at the collaborative ART services is not revealed in any manner.

22) XYZ shall maintain the records for a period of five years from the time that this Agreement is terminated or lapsed by efflux of time.

23) XYZ shall constitute a grievance redressal mechanism. [A model grievance redressal mechanism is annexed hereto at **Annexure 1**] Further, XYZ shall forward the nature of complaints received and action taken thereon to SACS/NACO in an anonymised manner, on a monthly basis.

24) XYZ shall continue to provide space and staff for the ART center.

IV. COMMENCEMENT

1) This Agreement shall become effective upon signature by both the Parties and It shall remain in full force from the last date of renewal till 31st March (year).

V. RENEWAL OF AGREEMENT

1) This Agreement is renewable based on the satisfactory performance of XYZ and with mutual understanding between SACS and XYZ, with intimation to NACO.

2) Six months prior to the expiry of the Agreement due to efflux of time SACS shall intimate XYZ if it intends to renew or not to renew the Agreement.

3) In the event that XYZ decides not to renew the Agreement, XYZ shall intimate SACS/NACO three months in advance about its inability to continue to provide treatment to the patients enrolled. If XYZ expresses its inability to do so, they shall give notice to the patients and SACS about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by SACS. Further, upon such referral, XYZ shall forthwith forward a copy of all medical records of the patients to SACS or a person designated by SACS to receive such medical records. Thereupon, SACS will be responsible for ensuring that the patients continue to receive the ARV drugs.

4) In the event that SACS, under the aegis of NACO, desires to renew the Agreement, the terms and conditions of this Agreement, as may be amended, will apply de novo. It is made expressly clear that in that event, XYZ will have to re-apply to SACS to continue the PPP ART centre and SACS shall take approval from NACO regarding the same.

5) Both parties shall ensure that there is no interruption in the treatment of the patients.

VI. TERMINATION OF AGREEMENT

1) The XYZ shall ensure that the infrastructure and manpower at centre is provided as per operational guidelines and in event of any deficiencies / reduction/withdrawal of space or staff, SACS, under the aegis of NACO, will exercise its option to terminate the agreement unilaterally.

2) Any party may terminate this Agreement without giving any reasons after giving three months' notice to the other party at the address provided in this Agreement for correspondence or the address last communicated for the purpose and acknowledged in writing by the other party.

3) On such notice of termination being received by any party, XYZ shall intimate SACS/NACO about its inability to continue to provide treatment to the patients enrolled. If XYZ cannot continue to provide treatment, they shall give notice to the patients and SACS about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by SACS. Further, upon such referral, XYZ shall forthwith forward a copy of all medical records of the patients to SACS or a person designated by SACS to receive such medical records. Thereupon, SACS will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY XYZ

1) In case XYZ is not able to provide services as per agreement or defaults on the provision of this Agreement or declines to provide medications to the patients or otherwise enters into any malpractices, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with SACS, NACO, MOHFW, Ministry of Home affairs and External Affairs. This action shall be intimated to their parent organization/International NGO/PSU also for necessary action by them.

2) If XYZ is found to have made any charges for the treatment which was to be given free of charge under this Agreement or to have not provided the medicines to the named patients or to have otherwise misappropriated the funds or goods released by NACO to XYZ, then without prejudice to any other right or consequence or mode of recovery, NACO/SACS may recover the amount thereof from XYZ and/or its office bearers as arrears of land revenue.

VIII. SETTLEMENT OF DISPUTES

1. Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this Agreement shall be referred to and settled by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.
2. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV/AIDS and care, support and treatment of PLHIV.
3. The place of arbitration shall be either SACS or the site of the collaborative ART services, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.
4. The decision of the arbitrator shall be final and binding on both the parties.

LAW APPLICABLE

This Agreement shall be construed and governed in accordance with the laws of India.

IX. ADRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed for and on behalf of XXYYZZ A Unit of XXYYZZ AABBCC ABC XXYYZZ Signature ..... Date ..... In the presence of Name and Signature ..... Date	Signed for and on behalf of Project Director, SACS/DACS Competent authority SACS/DACS Signature ..... Date ..... In the presence of Name and Signature ..... Date.....

[In case the contract is entered into by the _____, through the _____ these needs to comply with the Rules of Business laid down in this behalf.]

SCHEDULE I

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO/SACS TO XYZ (NACO/SACS shall provide first line ARV drugs to XYZ and other ARVs may be provided to XYZ on approval from SACS)

S. No	LIST OF ARV DRUGS
	Adults
1.	Tenofovir 300 mg+Lamivudine 300 mg+ Efavirenz 600 mg (FDC)
2.	Zidovudine300+Lamivudine150+Nevirapin200 (FDC)
3.	Dolutegravir 50mg
4.	Tenofovir 300 mg+Lamivudine 300 mg+ Dolutegravir 50mg (FDC)
5.	Zidovudine300mg+Lamivudine 150mg (FDC)
6.	Tenofovir 300 mg+Lamivudine 300 mg (FDC)
7.	Nevirapine tablet 200 mg
8.	Efavirenz 200 mg, 600 mg
9.	Lopinavir 400 mg/Ritonavir 100 mg (FDC)
10.	Atazanavir 300 mg/Ritonavir 100mg (FDC)
11	Darunavir 600mg (single tablet), Ritonavir 100mg (single tablets)
	Pediatric
11.	Tablet. Zidovudine 60+Lamivudine30 (FDC)
12.	Tablet. Zidovudine 60+Lamivudine30+Nevirapine 50 (FDC)
13.	Tablet. Abacavir 60+Lamivudine30
14.	Tablet. Efavirenz 200 mg
15.	Lopinavir/ ritonavir 100/25 tablet
16.	Lopinavir / ritonavir syrup(or pellets)
17.	Nevirapine tablets 50mg (dispersible)
18.	Nevirapine syrup 50mg/5ml

SCHEDULE II

MODEL FOR A ONE YEAR AGREEMENT

Year	ART centre	Number of PLHIV for whose treatment ARV drug stock is to be provided
2020-21		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPOSED TO BE PROVIDED

Address of site	XXYYZZ – Address
Outpatient	
Days	Monday to Saturday
Timings	08.30 am to 04.30 pm (As per hospital timings)
Inpatient care	
Number of patients registered	
Number of patients receiving ART	
Average number of patients attending OPD everyday	
Criteria followed in administering ARVs	As per NACO Guidelines
Treatment for OIs	As per NACO Guidelines
First line regimen	TLE/TLD/ZLN **(Other ARVs as per requirement)**
Description of follow-up of patients	As per NACO Guidelines
Facilities available	As per NACO Guidelines for ART center
Personnel and their qualifications	As per NACO Guidelines for ART center

ANNEXURE I

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the HIV/AIDS (Prevention & Control) Act 2017 and it would be advisable for XYZ to constitute a grievance redressal mechanism at the outset.]

(a) XYZ shall appoint a person of senior rank, working full time in the organisation, as the Complaints Officer, who shall, on a day-to-day basis, deal with complaints received from an aggrieved person or an authorised representative of such a person.

(b) Every aggrieved person or an authorised representative of such person, who has a grievance against the XYZ/or its staff, about the services provided or refused, has the right to approach the Complaints Officer to attend to such a complaint and shall be informed of such rights by XYZ.

(c) The Complaints Officer may inquire, suo motu or upon a complaint made by any aggrieved person or authorised representative of such person, into the complaint.

(d) The Complaints Officer shall act in an objective and independent manner when inquiring into the complaints made.

(e) The Complaints Officer shall inquire into and take action to redress the complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall try to take corrective action within one day.

(f) The Complaints Officer, if satisfied that there has been an unfair/arbitrary refusal of services or deficiency in the services provided, shall (i) first direct the staff of XYZ to rectify the cause of the grievance, (ii) then counsel the concerned person, alleged to have committed the act, and require such person to undergo sensitisation and training. Upon subsequent violations of similar nature, by the same person, the Complaints Officer shall recommend to XYZ to initiate disciplinary action against such person and, XYZ shall take the needed actions.

(g) The Complaints Officer shall inform the complainants of the action taken in relation to the complaint and reassure them that such a situation will not happen again.

Annexure 26
SOP for screening & triage PLHIV for COVID-19

1. All PLHIV visiting ART centre should be screened for COVID-19 symptoms and referred for testing based on MOHFW guidelines for COVID-19.
2. PLHIV should be encouraged to contact and inform ART centre staff in advance, if he/she is having any COVID-19 related symptom (e.g. cough, fever, shortness of breath etc) and planning to visit ART centres. ART MO should do a telephonic assessment of these PLHIV and suggest suspected case to visit the COVID -19 screening facility.
3. In case, patients turn up at ART centre, triage of patients with COVID-19 related symptoms should begin outside the ART centres. There should be clear signs displayed at the entrance of the ART centre directing patients with respiratory symptoms to immediately report to the COVID-19 screening facility.
4. Screening can be undertaken by a dedicated ART staff (based on a duty roaster) at triage before the entrance into ART centre. This staff should be trained on triage procedures, screening for COVID-19, and appropriate personal protective equipment (PPE) use.
5. If a PLHIV is found to be at risk of COVID-19 on screening, then he/she should be provided a mask and referred to the nearest COVID-19 screening centre. The ART centre should have a mapped list of COVID-19 screening centres for referral.
6. Those who are not found positive for COVID-19 but still have respiratory symptoms, should be screened for TB as per guidelines.
7. Social distancing norms should always be followed at ART for all PLHIV.
8. Visual alerts (IEC material) should be displayed at the entrance of the facility and in strategic areas (e.g., waiting areas) about respiratory hygiene and cough etiquette and social distancing.
9. The ART centre should follow the rules/policies of the parent hospital/institute/state where they are located, w.r.t. rotation policy for staff, quarantine of staff, etc.

Annexure 27
Summary of M & E tools

Tool	What information	Purpose of information	Frequency of data collection
Care and Treatment Records and Registers			
Patient Visit Register	Standardized and key information about each patient visiting the ART centre. To be maintained at ART centres	Optimize patient flow, information on TB screening and TB infection, pregnancy, record of OPD register and daily foot fall can be calculated.	On daily basis at the time of patient reporting to the ART centre
HIV Care Register	Standardized and systematic key variables of each patient at time of registration at ART centre to start of ART To be maintained at ART centres and LAC plus	Generate HIV care number; Capture baseline status, patient monitoring and follow up during preparedness phase; Monitor gap in ART initiation	At first visit (column 1-15); At start of ART (column 17); If ART delayed for > 15 days after enrolment then (Column 16)
Patient Treatment Card (White Card)	Standardized and systematic key variables of each patient registered in HIV care To be maintained at ART centres and LAC	Patient monitoring to report key variables of each patient; Programme monitoring	To be made at the time of patient registration in HIV care. To be updated at each visit
Patient Booklet (Green Book)	Patient details, treatment details and follow up clinical information including laboratory results (To be made at the time of registration) To be maintained at ART centres and LAC	Patient management to ensure appropriate lifelong follow up; patient empowerment and self-awareness; detailed clinical history that can be useful while interdepartmental referral.	During each visit to the centre (both routine and special visits)
ART Enrolment Register	Standardized and systematic key variables of each patient on ART care To be maintained at ART centres and LAC	Patient monitoring to report key variables of each patient	At ART initiation (Column no 1 to 10) (from the white card) Column no 11 and 12 in case of substitution or switch, column no 13 if ART discontinued and column no 14 if linked to LAC
Consent Form	To be maintained at ART centres and LAC plus	To inform the patient that treatment would be provided as per the national guidelines and the patient agreed to adhere to them and has been informed of possible adverse effects	-While registering the PLHIV in HIV care

Information Management System (IMS)	Web-based platform To be maintained at ART centres and LAC	Case-based recording and reporting system that captures each patient's demographic, clinical, laboratory and pill pick -up information in a longitudinal manner. It captures key variables of each patient longitudinally. Primary source of data is the white card.	To be updated during every visit
Master Line List	Key patient monitoring variables in excel based format To be maintained at ART centres and LAC	Monitor clinical, laboratory and pill pick -up information	Autogenerated from IMS (with longitudinal data points)
LFU Tracker Sheet	Line list of patients who are MIS and LFU To be maintained at ART centres	To track and follow up MIS/LFU & not initiated on ART	Autogenerated from IMS
PEP Register	Key demographic information and details about occupational exposure to HIV To be maintained at ART centres	To monitor the health care personnel exposed to HIV and provide treatment and list the modes of exposure	As per referrals
Death Register	Standardized systematic information about patients reported died To be maintained at ART centres	To monitor death rate and also monitor the LFU list	Autogenerated from IMS (details to be added to white card as and when a death is reported and entered into IMS)
HIV-TB Tools			
HIV-TB Line List	Line list of patients with presumptive TB	Ensuring fast tracking and monitoring of presumptive TB	Autogenerated from IMS. Soft copy to be maintained at ART centres and reviewed on monthly basis
HIV-TB Register	Register to capture TB treatment details	follow-up and monitoring of HIV-TB co-infected patients	HIV-TB register to be autogenerated from IMS. Nikshay register to be maintained in hard copy
TB Treatment Card	Standardized and systematic key variables of patients coinfected with TB	Demographic and clinical details of HIV- TB cases	To be made at the time of initiation of TB treatment. (To be updated at each visit)
LAC/LAC plus			
Monthly LAC Report (revised format)	Performance indicators for the reporting month	The reports is used for programme monitoring like retention, SCM and analyses of key outcome indicators	Auto-generated from IMS Every month

SACEP Tools			
Request and Reply Form	SACEP Referral and Reply form (kept at all ART centres and to be used for referring patients for SACEP review)		To be generated from IMS by ART centre when referring the patient. The reply portion to be sent back to referring centre by SACEP after the evaluation of the patient (Computer printed form only). The referring ART centre will then reply back to the CoE/pCoE/ART plus centre on the action taken on the SACEP's recommendations
SACEP Register	SACEP register (all patients being referred to SACEP should be entered)		• To be maintained at all ART centres and at SACEP of ART plus/CoE/pCoE/ ART centres. • To be autogenerated from IMS (Soft copy to be maintained)
SACEP Meeting Format	This format should be prepared before every SACEP meeting for all patients (children and adults) to be reviewed in that particular meeting for suspected treatment failure		- To be autogenerated from IMS (at CoE/pCoE & ART plus centre) - To be prepared before every SACEP meeting, given to all members during the meeting and maintained at all CoE / pCoE / ART plus centres (in file ring binder and soft copy)
Referral Summary	List of patients referred to SACEP for review during the financial year		To be autogenerated from IMS by financial year (to be linked with Line list of PLHIV with unsuppressed VL) To be maintained for all PLHIV referred to SACEP at all ART centres in one continuous excel sheet (soft copy only) for the financial year.
Stock Registers			
Antiretroviral Drug Stock Register (Common for Adult and Paediatric Drugs)	Stocks of each ARV drug	Programme monitoring: drug consumption and available stocks	To be autogenerated from IMS. Soft copy to be maintained
OI Drug Stock Register (Common for Adult and Paediatric Drugs)	Stocks of each OI drug	Programme monitoring: drug consumption and available stocks	To be autogenerated from IMS. Soft copy to be maintained
Antiretroviral Drug Dispensing register (Adult and Paediatric Patients)	Drugs and no. of tablets dispensed	Patient monitoring for accounting for no. of tablets dispensed	Integrated with IMS. (Physical copies to be discontinued after guidance from SACS)

OI Drug Dispensing Register (Common for Adult and Paediatric Patients)	Drugs and no. of tablets dispensed	Patient monitoring for accounting for no. of tablets dispensed	Integrated with IMS (Physical copies to be discontinued after guidance from SACS)
CD4 Kit and Consumable Stock Register	Stock of CD4 kits and consumables	To monitor the consumption and stock of CD4 kits and other consumables at the parent ART centre and linked centres	To be autogenerated from IMS. Soft copy to maintained. (Physical copies to be discontinued after guidance from SACS)
Fixed Asset Register	Details regarding all fixed assets available at ART centre	To track fixed assets quantity, condition, and maintenance records	Every time a fixed asset is purchased or provided to the centre
Expired Drug Disposal Register	Drugs and no. of tablets dispensed	Programme monitoring: quantity of drug expired	As and when expiry occurs
Referral forms			
ICTC to ART Referral Form (Common referral form may also be used)		To guide patients who are referred from ICTC to ART centre (to ensure linkage)	Every time a new HIV diagnosed person is referred to the ART centre
Transfers Out Form	Details of the patient being transferred out along with the details of the ART centre where the patient is going to register along with original copy of the white card	To ensure the patient reaches the new ART centre and referring centre is informed	Integrated with IMS. Patient to be given a printout of this form
AEB/PEP Notification and consent form	To record the details of the person exposed and the type of exposure	The form would help the PEP in-charge to take appropriate decision on PEP To record that the person has initiated PEP at his or her own will	Every time a person is exposed
Programme performance monitoring reports			
ART centre Monthly Progress Report	ART centre performance indicators for the reporting month	The report is used for programme monitoring like retention, SCM, HR and analysis of key outcome indicators	Every month
Private sector reporting format	To report patients being provided ART in the private sector (facilities not part of PPP model)	Gives information about access to treatment services and if further scale up of treatment services is required to achieve the 2nd 90	Quarterly

Annexure 28
Score card for monitoring of ART services

NACO has identified key indicators to gauge the performance of each ART centre and developed a score card to objectively assess the performance of each site and provide needed feedback to SACS. The indicators are selected based on actionable outcome, objectivity and relevance to asses core areas of treatment initiation, retention, suppression and data accuracy. The indicators could be revised considering change in programme priorities.

- Each indicator is assigned three colour codes (Red, Yellow and Green)
- The colour is determined based on the score achieved for the indicator based on its numerical value
- Any indicator in red requires an immediate action
- Score card is dynamic (scores may change for each indicator every quarter)
- Performance of ART centre (and in turn SACS) can be understood by number of indicators in red zone

Use of score card by SACS: NACO prepares the quarterly score for the state. SACS to disseminate the score card to all the ART centres in the state with a centre wise feedback and seeking action taken report in a fortnight. States must organize a review either a physical/virtual to share the feedback with the centres. State may prioritize site visits to the centres that scored low and support them to mitigate gaps. SACS to compare values of current and previous score card to understand change in performance or action taken.

Sl. No	Indiactor	Numerator	Denominator	Indicator Score		
Section 1] ART Care - New PLHIV (Financial Year) - (20)						
1	Proportion of PLHIV initiated on ART out of those who are registered in current FY	PLHIV initiated on ART	PLHIV registered in HIV Care during the current financial year (April - reporting month)	0 to 84.9%	85% to 96.9%	97% and above
2	Proportion of PLHIV who became LFU, MIS 2, MIS 3 and opted out, out of those initiated on ART in FY	PLHIV whose status is LFU, MIS 2, MIS 3 and opted out	PLHIV initiated on ART in the current financial year (April - reporting month)	6.1% and above	3.1% to 6%	0 to 3%
3	Proportion of PLHIV who died out of those initiated on ART in FY	PLHIV reported died	PLHIV nitiated on ART in the current financial year (April - reporting month)	5.1% and above	2.1% to 5%	0 to 2%
Section 2] Overall ART Care and Retention (25)						
4	Proportion of PLHIV on MMD (3 Months) out of alive on ART at the end of the reporting quarter	PLHIV on MMD (3 month dispensation) out of PLHIV on ART	PLHIV alive on ART	0 to 44.9%	45% to 59.9%	60% and above
5	Proportion of PLHIV on ART retained at the end of the reporting quarter	PLHIV on ART at the end of the reporting quarter.	PLHIV Alive on ART (excluding MIS 2 and MIS 3) at the end of the previous quarter; Plus PLHIV newly initiated on ART, tracked back and transferred in; and minus transferred out during the reporting quarter	0 to 96.9%	97% to 98.4%	98.5% and above
6	Proportion of PLHIV who are reported MIS 2, MIS 3, LFU and opted out during the reporting quarter.	PLHIV who are reported MIS 2, MIS 3, LFU and opted out during the reporting quarter.	PLHIV alive on ART (excluding MIS 2 and MIS 3) at the end of the previous quarter; Plus PLHIV newly initiated on ART, tracked back and transferred in; and minus transferred out during the reporting quarter	2.1% and above	1.1% to 2%	0 to 1%

Section 3] Viral load coverage and suppression (20)						
7	Proportion of PLHIV on ART with a VL result documented within the past 12 months out of those who have completed six month of ART at the end of the reporting quarter.	PLHIV on ART with a VL result documented within the past 12 months.	PLHIV alive and on ART eligible for VL testing (PLHIV those who have completed six-month on ART) at the end of the reporting quarter.	0 to 59.9%	60% to 79.9%	80% and above
8	Proportion of PLHIV on ART with suppressed Viral load (based on latest result) out of those with a VL result documented within the last 12 months.	PLHIV on ART with suppressed Viral load (based on latest result) within the last 12 months	PLHIV on ART with a VL result documented within the last 12 months.	0 to 89.9%	90% to 94%	95% and above
Section 4] HIV-TB prevention & care (15)						
9	Proportion of PLHIV tested for TB out of those identified as presumptive TB during the reporting quarter	PLHIV tested for TB	PLHIV identified as presumptive TB during the reporting quarter	0 to 94.9%	95% to 99.9%	100%
10	Proportion of PLHIV initiated on ART out of those diagnosed with TB during the current FY	PLHIV initiated on ART	Co-infected patients enrolled in HIV/TB register during the current financial year (April till reporting month)	0 to 84.9%	85% to 96.9%	97% and above
11	Proportion of PLHIV started TPT out of those eligible at the end of the reporting quarter.	PLHIV started TPT	PLHIV eligible for TPT at the end of the reporting quarter.	0 to 69.9%	70% to 84.9%	85% and above
12	Proportion of PLHIV completed TPT during the quarter	PLHIV completed TPT during the quarter	PLHIV started on TPT six months prior (two quarter back)	0 to 69.9%	70% to 84.9%	85% and above
Section 5] Second line and third line cascade (Viral load result utilisation) - (15)						
13	Proportion of PLHIV with unsupressed VL result (in the last quarter) undergone repeat VL testing by the end of the reporting quarter.	PLHIV with unsupressed VL result (in the last quarter) undergone repeat VL testing by the end of the reporting quarter.	PLHIV who were unsuppressed as per first VL test in last quarter.	0 to 89.9%	90% to 94.9%	95% and above
14	Proportion of PLHIV referred to SACEP, of those who are virally unsuppressed as per the repeat VL test during the reporting quarter	PLHIV referred to SACEP, of those who are virally unsuppressed as per the repeat VL test during the reporting quarter	"PLHIV who are virally unsuppressed as per the repeat VL test during the reporting quarter"	0 to 89.9%	90% to 94.9%	95% and above
15	Proportion of PLHIV switched to second line or third line of those recommended by SACEP during current FY	PLHIV switched to second line or third line, of those recommended by SACEP during current FY	PLHIV recommended for switch (second line or third line) after review by SACEP during the current FY (April – reporting month).	0 to 79.9%	80% to 94.9%	95% and above
Section 6] Data Quality (5)						
16	Proportion of mismatch between MPR and SOCH data	Variance between PLHIV on ART reported in SOCH and MPR	Total number of PLHIV alive & on ART as per SOCH	5.1% and above	0.1% to 5 %	0%
Total Score				0 to 59.9%	60% - 79.9 % (and scoring for >7 of the indicators should not be in red)	80% and above (and scoring for >3 indicators should not be red)

Annexure 29
Data quality assessment format

- Crosschecking (comparing) monthly reported results with patient records (white card) and IMS
  - Compare the total number of patients ever registered with the number in the HIV care register and IMS
  - Compare the total number of patients ever started on ART with the number in the enrolment register and IMS.
  - Compare total PLHIV initiated during the last quarter with the number in the ART enrolment register and IMS during last quarter
  - Select 20 patient records randomly from IMS based on ART enrolment number
- Review white card and IMS for completeness and updated entries
- Cross check the status of PLHIV (on ART, LFU, died, opted out, stopped treatment) with white card
- Cross check the important variables (ART regimen, last date of pill pick up, VL result adherence, address and phone number) with white card
- Review IMS and white card for completeness and updated entries

1.	**Ever registered in HIV care register**	**Ever registered in IMS**	**Difference**
2	**Ever started on ART in enrolment register**	**Ever started on ART in IMS**	**Difference**
3.	**PLHIV initiated during the last quarter as per ART enrolment register**	**PLHIV initiated during the last quarter as per IMS**	**Difference**
S. No	**HIV care No**	**Status in white card**	**Status in IMS**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
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16.			
17.			
18.			
19.			
20.			
	Total discrepancy between IMS and white card	No ..... & %.....	

Annexure 30
Quarterly reporting format for private sector hospitals/clinics providing ART services

Financial Year			**Name of Doctor**	
Reporting of Quarter			**Address of Clinic/Hospital**	
Date of submission			**District**	
Name of Clinic/Hospital			**State**	
Indicators	**Male**	**Female**	**TS/TG**	**Currently Pregnant Women**
A. No. of PLHIV * Alive ON-ART in the reporting period				
B. No. of patients underwent HIV viral load test among (A) during last one year*				
C. No. of patients virally suppressed # among (B)**				
*Include unique individuals only. Do not include repeat visit of same patient in reporting period;				
**Based on the last VL test done in last one year;				
# Virologic Suppression indicates a viral load of less than 1000 copies /ml after at least six months on ART				

Annexure 31
Activity calendar for ART centres

R- Responsible, A-Accountable, I-Informed, C-Contributes

Activities	Care coordinator	Counsellor	Nurse	Data Manager	Pharmacist	LT	SMO/ MO	Nodal Officer	SACS CST in charge
DAILY									
Phone calls to patients who are **not initiated on ART** - If there are no contraindications for rapid ART, call within 7 days of registration - If ART is deferred (for management of OI, Comorbidity etc.), call within 7 days after appropriate action taken/completed	R	R	C	C			A	I	
Phone calls to **on-ART patients** who have missed their appointments (within 48 hours of missing appointment)	R	R	C	C	C		A	I	
Telephonic follow-up of all PLHIV who are **newly initiated on ART in the last 3 months**		R		C			A		
Daily visits to hospital wards/ in patient departments to follow up with PLHIV for ART initiation before discharge		C	R				A	I	
Phone follow up PLHIV with unsuppressed VL		C		C		R	A	I	
e-Referral to SACEP of PLHIV with unsuppressed VL as per the repeat test (without waiting for patient to come)		C	C	R			R	A	I
WEEKLY									
Sharing of line list with CSC for follow up and home visits: - PLHIV not reached after 3 phone attempts or didn't agree to come; or - PLHIV didn't return within 7 days of due date/ mutually agreed date	C	C	C	R			A	I	
Arrange the cards systematically, once every week, preferably on Saturdays	R	R	C	R	C	C	A		

MONTHLY									
Meeting of the ART staff every first Saturday of the month	**C**	**C**	**C**	**C**	**C**		**R**	**A**	**I**
ART-CSC co-ordination meeting (Preferably 5th of every month)	**C**	**C**	**C**	**C**			**R/A**	**I**	
Validate outcomes reported by CSC in tracking format		**R**		**R**			**A**	**I**	
Participate in monthly DAPCU meetings (ICTC-ART, LAC-ART coordination)		**C**	**C**	**C**			**R/A**	**I**	
HIV-TB co-ordination meetings to ensure smooth implementation of HIV-TB Initiatives		**C**	**R**	**C**			**A**	**I**	
Submission of MPR to SACS (by 4th of every month)		**C**	**C**	**R**	**C**		**R**	**A**	**I**
QUARTERLY									
Physical verification of the stock of all ARV Drugs and cross check with MPR (last day of every quarter)					**C**		**R**	**A**	**I**
Data verification (first Saturday of every quarter)	**C**	**C**	**C**	**C**	**C**		**R**	**A**	**I**
Drug transfer to LAC as per requirement				**C**	**R**		**A**	**I**	
Participation in SACS quarterly review meeting		**C**	**C**	**C**	**C**	**C**	**R**	**A**	

Notes:

1) All the above-mentioned activities are to be performed with support of all ART centre staff. ARTC staff must function as a TEAM.
2) The activities specified in the table above are in addition to the routine patient care and management which is done every day at the ART centre.
3) LAC coordination may also be included in DAPCU meetings. In districts where DAPCUs don't exist, separate meetings may be conducted
4) SACS officials/ RC/TE to ensure that ART activity calendars are followed

Annexure 32
ART supervisory and mentoring visit format

Supervisory visit to the ART centre should be taken up by the JD(CST)/DD(CST)/AD (CST)/In charge (CST)/ Regional Coordinator/ Technical Expert (CST) of the TSU. All the ART centres in the state should be visited at least once a quarter. The CST personnel at the SACS and the Regional Coordinator/ TE should share the tour plan to prevent duplication of visits. Any centre having issue in providing ART services should be visited on priority either by the CST in charge or the RC/TE. Below is the guidance for completing **supervisory and mentoring visit format**

For completing the Summary Recommendations form, please list and describe the problem precisely under the following heads:

A. Infrastructure and institutional commitment

B. HR and training

C. Service delivery

D. Coordination and Linkage

E. Laboratory and radiological services

F. HIV-TB coinfection

G. Drug stock management

H. Tracking activities

I. Recording and reporting

J. Data quality

K. Patient feedback (based on interaction/exit interview with the patients)

- Based on the problems identified and action plan (Section2) should be prepared in consultation with the staff.
- Implement the solutions immediately, whenever possible.
- Gaps that require nodal officer's intervention should be discussed and followed up after the visit.
- Before leaving the centre, explain to the nodal officer any problems you found and solutions you implemented. If you need help in solving a problem, discuss it with the officers / authority concerned.
- In the last column write the name or designation of the person who will be responsible for implementing the recommendations at the ART centre. Remember to leave a copy/ or send a copy of the recommendations with the nodal officer.
- Please refer to Section 18 for details

ART Supportive Supervision Visit Format

Name of ART centre: _____

Date of visit _____

Name of Supervisor: _____

Name of ART centre in charge: _____

Section I: Observations

A. Infrastructure and institutional commitment			Remarks
1) Is the centre having adequate space and infrastructure?	Yes	No	
2) Are there proper signages (visible and regional language) placed for the patients directing towards ART centre without any difficulty?	Yes	No	
3) Is drinking water and toilet facility available for both the ART staff and patients ?	Yes	No	
4) Is the centre having TV/ Computers/ Printers/ Phone/ Internet connection (all should be available)?	Yes	No	
5) Is there display of IEC materials including details of the nearby ART centres and Link ART centres?	Yes	No	
6) Is complaint box installed in the waiting area of ART centre so that it is visible and accessible to PLHIV?	Yes	No	
7) Is condom box available in the waiting area of ART centre so that it is visible and accessible to PLHIV?	Yes	No	
8) Has the centre sensitized the hospital staff on activities of the ART centre?	Yes	No	
9) Are PEP drugs for emergency use available at casualty, labour room, OT?	Yes	No	
10) Is ART team in place, trained and conducting meeting?	Yes	No	
11) Is the Nodal officer actively involved in the day to day activities of the ART centre?	Yes	No	
12) Is the ART centre integrated with the Department of Medicine and any PGs and Interns are posted from the Medicine department?	Yes	No	
13) Is there coordination between the ART centre and the other departments of the hospital?	Yes	No	
14) Is the institution providing laboratory/radiological investigations free of cost to all PLHIV?	Yes	No	
15) Are there any difficulties faced by the PLHIV for admission and surgeries in the hospital OPD or the IPD?	Yes	No	
16) Does the ART centre use the score card and knows about the indicators for which the performance is not optimal ?			
HR and Training			
17) Is the ART centre having staff as per NACO guidelines (SMO/ MO/ Staff Nurse/ Counsellors /Lab Technician/ Pharmacist/ Data Manger/ Community care coordinator)?	Yes	No	
18) Are the ART centre staff trained as per NACO guidelines (Hands on Training/Induction training/refresher training)?	Yes	No	
Service Delivery			
19) Is the centre following triage of patients (new registration, stable, unstable, patients with respiratory symptoms)?	Yes	No	

20) Are counsellors counselling the patients on adherence and recording pill count. Are patients with less adherence counselled and provided option for identified barriers to adherence?	Yes	No	
21) Are all PLHIV put on ART without any delay as per the NACO guidelines?	Yes	No	
22) Are baseline investigation and follow up investigations being done as per guidelines (check from white cards)?	Yes	No	
23) Are all eligible patients initiated on Cotrimoxazole prophylaxis?	Yes	No	
24) Is base line and follow up CD4 test being done as per guidelines?	Yes	No	
25) Are all PLHIV referred for viral load testing as scheduled (for PLHIV on first/ second/third line ART)?	Yes	No	
26) Is the centre following DSDM model for flow of patients (mention types of DSDM models functional at ART centre)?	Yes	No	
27) Are stable PLHIV receiving MMD. What proportion of PLHIV alive on ART are receiving MMD?	Yes	No	
28) Are LACs timely referring patients for CD4/Viral Load testing as per NACO guidelines?	Yes	No	
29) Are all the patients with unsuppressed viral load provided repeat VL test after step up counselling?	Yes	No	
30) Are all the patients with repeat unsuppressed viral load referred for SACEP?	Yes	No	
31) Are all the patients recommended for II or III line ART by SACEP switched to recommended regimen ART without any delay?	Yes	No	
Coordination and Linkages			
32) Is there coordination between the ART centre and NTEP sites and monthly meetings done regularly?	Yes	No	
33) Is the centre participating in DAPCU meeting for coordination between the ART centre and ICTC/PPTCT services?	Yes	No	
34) Is the centre having regular coordination meeting with CSC and LAC?	Yes	No	
Laboratory and Radiological Services			
35) Is the centre having CD4 machine/linkage to CD4 site and CD4 tests / collection done daily?	Yes	No	
36) Is the centre having linkage to viral load laboratory and is timely receiving the viral load test reports?	Yes	No	
37) Is there any issue about laboratory or radiological investigation (Queue management, delayed appointment, PAP smear testing)?	Yes	No	
HIV TB coinfection			
38) Is 4S screening done for all the patients visiting the ART centre (3 Stage 4S Screening being followed and recorded properly) and details are recorded in patient visit register and white card?	Yes	No	
39) Is there coordination between the ART centre and NTEP sites, in relation to referral and linkages for 4S positive, NAAT testing, reporting, TB diagnosis and ATT initiation (Check HIV-TB line list for referral)?	Yes	No	
40) Are eligible PLHIV initiated on TB Preventive therapy?	Yes	No	
41) Are TB co-infected PLHIV timely initiated on CPT, ATT and ART?	Yes	No	

42)	Is the ART centre co-located with DMC/ CBNAAT site for TB referrals or the specimens being transported to the linked site?	Yes	No	
43)	Is the centre having/maintaining complete HIV-TB line list and HIV-TB register?	Yes	No	
44)	Are there enough stock of INH and TB drugs?	Yes	No	
Drug stock management				
45)	Is the centre having enough stock of Cotrimoxazole tablets?	Yes	No	
46)	Is the centre having enough stock of all ARV drugs?	Yes	No	
47)	Is the centre following FEFO principle while stocking and dispensation?	Yes	No	
48)	Was there any Drug expiry in the past 3 months?	Yes	No	
49)	Is the regimen wise consumption matching with the no. of patients on ART?	Yes	No	
50)	Is the Drug stock register updated?	Yes	No	
51)	Are the drug stocks matching after verification of the physical stock with the drug stock register?	Yes	No	
52)	Is the drug dispensing register maintained and updated?	Yes	No	
53)	Is the centre using IMS and doing daily entries of dispensation in IMS?	Yes	No	
Tracking activities				
54)	Are PLHIV with missed appointment followed up telephonically within 48 hours?	Yes	No	
55)	Is the centre linked to CSC and is sharing the MIS/LFU list?			
56)	Are lists of not initiated on ART, newly initiated on ART and poor adherence being shared by ART centre with the CSC for provision of services and retention improvement?	Yes	No	
57)	Is the discussion about lists (as mentioned above) happening in monthly ART CSC coordination meetings and retention improvement observed?	Yes	No	
58)	Are the ART CSC coordination meetings conducted and the ART centre receives the report from the CSCs in the standard format?	Yes	No	
59)	Is the centre following the NACO guidelines to identify ART failures and referring all patient with failures in correct format and along with all the required investigations?	Yes	No	
Recording and Reporting				
60)	Is green book issued to all the patients both Pre ART and on ART?	Yes	No	
61)	Are white cards complete for all the patients registered at the centre (Pick 20 cards at random and verify for completeness of white card)?	Yes	No	
62)	Are all the records maintained, updated and properly stored (check all registers, particularly HIV care and ART enrolment register)?	Yes	No	
63)	Is confidentiality of the records maintained?	Yes	No	
64)	Is the centre using IMS and patient details recorded in IMS/ MLL daily?	Yes	No	
65)	Are the LACs using IMS and details of PLHIV at LACs recorded in IMS daily?	Yes	No	
66)	Is the daily due list available and followed up?	Yes	No	

67) Is the CD4 and VL due list available and followed up?	Yes	No	
68) Is the list of PLHIV with unsuppressed Viral load available and followed up?	Yes	No	
Data Quality			

- Crosschecking (comparing) monthly reported results with patient records (white card) and IMS
  - Compare the total number of patients ever registered with the number in the HIV care register and IMS
  - Compare the total number of patients ever started on ART with the number in the enrolment register and IMS.
  - Compare total PLHIV initiated during the last quarter with the number in the ART enrolment register and IMS during last quarter
  - Select 20 patient records randomly from IMS based on ART enrolment number
- Review white card and IMS for completeness and updated entries
- Cross check the status of PLHIV (on ART, LFU, died, opted out, stopped treatment) with white card
- Cross check the important variables (ART regimen, last date of pill pick up, VL result adherence, address and phone number) with white card
- Review IMS and white card for completeness and updated entries

1.	Ever registered in HIV care register	Ever registered in IMS	Difference
2	Ever started on ART in enrolment register	Ever started on ART in IMS	Difference
3.	PLHIV initiated during the last quarter as per ART enrolment register	PLHIV initiated during the last quarter as per IMS	Difference
S. No	**HIV care No**	**Status in white card**	**Status in IMS**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
	Total discrepancy between IMS and white card	No ..... & %	

Exit Interview: The Supervisor who visits the ART centre should interact with the patients and try to understand the following from the patients:				
1) Is sitting arrangements for the patients in the waiting area appropriate?	Yes	No		
2) Did you face any problem in getting registered/services at the ART centre? (Check for problems specific to ART services) *(If yes, explain in remarks column)*	Yes	No		
3) Did you feel comfortable while talking to staff at ART centre (counsellor/staff was empathetic, attentive to your problems)	Yes	No		
4) Do you meet the counsellor on each visit?	Yes	No		
5) Do you meet the doctor on each visit?	Yes	No		
6) Do you know how long you will need to continue with the ART? *Lifelong=yes; Any other/Don't know=No)*	Yes	No		
7) Are you aware of common adverse effects of the ART and what to do if you have adverse effects?	Yes	No		
8) What do you know about the importance of taking regular ART? *Have been advised not to miss even a single dose=yes; Not advised/do not know or understand the importance=no*	Yes	No		
9) During every refill does the counsellor count the number of pills that you carry.	Yes	No		
10) Do you know about your next date of visit to ART centre?	Yes	No		
11) Do you know the importance of suppressed VL?	Yes	No		
12) Were you screened for cough symptoms?	Yes	No		
13) Are you availing any social welfare schemes? *If no, reason*	Yes	No		
14) Did you feel that staff treated you with dignity and was supportive and helpful	Yes	No		
15) Were you comfortable in asking your questions with ART staff				
16) Have you ever faced problems in accessing services from the ART centre? If yes, specify *(Related to stigma and discrimination; Not related to stigma discrimination)*	Yes	No		
17) Have you ever been charged for routine tests pertaining to ART services at this centre?	Yes	No		
18) Have you been prescribed ARV drug/s from outside by the ART staff?	Yes	No		
19) Have you been prescribed drugs for OIs from outside by the ART staff?	Yes	No		
20) Have you been ever asked to go to a private clinic for ART by an ART staff member?	Yes	No		
21) Check the green book for completeness	Yes	No		
22) Do you have any suggestion for us				

Key observations:

Domain	Observations
Infrastructure and institutional commitment	
HR and Training	
Service Delivery	
Coordination and Linkage	
Laboratory and radiological Services	
HIV-TB coinfection	
Drug stock management	

Tracking activities	
Recording and Reporting	
Data quality	
Patient feedback	

Section II: Action Plan

Gaps/ issues identified	Root causes	Interventions to address the root causes	Indicator (process/ outcome)	Monitoring frequency (daily/ weekly/ monthly)	Expected outcome	Timeline	Responsible person	Expected outcome met*	Remarks
								Date..... Yes ☐ No ☐	

Date: ..... Signature and Name.....

* expected outcomes to be assessed during follow-ups with the sites

Annexure 33
Format for quarterly physical verification of ARV drugs

Name of the ART centre .....

Date .....

Name of the drugs	Stock as per Drug stock register/IMS	Stock available (as per physical count)	Stock available at LACs	Discrepancy	Reason
A	B	C	D	E=B-(C+D)	
TLD					
DTG					
AL					

Signature of the Nodal Officer .....

Annexure 34
List of drugs commonly required for prophylaxis/prevention and management of OI Infections

Drugs to be supplied by the facility where ART centre is located	Drugs to be procured by SACS/ART centre as per requirement (if not available in institution)
Tab Metronidazole 400mg	Tab Nitazoxanide 500 mg
Tab Albendazole 400 mg	Tab Flucytosine 500 mg
Tab Ciprofloxacin 500mg	Tab Valganciclovir 450 mg
Tab Prednisolone 10 mg	Inj. Gancyclovir 500mg
Tab TMP-SMX DS 160/800mg*	Cap. Gancyclovir 250 mg
Tab Azithromycin 500mg	Tab Itraconazole 200mg
Tab Fluconazole 150 mg	Tab Clarithromycin 500mg
Cap. Amoxyclav 625 mg	Tab Fluconazole 400mg
Other common drugs like Paracetamol, Disprin, Anti-allergic, Anti-diarrhoel, Antacids, etc.	Clotrimazole ointment
	Tab Clindamycin 300 mg
	Tab Sulfadiazine 500 mg
	Inj. Amphotericin B deoxycholate 50 mg/ Inj. Liposomal amphotericin B 50mg
	Tab Acyclovir 400mg
	Tab Levofloxacin 500mg
	Injection Cefotaxime 500mg/1gm

*In case not available with facility in sufficient quantity, SACS may procure. However, adequate efforts should be made to get this drug through facility/health system

Note: TPT and ATT drugs to be provided by NTEP

Annexure 35
List of Items that can be procured under standard precautions (universal work precautions)

(as per requirement/patient load and if not available through health facility)

1) Disposable gloves
2) Disposable laboratory gowns
3) Disposable apron
4) Disposable face mask
5) Disposable caps
6) Shoe covers
7) Rubber boots
8) Hand rub/ disinfectant solution for hand wash
9) Needle destroyer
10) Sharp disposal containers
11) 1% Sodium hypochlorite (5 litres canister of 4-5%)
12) 10% Sodium hypochlorite (5 litres canister of 40% solution)
13) Spirit/70% alcohol
14) Cotton
15) Tissue paper rolls
16) Cloth aprons/ coats
17) Colour coded waste disposal bags
18) Colour coded waste disposal bins
19) Biohazard labels
20) Band aids
21) Needles/syringes
22) Rubber gloves for dirty washing and waste handling
23) Measuring cylinder glass 1 litre
24) Covered discard jars/discard buckets with lid
25) Any other item with prior approval of NACO/SACS

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India's Voice Against HIV

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