Government of India
Ministry of Health & Family Welfare
National AIDS Control Organization

Operational Guidelines for ART Centers

March 2007

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FOREWORD

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Foreword

The Government of India launched free ART initiative on 1st April, 2004 at eight government hospitals in six high prevalence states. Since then, this is being scaled up in a phased manner and presently we have 107 ART Centres providing free ART to 60,000 PLHA's across the country. The aim is to provide ARV to 300,000 patients through 250 ART Centres by 2010.

The experience in the scale up of ART over last 3 years has posed several challenges in implementing the program particularly with respect to continuous supply of ARV drugs, infrastructure at ART Centres and quality of care being offered to the patients. One of the most challenging areas in providing ART is ensuring very high levels of adherence to therapy in order to avoid drug resistance. In the evaluation carried out last year, it was observed that there are a number of operational problems at ART Centres & these vary from state to state. These operational guidelines for ART Centres are to ensure uniformity in the patient care across the country as well as to guide the centres on various administrative, financial and operational issues, so that the quality of services offered to patients is in accordance with the laid down protocols.

The guidelines describe the functions of the ART Centres, facilities required in terms of physical infrastructure, general and medical equipments, human resources and linkages & referrals from and to the centre. The roles and responsibilities of different categories of health care providers have been clearly spelt out. The mechanism for maintenance of drugs and patients records and M&E tools have been given in detail. The guidelines also specify issues related to financial management including audit and expenditure. The guidelines also describe the flow of the patient from first visit to the hospital for diagnosis, provisioning of ART and regular follow up.

I would like to acknowledge the contributions made by in-charges of different ART Centres and PDs of different States implementing ART. I would also like to acknowledge the work done by Dr. D. Bachani, Joint Director, NACO, Dr. B.B. Rewari, National Program Officer (ART) and inputs by WHO field Consultants on ART. I hope the guidelines would be able to standardise the treatment at ART Centres and help in better care for PLHAs. It is hoped that these guidelines will assist all concerned in further streamlining the services at ART Centres as centres providing excellent and high quality care.

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1 Introduction

India has an estimated 5.2 million HIV-infected people. The free ART initiative of the Government of India was launched on 1st April, 2004 at eight institutions in six high prevalent states and the National Capital Territory of Delhi. Since then, it is being scaled up in a phased manner. By December 2006, a total of 107 ART centers in 31 States and Union Territories are functional. More than 56,000 patients are receiving free antiretroviral (ARV) drugs at these centers. In addition another 10,000 patients are receiving free ART at NGO/inter-sectoral ART centers. It is expected that about 100,000 patients will be put on the free ART programme by end 2007 and 300,000 patients will be on free ART at 250 ART centers under NACP-III.

The plan to expand and scale up ART services in India includes

a) Identification of the institutions

b) Strengthening of laboratory infrastructure in the form of CD4 machine (or linkages)

c) Capacity building of faculty of the host institute, including the contractual staff by training on ART

d) Procurement of ARV and OI drugs.

As we are expanding the access to ART rapidly, it is very important to raise the standards of care and programme management to ensure that ART is carried out efficiently and that it is well documented and coordinated. There is therefore a need for establishing and maintaining a well set up and run national ART monitoring and surveillance (M & E) system that will provide accurate data and also assist in supervision of the programme. Efforts to prevent or delay drug resistance have to be optimised as only first line ARV are available in the national programme and second line drugs are ten times costlier than the first line.

India has the capacity to scale up ART with advantages that many other countries do not have. These include having an established domestic drug manufacturing base and the enviable pool of trained health professionals. However, the unprecedented challenges for programme management and service delivery must be candidly identified, and addressed in a systematic manner.

A public health approach for the provision of ART implies that ART regimens should be standardised, easy to use and have minimal adverse affects. Scaling up ARV treatment also calls for early involvement of a range of stake-holders, including those with HIV and other community members.

Selection of first line regimen is determined on the basis of a number of considerations such as potency, profile of side-effects, ability to keep future treatment options open, ease of adherence, risks during pregnancy and the potential for developing resistant viral strains. The current recommendation in all circumstances is for a triple drug regimen.

It is desirable to have certain specific services, facilities and protocols in place before starting ART. These are necessary due to the complexity of accessing and continuing the therapy, the need for close clinical and laboratory monitoring and the cost of therapy. These services include:

1. Easy access to an ART center, ideally located in the medical OPD of the hospital with adequate space and privacy for examination, counselling and group therapy and with medical and general equipment necessary to carry out best practices
2. Medical services with trained physicians and other health care personnel capable of identifying and treating common HIV-related illnesses and OIs as well as effective OI prophylaxis

3. Care and support services to provide treatment adherence counselling and psychosocial support to PLHA and their families. These services should ideally involve trained health care providers, people living with HIV/AIDS and community based care organisations.
4. Reliable laboratory services capable of performing routine laboratory investigations such as HIV antibody testing, pregnancy testing, complete blood count and serum bio-chemical tests. Access to a laboratory capable of performing CD4 count which is essential to monitor therapy.
5. Reliable and affordable access to quality antiretroviral drugs, and drugs to prevent and treat OIs and other related illnesses.

SECTION

2 Guidelines for Service Providers

These guidelines focus on the objectives, criteria for selection, required infrastructure, equipment, supplies and human resources, monitoring tools and financial guidelines for an ART center. These will provide directions for setting up new ART centers and guide the existing ones to effective implementation of services.

2.1 The Goal and Objectives of NACP

2.1.1 Goal

The goal of NACP III is to **halt and reverse** the epidemic in India over the next 5 years by integrating programmes for prevention and care, support & treatment. To achieve this goal , NACP III will pursue four main objectives:

2.1.2 Objectives

1. Prevention of new infections in high risk groups and general population through:
   a. Saturation of coverage of high risk groups with targeted interventions (TIs)
   b. Scaled up interventions in the general population
2. Increasing the proportion of people living with HIV/AIDS who receive care, support and treatment
3. Strengthening the infrastructure, systems and human resources in prevention and treatment programmes at the district, state and national levels.

2.1.3 Objectives of ART centers

Keeping the above in mind, the **main objective** of Anti-retroviral Therapy (ART) is to provide comprehensive services to eligible persons with HIV/AIDS. The **specific objectives** of an ART center are to:

i. Identify eligible persons with HIV/AIDS requiring ART through laboratory services (HIV testing, CD4 Count and other required investigations)

ii. Provide free ARV drugs to eligible persons with HIV/AIDS continuously

iii. Provide counselling services before and during treatment for ensuring drug adherence

iv. Educate persons and escorts on nutritional requirements, hygiene and measures to prevent transmission of infection

v. Refer patients requiring specialised services or admission.

vi. Provide comprehensive package of services including condoms and prevention education

2.2 Functions of ART center:

PLHA should be given holistic care at ART centers. This is possible only if the team is committed and has a comprehensive understanding of the problem and care. Functions of ART center can be categorised as medical, psychological and social as indicated below

2.2.1 Medical Functions

- To diagnose and treat Opportunistic Infections
- To screen PLHA for eligibility to initiate ART
- To monitor patients on ART and manage side-effects, if any
- To provide in-patient care as and when required.

- To facilitate linkages between other service providers
- To facilitate easy access to specialist's care as necessary.

2.2.2 Psychological Functions

- To provide psychological support to PLHA accessing the ART center
- To provide counselling for adherence to ARV drugs
- To educate PLHA on proper nutrition
- To advise for risk reduction behaviour including usage of condoms

2.2.3 Social Functions

- To facilitate PLHA to access available resources provided by government and NGO agencies
- To facilitate linkages between other service providers and patients, like educational help for the children and Income generation programmes

2.3 Eligibility Criteria for Setting-up ART center

The following criteria would be used to set-up ART centers in Government Sector, Public Sector Undertakings and Non-government organisations:

i. Prevalence of HIV infection in the State/ District (preference given to category "A' & 'B' districts) and estimated number of persons with HIV/AIDS

ii. Availability of existing ART services in the State/Region/District

iii. Services provided and human resources available in critical departments in the hospital (Medicine, Microbiology, Obstetrics & Gynaecology, Paediatrics, Dermatology / Venereology)

iv. Availability of adequate space for setting up ART center within the hospital area

v. Willingness to assign minimum one faculty from Departments of Medicine and Microbiology to support ART center on a daily basis

vi. Agreeing to follow NACP technical and operational guidelines prescribed by GOI

vii. Commitment to regularly furnish information on facilities, services and outcomes in prescribed formats to SACS and NACO

2.3.1 Feasibility Assessment for ART centers

A feasibility assessment team comprising of officers from NACO, SACS and independent referees/ consultants would visit identified sites before sanctions are issued for setting up new ART centers. The team would assess feasibility of starting the ART center on the basis of check-list on parameters given in para 2.3 above

2.4 Preparedness of Institution

Once an ART center has been sanctioned for a hospital, a team of 10 members consisting of faculty members from the Departments of Medicine, Paediatrics, Obstetrics & Gynaecology and Dermatology (and/or Venereology) is selected by the hospital and deputed for a 4-day training at one of the NACO identified ART training centers. The team is to be headed by the inchrage of ART center who is the Head of Department (HoD) of Medicine, or a senior faculty of the same department appointed by the HoD ad the Nodal Officer. This is followed up by training of all faculty members of the Department of Medicine and Paediatrics. Medical Officers and other contractual staff appointed to the ART center will also undergo job-oriented training at NACO identified ART training institutes.

2.5 Infrastructure

2. 5.1 Location and Access to ART Center

The ART center should be located ideally in the Medicine OPD. If this is not feasible, the hospital in consultation with the SACS should choose a place within the same campus which is accessible to patients and keeping in mind cross-referral to and from various departments. Signs depicting directions to the ART center should be clearly placed by the institution at strategic locations so that there is no difficulty in locating the center within the hospital. The boards for such marking may be created and

put in place by the institution concerned or by the SACS for uniformity within a state.

2.5.2 Space for ART Center

A minimum of 800 sq. ft. area is required for an ART center having on average 500 patients (i.e. 20/day) on roll. It should have adequate number of rooms each measuring at least ten feet by ten feet (10' x 10') for the following staff/services listed below:

a. Examination Room: for Medical Officers to examine the patients

b. Counselling Room: For individual, group and family counselling

c. Pharmacy: For stocking 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. There should also be a separate facility in the same room for storage of paediatric ARV preparations

d. Laboratory: For collection and storage of samples and carrying out tests by the lab. technician

e. Office Space: for registration, record keeping and data entry by Record Keeper cum Computer Operator (Data Manager)

f. Waiting Area: This should be of adequate area where patients and accompanying persons can wait and where group therapy/ counselling could also be conducted. Television and other audio-visual facilities may be installed here for educational purposes

g. Adequate space should be individually identified and provided for different ART centers taking into consideration the need of the particular center. As NGO and peer support at the center itself has proved to be an asset to patients and to the hospital, space should also be provided for volunteers from these organisations

In case the institution does not have enough constructed area for ART Centre, but have vacant space, they will send a proposal to NACO for building an ART Centre with adequate space and facilities like waiting space, drinking water and toilet facilities.

The ART center should be kept neat and tidy and should maintain the 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.

2.5.3 Furniture and general equipment

The ART center should be furnished adequately but must have the following:

a. Tables, chairs and stools for staff and patients

b. Examination Table with curtains

c. Office shelves for supplies, records and stationery etc.

d. Appropriate furniture for computer and printer and office stationery

e. Secure Cupboards for storing patient records, ARV and other medicines, laboratory kits, consumables and other equipment. These cupboards should have locks to prevent theft of material and data

f. Drinking water and waste disposal systems

These items can be procured from the contingency grant provided for the ART center.

2.5.4 Medical equipment and Accessories

A set of general medical equipment like a weighing balance, height measurement pole, blood pressure (BP) apparatus, stethoscope, ophthalmoscope, otoscope, torch or another suitable light source and knee hammer should be available for each medical officer at the ART center. These items may procured by the SACS. In addition, models and charts, demonstration and counselling aids, such as a penis model for condoms and pill boxes should also be made available at the center.

2.5.5 CD 4 machines

Each ART center should have access to CD4 tests either directly or by a clear linkage mechanism for conducting regular uninterrupted CD4 counts at a designated center. The center must follow the instructions on collection and transport of samples (and not patients) from testing site to the identified site where the test is to be conducted. The reagents and other consumables needed for CD4 test would be procured by NACO and supplied to the centers. The machines should be utilised optimally to ensure that there is minimal waiting period for CD4 test.

All those patients who are screened for ART or are on ART will have their CD4 count done free of cost to a maximum of two tests per year unless desired more frequently by the clinician. But if a patient desires to get it done more than twice a year, he shall have to pay Rs. 250 per additional test.

2.5.6 Computers and Audio –Visual Equipemnt

All ART centers are provided funds for procurement of a desktop computer. This PC should conform to currently acceptable specifications and should include a reliable chipset, motherboard, at least 256 MB of RAM, at least 40 GB of hard disk space, a fifteen inch picture tube (CRT) colour monitor, a keyboard, optical scroll mouse, a DVD reader cum CD/ DVD writer, an appropriate cabinet with power supply, FDD, two to four USB ports, a UPS capable of giving necessary power back up of minimum 30 minutes and a built in modem. In addition, computer peripherals should include a laser printer (black and white), a scanner and a broadband (or other, if broadband is not available in the concerned town or city) Internet connection. Expenditure on Internet connection including recurring expenses can be incurred out of contingency grant provided to the ART center every year. For educational purpose, a TV with accessories may be procured and installed in the Group-Counselling Room/ Waiting Area. The CDs shall be provided by NACO/SACS.

2.6 Human Resources

2.6.1 ART team

The ART team should consist of trained faculty from the Department of Medicine and Departments commonly linked with care and support of PLHA (Microbiology, Obstetrics & Gynaecology, Paediatrics, Dermatology and Venereology). In addition, the team should also have dedicated staff sanctioned for the ART centers and appointed through redeployment or on contractual basis. In case of contractual appointments, an open advertisement followed by interview of eligible applicants should be undertaken to select the most suitable candidates. The appointment of contractual staff should be done by the steering committee in the institution. This steering committee will interview, appoint the contractual staff, and renew the contract and approve the yearly increment. This committee can terminate the appointment if a situation arises for it.

The steering committee should be headed by the Head of the Institution, and the Nodal Officer ART shall be the Member Secretary. The appointing authority will be the Head of the Steering committee (the head of the institution). During the appointment of contractual staff, SACS representative should be invited as a special invitee. Attitude of candidates should be given due weightage in the selection process. Experienced, retired persons can also be re-appointed up to the age of 62 years. Contractual appointments should preferably be made for a period of 3 years to ensure continuity. There should be an annual appraisal system for consultants/contract staff based on which continuation should be decided.

To avoid delay in salary disbursement, NACO shall disperse the whole year money for ART component as one installment to SACS, with the instruction to SACS to transfer total amount to individual institutions/ART centers with in 30 days time.

As the number of patients on ART is increasing and has crossed 1000 at many centers, it has been decided that additional posts sanctioned for ART centers would be in proportion to the number of patients enrolled for ART at each center. The following structure has been proposed under NACP III.

Post	N0. of PLHA enrolled on ART			
	<500	500-1000	1000– 2000	>2000
Senior Medical Officer	1	1	1	1
Medical Officer	None	1	1	2
Lab. Technician	1	1	1	1
Counselor	1	1	2	4
Pharmacist	None	1	1	1
Record keeper cum DEO	1	1	1	1
Nurse	1	1	1	1
Community Care Coordinator	None	1	1	1

While one nurse is provided by the programme on a contractual basis, the hospital should also provide 1 nurse who can be trained on a Counsellor training curriculum of two weeks at an identifies centre.. In addition the hospital should ensure that cleaning and other support staff are provided to the ART center as are to other departments of the hospital. The department of medicine should also post senior residents and consultants – and the department of paediatrics should post paediatricians to the ART center on a regular basis to assist and guide the center and also to provide quality care to PLHA receiving ART.

While additional human resources would be provided under NACP, HoD of Medicine Department has the authority to utilise their services in the department and utilise services of experienced persons already available in the Department for rendering ART services.

2.6.3 Trained Institutional Faculty

The ART center is an integral part of the Department of Medicine. Therefore the ART team at the center should be headed by the Head of the Department (HoD) of Medicine. The HoD may nominate a senior faculty of Medicine as the nodal officer of the ART center. In addition, two to four physicians, two paediatricians, two obstetrician-gynaecologists and one or two dermatologists (or venereologists) should be part of the team. NACO will train all the members of the team for continuous supervision and optimal utilisation of the center. A sense of ownership should prevail in the Department of Medicine of which the ART center is an integral part. The faculty deputed for training should be willing and should have minimum 3 years of service left before retirement and they should actively participate in HIV delivery in the institution. The institutions which excel in integration of HIV services without any stigma and discrimination shall be developed as Model Centers.

2.6.4 Human Resources & their Job Responsibilities:

2.6.4.1 Nodal Officer of ART Centre (Head, Dept. of Medicine/ Nodal Officer deputed by the HOD)

- Overall responsibility of the functioning of the ART centre
- All administrative matters relating to the centre.
- Act as a team leader to constantly guide and mentor the ART staff (Medical Officers, Counsellor, Laboratory Technician, staff nurse, Pharmacist (if any) and Data manager
- Coordinate and develop referral system and linkages with other Departments of the hospital and other facilities developed under NACP, NGOs, and Positive Network Groups etc.
- Ensure adherence to the highest standards of quality and excellence in patient care.
- Ensure that PLHAs are not discriminated in the hospital and are not denied admission/ care.
- Review and monitor the functioning of the centre every week and ensure submission of reports as required.

2.6.4.2 Senior Medical Officer (ART)

The Senior Medical Officer (SMO) of the ART center should ideally be a specialist (MD) in Internal Medicine, trained in ART by NACO at one of the designated training centers and capable of dealing with medical complications of HIV/AIDS and the side effects of ARVs. In the event that a physician cannot be appointed, the SMO may be a post-graduate degree holder of any other clinical speciality.

(S)he should be able to supervise the administrative and medical functions of the ART center on a day-to-day basis and provide leadership to the staff to work as a cohesive team and deliver the services effectively. The SMO should also directly supervise the staff at the center, ensure that record keeping and reporting are carried out properly and on time and see that all the guidelines for running and maintaining the ART center are abided by.

2.6.4.3 Medical Officer (ART)

The Medical Officer (MO) should be at least MBBS and trained by NACO at one of the designated training centers. The MO will, in the absence of the SMO, look after all his/her tasks and responsibilities and ensure the proper running of the ART center. Routinely, the MO should support the SMO in ensuring quality services and care to PLHA on ART as per the guidelines and standards set by the national programme.

Specific tasks of the SMO and MO will include:

- First contact for the patient regarding his medical needs. They should examine the patient, advise required investigations including CD4 count, review the investigations and prescribe the treatment (this includes ART, referral to other departments such as RNTCP centers for treatment of tuberculosis, treatment of STIs and prophylaxis and/or treatment of opportunistic infections)
- Refer the cases to the ART center in-charge or any other specialist 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
- Complete and/or supervise the recording of information in the various recording and reporting tools used by the ART center, including software for data recording, if and when installed. It should be ensured that these records are updated on a daily basis and reports are sent to the correct authorities, in the correct format and on time
- Coordinate various functions of the ART center under supervision of the Nodal Officer of ART center
- Monitor the consumption and availability of ARVs, other medicines and supplies and to 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 PLHA.

  Training schedule for ART medical officer is at Annexure V.

2.6.4.4 Counselor

The counselor at the ART center should hold a masters degree in social work (preferably specialised in psychiatric social work) or in psychology and should also be trained by NACO at one of the designated training centers. Qualified and competent PLHA, if available, should be given preference while appointing a counselor. The candidate would undergo a 2-week training programme in counselling at a designated training institution. Alternatively, a qualified Graduate Nurse in service can be redeployed, or a retired nurse can be appointed on contract against the post of Counselor. In both these situations, the Counselor Nurse would take up a one-month training programme on counselling in designated training institutions in the country.

The counselor plays a very important role as a member of ART team and his/her responsibilities are crucial for the success of the programme and improved outcomes of the patients. The counselor deals with the following:

- Disclosure to the family of the HIV+ persons
- Address issues of stigma and discrimination and rights of PLHA
- Address issues related to ARV treatment. These should include:

- Pre ART or treatment readiness exercises, encourages and helps in finding guardian support
- Explains the details of treatment and its importance, side effects of the ARV drugs and limitations of ART (e.g. issues concerning failure of first line therapy and lack of options for HIV 2 infection at present)
- 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 organisation that can do so.
- Direct patients to linked or referred centers and departments and assist in palliative and home-based care
- Repeatedly stress on positive living, prevention and condom use and dispense condoms
- Complete the required sections in the recording and reporting tools kept by the ART center (details are mentioned separately)

2.6.4.5 Pharmacist (for ART centers with > 500 patients on ART)

The pharmacist should be qualified and hold a degree or a diploma in pharmacy. This important member of the staff at the ART center is appointed after the center starts at least five hundred patients on ART. Till such a time athat a pharmacist is posted, ARV drugs may be distributed by the nursing staff posted by the hospital in the ART center. The pharmacist should perform the following tasks:

- Dispense the drugs for OIs and ARV drugs
- Maintain the drug stock and drug dispensing registers
- Ensure that the center has stock of ARV drugs for at least 3 months
- Inform the ART Nodal Officer of the center as and when the stock falls below the 3 month backup stock
- Ensure adequate stock of drugs required for treatment and prophylaxis of OIs
- Advise the patients and family about importance of adherence during each visit
- Advise the patient on possible drug toxicities and reporting of the same if significant

2.6.4.6 Data Manager

The Data Manager should be a graduate with Diploma in Computer Applications (from a recognised institute or university) or 'O' Level course from DOEACC. He/She should also be trained by NACO in monitoring and evaluation (M & E) of the programme aimed to build the capacity of the person in recording data, preparing and sending reports and maintaining records properly. Following are specific tasks of Data Manager:

- Register patients in the ART centre and fill in the patient ID card, enter/transfer data in Pre-ART and ART enrolment registers and computer from registers and treatment cards when required (details are mentioned under record keeping)
- Prepare and send monthly report
- Prepare and send cohort reports under supervision of the Nodal Officer
- Assist in academic activities and undertaking analysis of data for special studies under supervision of the Nodal Officer of the ART centre.

2.6.4.7 Laboratory Technician

The Laboratory Technician (LT) should be trained in Medical Laboratory Technology (MLT) from an institution recognised by AICTE or State/Central Government. (S)he should be trained by NACO in ART related laboratory work, including CD4 count testing. The Lab technician is expected to perform following duties:

- Perform HIV tests at the ART center
- Collect the specimen for CD4 counts at the ART center and take these samples to the Department of Microbiology, test them and furnish the report to the ART center
- In case the ART center does not have a CD4 machine, the LT will be expected to transport samples of blood to a linked CD4 laboratory and to collect the results when ready
- Assist in performing tests in the Microbiology laboratory

2.6.4.8 Nursing staff

One or two nurses (depending upon the volume of patients) should be deputed to the ART center by the hospital (or institution). They should be in addition to one contractual nurse supported by NACO (qualification being same as far appointment of nurses in the hospital). Nurses play a very important role at the ART center and their responsibilities include the following:

- Dispensing of ARV drugs (till a pharmacist is added to the team)
- Counselling of patients
- Assisting in record keeping and maintenance of patient documents
- Streamlining and guiding patients at the ART center and helping the center t (o run efficiently and in an orderly fashion
- Coordinating and tracking the referrals made within the hospital by establishing linkage with various departments and in-patient wards
- Nursing care and follow-up of patients admitted in the hospital

2.6.4.9 Community Care Coordinator

The CC Coordinator should preferably be a PLHA,educated to intermediate(12th) standard, should have working knowledge of English and the local language.He can also be a volunteer from an NGO that is already working towards care and support of PLHA. (S)he will be expected to carry out the following:

- Provide assistance to PLHA enrolled at the ART center, within the hospital (OP and IP)
- Coordinate with the linked Community Care Center
- Keep track of drug adherence of patients on ARV, counseling them on the importance of regularity of visits and ARV dosage
- Augment the efforts of the counselor and other staff of the center in promoting positive living
- Assist in patient retrieval, where necessary and as far as possible
- Any other duty assigned by ART Centre incharge

2.6.4.10 Cleaning and other support staff from institute

The hospital should also provide cleaning staff and attendants for day-to-day maintenance of hygiene and running of the center as done for other departments or sections of the hospital. The level of hygiene and cleanliness of the ART center should be that of the highest standards, especially keeping in mind the lowered immune status of people living with HIV/AIDS

It is of utmost importance that the ART center is run with positive and synergistic team spirit. While job responsibilities outlined above 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 center.

2.7 Drugs & Medicines

2.7.1 ARV Drugs:

All ART centers are provided with ARV drugs directly by NACO. The number of patients for which drugs are supplied is estimated in consultation with the ART center concerned. The drugs are generally procured annually. The different types of ARV drugs and their proportions being supplied to ART centers are as below:

- The ratio of Stavudine vs. Zidovudine based combination is 40:60
- Among the Stavudine based combinations, Stavudine 30 mg is 90% and 40 mg is 10% (very few of our patients have weight more than 60 kg).
- The proportion of Efaviranz is 20% of total (as many of our patients have TB co-infection and need simultaneous ATT and ART). The patient should be shifted to NVP after ATT is complete.

Based on these norms, requirement of drugs have been calculated and the requirement for a unit of 100 patients per year is given below. These proportions are revised as per feedback from centers/exports.

S. No.	ARV Drug Combination Containing Ingredients	No. of Tablets
1.	Two drug combination tablets containing **Stavudine 30mg plus Lamivudine 150mg**	6120
2.	Two drug combination tablets containing **Stavudine 40mg plus Lamivudine 150mg**	680
3.	Two drugs combination tablets containing **Zidovudine 300mg plus Lamivudine 150mg**	10200
4.	Three drugs combination tablets containing **Stavudine 30 mg plus Lamivudine 150 mg plus Nevirapine 200 mg**	20160
5.	Three drug combination tablets containing **Stavudine 40mg plus Lamivudine 150mg plus Nevirapine 200mg**	2240
6.	Three drug combination tablets containing **Zidovudine 300mg plus Lamivudine 150mg plus Nevirapine 200mg**	33600
7.	Tablet **Nevirapine 200mg**	1200
8.	Tablet **Effaviranz 600mg**	7300

The drugs are supplied in 3 instalments in a year. All centers should ensure that they have a minimum stock of drugs for three months at their center. New patients should not be enrolled for ART without having 3 months stock of medicine. In such situations, information should be sent regarding non-availability of drugs to the following:

SACS: Joint Director I/c ART with copy to PD, SACS

NACO: Joint Director I/c ART with copy to National Programme Officer (ART) and AS&DG.

The drugs shall be stored in the main pharmacy of the institution and the centre will utilize them following first in first out principle. The drugs for PEP shall be made available in the casualty and one more are where they have easy round the clock accessibility.

Phone, fax numbers and e-mail of officers dealing with ART are given at **Annexure-1.**

2.7.1.1 Process for requisition and acceptance of ARV drugs

Nodal Officer of ART center should send requisition for ARV drugs to NACO under information to SACS. The requisition should indicate full consignee address (Nodal Officer, ART) with pin code, phone/ fax numbers and e-mail and qauantity of each drug received, utilised, balance available and additional requirement. Supply would be made to the consignee of ART center who would accept and receive drugs and store in medical store of the hospital/institution. Weekly/fortnightly indents would be sent by the ART center to the Store. Drug stock register should be kept with the store-keeper and a sub-stock register should be maintained at the ART center by Staff Nurse/Pharmacist.

2.7.1.4 Process of reporting ARV drug status

Monthly report would be sent by ART center to SACS and NACO indicating quantity of drugs received, utilised, balance and additional requirement, if any. Empty bottles should be destroyed to prevent recirculation

2.7.1.5 Impending drug expiry

Poor planning, over supply, lack of communication, decrease in patient load, faulty expected number could lead to impending drug expiry. Regular reporting and timely intimation to SACS and NACO is necessary to avoid such situations. ART center should inform NACO/SACS when expiry date of drugs supplied is within 6 months.

2.7.2 Drugs for Opportunistic Infections:

Requirement of different drugs required for treatment of Opportunistic Infections may vary from place to place. Bulk supplying all drugs may lead to expiry of uncommonly used drugs and shortage of more frequently used drugs. It has been seen

Drugs to be supplied by the Institution where ART center is located		Drugs to be procured by NACO and supplied to ART centers)		Drugs to be procured by SACS/ centre as per requirement)	
1	Metronidazole 400mg	1	Nitazoxanide 500 mg	1	Fluconazole IV- 200 mg
2	Albendazole 400 mg	2	TMP-SMX DS 160/800mg	2	Acyclovir IV 250mg
3	Ciprofloxacin 500mg	3	Azithromycin 500mg	3	Inj.Gancyclovir 500mg
4	Prednisolone 10 mg	4	Fluconazole 150 mg	4	Cap.Gancyclovir 250 mg
		5	Fluconazole 400mg	5	Itraconazole 200mg
		6	Clotrimazole tubes	6	Clarithromycin 500mg
		7	Clindamycin 300 mg	7	Ethambutol 800mg
		8	Sulfadiazine 500 mg		
		9	Inj Amphotericin B 50 mg		
		10	Acyclovir 400 mg		
		11	Cefotaxime 1g		
		12	Levofloxacin 500 mg		
		13	Cap.Amoxyclav 625		

that some of the drugs required for management of OI's are available in the hospitals formularies for treating these infections in non HIV infected persons. Hence the drugs for OI can be divided into three categories.

2.8 Linkages and Referrals

Mechanisms for establishing linkages and referral systems are necessary to meet immediate and long-term needs of the persons enrolled in a comprehensive HIV care program. PLHAs would need a wide range of services through out their span with HIV/AIDS, which may be different during the course of HIV infection and stage of the disease. These needs are related to:

- Physical health
- Psycho-social (and spiritual) health
- Nutritional status
- Economic status and concern for financial stability/security
- Quality of life

Age and gender of the PLHA are also important as they are critical determinants of access to services.

In the present health care delivery system, many of these services cannot be provided under one roof. There is, therefore, need to develop linkages and referral systems to take care of these needs. Following steps would help in establishing linkages within a district/region:

- Identification of organisations and facilities dealing with HIV/AIDS;
- Mapping of such organisations in the district/ region;
- Consultation for setting up linkages and referrals systems including procedures and schedules; and
- Evolving formats for referrals and feedbacks.

It will be advisable if representatives of all the centers meet regularly to discuss problems, if any so that the referral system is made effective and user-friendly. Looking at the various needs of the PLHAs, linkages and referral system need to be set up with other departments within the institution where ART center is located and with service providers and organisations outside the institution as elaborated below:

2.8.1 Referrals within the Institute

Persons living with HIV/AIDS for comprehensive care needs access to various departments/ services depending upon disease stage and occurrence of opportunistic infections. To facilitate effective referral system, a steering committee chaired by Head of the institute

(Principal/Dean or Medical Superintendent) with HoDs of Medicine, Microbiology, Obstetrics & Gynaecology, Paediatrics, Dermatology / Venereology and I/c Chest Diseases/DOTS as members, should be constituted. This committee should meet monthly/quarterly to review ART services.

ART center should have referral linkages with the following:

- Integrated Counselling and Testing center (ICTC)
- Antenatal clinics and Gynaecology Department
- Microbiology Department (for CD4 count and other investigations)
- Paediatric Department
- Dermatology and Venereology Department
- Chest Diseases / Tuberculosis center

2.8.1.1 HIV- TB Coordination

Patients attending ART centers with persistent cough for 3 weeks or more, accompanied by one or more of the following symptoms such as weight loss, chest pain, tiredness, shortness of breath, fever, particularly with rise of temperature in the evening, loss of appetite and night sweats must be suspected to have Tuberculosis.

When a person is suspected for TB, he should be referred to the nearest Designated Microscopy center (DMC) of RNTCP for examination. The main tools for diagnosing pulmonary TB are sputum smear microscopy, chest X-Ray, and culture of Mycobacterium tuberculosis bacilli.

Sputum smear microscopy: This is the primary tool for diagnosing TB as it is easy to perform, not expensive and specific with low inter and intra reader variation. It is simple and requires minimum training. It can be used for diagnosis, monitoring and defining cure of TB patients.

Chest X-ray: X-ray as a diagnostic tool is sensitive but less specific with large inter and intra reader variations. No shadow is typical of TB, 10-15% culture-positive cases remain undiagnosed and 40% patients diagnosed as having TB by X-ray alone may not have active TB disease. It is supportive to microscopy.

Culture: Culture of Mycobacterium tuberculosis bacilli is very sensitive and specific but is expensive as it requires a specialised laboratory set-up and results are available only after several weeks.

Patient flow for DOTs

After receiving the sputum results, the MO of the Health Institution is responsible for the categorisation of the patient for starting TB treatment, determining the DOT center which is convenient and near to the patients residence. DOT provider who is acceptable and accessible to the patient and accountable to the health system and making the patient-wise TB treatment box available at the DOT center along with the TB treatment Card, TB Identity Card and sputum containers for morning samples for follow-up sputum examinations. The feedback to the treating physician who has referred for treatment is provided as soon as the patient is received at the DOTS center within the district and through the District TB Control Officer (DTCO) if the patient is started on treatment outside the district. If the patient is admitted in the hospital then the treatment is started by the DOTS center of the hospital and on discharge the patient is provided medicine for 1 week and referred to the nearest DOT center for continuation of TB treatment.

Anti tuberculosis therapy and antiretroviral therapy (ART)

All TB patients co-infected with HIV should be treated with a rifampicin containing Anti-tubercular regimen under DOTS as per National Policy. In TB patients co-infected with HIV, TB treatment should be completed prior to starting ART, unless there is a high risk of HIV disease progression and death during the period of TB treatment (i.e., a CD4 count <200/mm3 or the presence of disseminated TB). In patients with very low CD4 counts requiring concomitant administration of ART and anti-TB treatment, the

ARV regimen should be modified by replacing Nevirapine with Efavirenz. On completion of TB treatment such patients can be switched back to Nevirapine.

2.8.2 Referrals outside the Institutions

Certain needs will demand a referral to facility that lies outside the institution where ART center is located. The counselor may be the best person to identify such needs and suggest the place of referrals. Hence, it is important that the counselor has a list of centers 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:

- NGOs actively working in the field of HIV/ AIDS including those involved in Targeted Interventions for High Risk Groups (CSW, IDU, MSM etc.)
- Other Government Hospitals & Private Hospitals
- Community Care centers
- Drop -in centers
- Home Based Organisations
- Local PLHA networks
- Rehabilitation centers

It is important to track and document the result of the referral. SMO is the key person responsible for making the referrals to other departments. Counselor/Nurse would be responsible to keep track of referrals made outside the hospital. ART center should maintain account of all the referrals made to the facilities within/outside the hospital. If feasible, PLHA network or a drop in center may be given the responsibility to coordinate linkages and referrals.

The Referral form and the Transfer out forms are at annexure II

2.8.2.1 Community Care centers

Under NACP-III, all ART centers will be linked to CCCs which will admit patients for five to seven days before starting ART. During this period, they will observe the patients for any adverse effects of ARVs and provide adherence counselling for patients being initiated on ART. These centers will focus on providing four types of services to PLHA (a) Counselling, in particular for drug adherence (b) Treatment support for minor OIs and TB or link to DOT centers (c) Referral and outreach for follow up of patients on ART (d) Nutritional Counselling; (e) Social support services. CCC will also have out reach workers trained in home based care to follow up with the families and ensure drug adherence. The Community Care centers will have a maximum capacity of 30 beds.

2.9 Monitoring & Evaluation

Continuous monitoring and supervision of all activities carried out at all the ART centers (Government, PSUs, Non-Government Sector) are important for monitoring effectiveness and quality of services. To facilitate a uniform and systematic monitoring, it is necessary to develop common monitoring tools and systems.

Care and Treatment Records
i. Patient ID Card
ii. Pre-ART Register
iii. Patient Antiretroviral Treatment Record
iv. ART Enrollment Register
Drug Dispensing and Stock Management Registers
v. Antiretroviral Drug Dispensing Register
vi. Antiretroviral Drug Stock Register
Programme Performance Monitoring Reports
vii. Monthly/Quarterly ART center Report
viii. Cohort Analysis Report
Supervision, Quality Assurance and Feedback Forms
ix. ART Treatment center Appraisal Form
x. ART Supervisory Checklist
xi. Summary Recommendations of Supervisory Visit

2.9.1 Monitoring Tools

Following set of registers and reporting formats have been developed by NACO and should be used uniformly by all the ART centers:

2.9.2 Recording information

Information is recorded and filled in the prescribed area and columns by relevant staff member of ART center as indicated below:

(i) **Patient ID card:** This should be made by the counselor and completed at every visit by the treating doctor. The card is to be given to the patient.

(ii) **Pre ART Register:** Information of all persons who are HIV positive and registered for HIV care (not necessarily receiving ART) is recorded in this register. Once the person is put on ART, (s)he is registered in the ART enrolment register and followed there. It is important to remember that one row in pre ART register is related to one HIV+ person.

a) Columns 1 to 12 are filled by the counselor

b) Columns 13 to 22 are completed by the treating doctor.

The pre ART register provides information on profile of registered patients, documents process from Care to ART (Checklist) and provided data for the monthly report.

(iii) **Patient Anti-retroviral Treatment Record (White Card):**

a) Area 1 to 3 to be filled by the counselor;

b) Areas 4 to 12 to be completed by the treating doctor.

c) The columns 10 and 15 needs to be filled or reconfirmed by the counselor.

d) Area 11 should be completed at every visit.

This record is triple folded card for patient information, for patient monitoring and programme monitoring to assess effectiveness of ART. The Information from these records is fed into the monthly ART center report.

(iv) **ART Enrolment Register:** Once a person is put on ART, (s)he is enrolled and followed in this register. Henceforth, no entries are made in the pre-ART register.

a) Columns 1 to 8 and column 18 are completed by counselor or record keeper with assistance from the counselor

b) Columns 9 to 17 are completed by the treating doctor. The record keeper may update the columns 9 to 12 under supervision of the treating physician.

This register has list of all patients on ART with medical details and monthly treatment status and contains information that is fed into the monthly ART center report and cohort analysis. This register can be updated by the record keeper with assistance of the relevant staff, based on patient ART treatment records (White card).

(v) **Anti-retroviral Drug Dispensing Register:** This register contains place for patients' name and signature, tablets dispensed. A separate page is maintained for each day. This register is maintained by pharmacist or the staff nurse, if the ART center does not have a pharmacist. It monitors daily drug consumption, ensures accountability and contains information which is carried forward to drug stock register.

(vi) **Anti-retroviral Drug Stock Register:** In this register, a separate page is maintained for each drug or drug combination. It contains information on name of the drug, opening stock, stock received, stock dispensed, drugs expired and the balance remaining. This register is also maintained by the pharmacist or the staff nurse if the center does not have a pharmacist. The drug stock register helps in monitoring drug stock, provides information to alert stock-outs and provides data required for the monthly report.

Each ART center is given a computer and application software for computerisation of data on a daily basis.

2.9.3 Reporting, Data Transmission and Analysis

Information from the prescribed records and registers is compiled and used in filling up various monitoring reports (see Annexure), which are forwarded to SACS and NACO. Monthly reports should be forwarded by 2nd of every month to CIMS with a copy by email to JD (ART) and NPO (ART) at NACO. Quarterly reports are to be forwarded in the months of July, October, January and April every year. It is intended to use electronic means of data recording and reporting

system wherein ART data will be fed into the CMIS at the state, district or even ART center level. A pilot project using an electronic smart card system for ART patients is also being tested and will be implemented under NACP-III.

The responsibility for information collection, reporting, management and analysis rests at four levels.

i. **ART centers:** Data generation, maintenance of patient records and registers, reporting to SACS and NACO and using the information in patient management, drug stocking and referral.

ii. **State AIDS Control Societies (SACS):** Data analysis, quality control, assessment of ART centers,supervision,feedbackanddissemination of information to state-level stakeholders and NACO.

iii. **NACO:** Compilation, analysis, monitoring, evaluation, planning, advocacy resource allocation, drug supply and dissemination of information to national and international stakeholders.

iv. **National Research Institutions:** Conducting special evaluation studies and operational research.

2.9.4 Communication tools

Apart from internet connection, ART center should be phone connections for external and internal (hospital) communication. The ART center will be expected to keep phone and Internet lines open and available to NACO, SACS, NGOs, CBOs, FBOs, Positive Network Groups, patients as well as to other departments of the hospital. The staff manning the center should get into the habit of routinely communicating (even reporting) through e-mail, while the use of the telephone should be used mainly for emergencies and to contact local support groups or persons. Each ART center should set up a free e-mail address with a company that is user friendly and has the ability to send and store large volumes of data.

Communication using postal or courier services should be retained for letters and documents that require signatures of officials. In urgent matters, documents with appropriate signatures may be scanned and sent as attachments through e-mail.

2.10 Responsibility of the SACS

Project Director, SACS should identify a senior technical officer, preferably, Additional Project Director (or Joint Director) as the Nodal Officer for ART programme.

2.10.1 Responsibilities of Nodal Officer for ART at SACS

- Supervision and monitoring of ART implementation in the State (should visit each ART at least once in 3 months).
- Coordination with Principals/Deans of Medical Colleges and Medical Superintendents/ Director of District Hospitals/Other Hospitals
- Identification of sites for new ART centers as per NACO criteria
- Identification of ART teams and organise their sensitisation on ART Services
- Coordination of ART services with active participation of NGOs and PLHA networks.
- Collate, compile and forward information relating to ART centers to NACO
- Organise training of various personnel involved in ART services
- Monitoring of supply and utilisation of ARV and OI drugs and diagnostic kits and equipment
- Increase in coverage of ART services in eligible persons with HIV/AIDS.

2.10.2 Supply and Monitoring of ARV Drugs

The management of supply logistics in respect of ARV drugs will be ensured by NACO. Only first line regimen will be offered as specified. Supplies will directly reach the ART centers. Any change in the procurement and distribution in future will be separately intimated by NACO. The Project Directors should closely monitor availability and utilisation of ARV drugs in each ART center and also ensure that

under no circumstances the center runs out of ARV drugs. Intimation on receipt, utilisation, stocks and requirement of ARV drugs should be sent to NACO on a monthly basis.

2.10.3 Documents, Guidelines and Monitoring Tools

NACO/SACS should ensure that each ART center has following documents and items:

- ART Technical Guidelines
- ART Operational Guidelines
- ART Training Manual (specialists and MOs)
- National Guidelines on Counselling; Handbook for Counselors
- National Guidelines on OIs, CD4 testing (including linkages), HIV testing
- List of ART centers in India
- Adequate stock of Registers, Treatment Cards, Reporting Formats, Referral Forms

2.10.4. Increase in Coverage of ART

To ensure high coverage of eligible AIDS adults (CD4 Count<200) and children (CD<20%), who should receive ART, active identification of eligible patients and linkages with various facilities need to be established... To facilitate this task, following activities need to be organised by the SACS in a systematic manner:

2.10.4.1 Public Awareness

There is evidence to show that level of general awareness towards HIV/AIDS has increased in the population. However, knowledge and utilisation about various services available for prevention, counselling, testing, care and treatment is low. This has resulted in sub-optimal utilisation of various services. SACS should publicise availability of services offered in details through various means of communication (TV, Radio, Newspapers, and Brochures). Location and services offered by ICTC, CCC, TIs, ART centers, TB centers and STD Clinics need to be disseminated at State/District level. Channels and newspapers should be selected based on targeted audience and coverage. Funds available to SACS for IEC may be utilised for this purpose.

2.10.4.2 Referral System & Linkages

There is lack of adequate linkage and referral system between ART centers and other facilities. People found to be HIV+ should be referred to ART centers and if CD4 count is less than critical level, should be put on ART. There should be linkages between these centers and ART centers as indicated in para 2.8.1 and 2.8.2:

2.11 Financial Management

Funds required for running an ART center are provided to each ART center for utilisation as per guidelines.

2.11.1 Bank Account

The ART center should open a separate bank account for management of funds. The account can be opened in the name of 'ART center – XXXX (name of the institution)' to be operated jointly by 2 – 3 persons including Nodal Officer of ART center. This is essential for proper and timely utilisation of funds made available to ART center. Payment should be made by cheques except for small contingent expenses. A cash book will be maintained by ART center to meet petty cash expenses. For this purpose, the nodal officer may draw imprest money not exceeding Rs. 5000 at a time.

2.11.2 Audit of Accounts:

SACS will get accounts of each ART center audited. Audited Statement of Accounts and Utilisation Certificate for the preceding financial year of each ART center should be submitted to SACS with copy to NACO by 30th June each year. Further release of grants would be subject to submission of these documents.

2.11.3 Guidelines for xpenditure:

ART center would incur expenditure as per norms given in table below:

For SMO an increment of Rs 750 p.a. and for MO an increment of Rs. 500 p.a. has been approved. For other contractual employees the increment is Rs. 400 p.a. All contractual employees are entitled to 30 days accrued/earned leave (i.e. 2 *1/2* per month) & 10 days sick leave

Post	**Existing Salary (Rs. pm)**	**Proposed Salary range (Rs. pm)**
SMO	25000	25000–30000
MO	20000	20000–25000
LAB Tech	6500	6500–8500
Pharmacist	6500	6500–8500
Counselor	6500	8000–10000
Data Manager	6500	8000–10000
Staff Nurse	–	10000–12000
Care Coordinator	–	3000–4000
Total cost of salaries per year	**Rs. 8.52 lakhs**	**Rs. 10.44 – 12.96 lakhs**
Contingency	**Rs. 0.5 lakhs**	**Rs. 0.5 lakhs**
Operational costs per year (*Telephone, Internet, stationary, printer cartridge, postal charges, local travel*)	**Nil**	**1 lakh**
Non recurring one time grant *(Computer & accessories, TV & DVD, Furniture, Almirah, Storage racks)*	**Additional Rs. 50,000/- (for computer in the first year only)**	**2 lakh**
Total per year	**Rs. 9.02 lakhs**	**Rs.13 lakhs – Rs. 14.5 lakhs**

SECTION

3 Patient Focused Guidelines

3.1 Disease Stages

In the course of an HIV infection and its progression, the person goes through various stages from a healthy state to full blown AIDS. These are described below:

3.1.1 Stage 1: From seeking health care to diagnosis

At this stage the HIV status of the patient is unknown. Any patient who seeks medical care generally visits the out-patient department for assistance. Although any department may be visited, depending on the nature of the clinical presentation, most of those suffering from the symptoms of HIV infection tend to visit the medicine OPD. The patient undergoes a clinical check-up followed up often with laboratory support to establish a diagnosis. In the event that there are symptoms and signs or other evidence suggestive of HIV infection (***Annexure III***), then the patient is referred to a Integrated Counselling and Testing center (ICTC) or a Prevention of Parent to Child Transmission (PPTCT) center, where the patient undergoes pre-test counselling, HIV testing and post-test counselling.

The importance of early identification of HIV positive status cannot be overstated as this could help prevent and significantly delay morbid conditions as well as help prevent transmission of the infection to others. It is also important that OIs are identified early so as to be able to reduce their impact on patients and improve the quality of live.

3.1.2 Stage 2: Process from diagnosis till need for ART

The HIV status should be made known to a patient at ICTC or PPTCT center where (s)he is counselled before (pre-test) and after (post-test) testing. The patient at this stage may be asymptomatic or have symptoms suggestive of HIV infection or AIDS. When there are no symptoms, the patient should be directed to Community Based Organisations (CBO). The emphasis of management of asymptomatic patients should be through counselling, on the need to involve families, motivate patients towards positive attitude and thinking. The patient is referred to the ART center for registration in the Pre-ART Register. The patients should be screened periodically and managed for Sexually Transmitted Infections (STI), Tuberculosis (TB) and various Opportunistic Infections (OI). WHO clinical staging and CD4 count should be established and documented. Early diagnosis and management of OIs including prophylaxis form the main stay of management in this stage.

Counselling should be aimed at ensuring risk reduction behaviour of the patient. At the same time, efforts should be made to elicit family and community support for the patient. (S)he should also be counselled to (i) promote positive healthy living, (ii) have an appropriate balanced diet (iii) return to work, or if the same not possible, redirected to other acceptable job profiles and (iv) seek appropriate health and social support.

When appropriate, and if necessary, (i) early referral to community support systems, (ii) treatment for substance abuse and (iii) management of co-morbid psychiatric illness should be carried out.

As many of the patients at this stage are likely to proceed to receiving ART at some point in the future, repeated counselling should also be targeted at ensuring adherence to ARVs, when ART is started. Patients and families should be convinced that adherence is integral to a positive and successful outcome once ART is started.

Several patients are ill when they come to know of the positive HIV status. Such persons should be examined in the Department of Medicine (or other concerned department) as out-patients and based on clinical features and laboratory investigations, diagnosis is established and appropriate treatment given. When stable, the patient should be referred back to ART center.

3.1.3 Stage 3: Process from decision to start ART

Patients who have a confirmed HIV positive status and fulfil the criteria for starting ART could belong to two groups, (a) those who are already registered at ART centers in the pre-ART care and (b) those who have just been recognised and are hitherto unregistered with the ART center. Those who fall in the former category should have their WHO clinical stage (Annexure IV) and CD4 count documented in addition to clinical and laboratory screening as recommended by the national programme. Adherence counselling should be given or repeated and family (or guardian) support established. The patient can then be started on ART and registered in the ART enrolment Register.

Patients who are being seen for the first time at the ART center and who are clinically eligible for receiving ART, should receive intensive adherence counselling on at least two sittings while they are undergoing clinical and laboratory screening. The WHO clinical staging and CD4 counts should be documented at this time. Family and/or social support, including guardianship support also needs to be established at this stage. An NGO linkage is also essential for follow up of the patient. Finally, when all these issues have been dealt with, the patient can be started on ART and registered in the ART enrolment register.

During the first fifteen days of ART a close watch needs to be kept on patient, especially to look for side effects of Nevirapine. Group and individual counselling to address adherence issues and risk reduction behaviour and counselling to help the patient lead a positive healthy lifestyle should be repeated during each visit of the patient, especially during the early days of ART.

Broadly, patients coming for follow up visits fall into three categories, namely:

(a) Those who are seriously ill,

(b) Those who have significant illness(es) and

(c) Those who are free of any complaints.

Those suffering from severe forms of illnesses, including drug reactions, IRIS, OIs and disease manifestations should be attended to immediately by the medical personnel at the ART center or in the emergency room, if the patient were to present there. They should be admitted and treated in the Department of Medicine (or another department, as per the nature of the problem).

Patients who are moderately ill, but do not require admission may present with physical signs and symptoms of their illness. They may also be suffering from psychological disturbances, depression or other psychiatric manifestations. Such patients may be managed at the ART center or referred to the Department of Medicine (or other appropriate department) for further assessment and management. Patients who do not maintain acceptable adherence levels and those with mild to moderate psychiatric problems, should undergo intensive counselling at the ART center in addition to being provided medical care and support.

The third group of patients are those who are symptom free and have maintained adequate adherence levels. They should undergo a routine counselling session including adherence counselling and be examined by the medical officers of the ART center. Routinely, all patients should be examined for TB, IRIS, new OIs and drug related side effects. A pill count should be done to check adherence. If there are no issues, they may collect their ARVs and leave.

In all the above conditions, irrespective of the patient's condition, the ART center should provide counselling for

(i) Adherence;

(ii) Family and social support;

(iii) Risk reduction behaviour particularly use of condoms;

(iv) Substance abuse;

(v) Proper dietary intake;

(vi) Positive healthy living; and

(vii) Accessing appropriate health care services, when required.

In addition and as per the ART technical guidelines, patients should also have periodic CD4 count testing, weight check, ambulatory status and routine laboratory investigations, including Hb, carried out.

3.2 Confidentiality and Discrimination Issues

Irrespective of HIV status of a person, all patients are entitled to receive general and specialty out-patient and in-patient services in a hospital. Confidentiality should be maintained at all levels irrespective of HIV status as per accepted medical ethics and the law. Maintenance of confidentiality should help to reduce discrimination against PLHA during the management of the patient in any hospital. It may also be noted that hospital infection control policies and measures, when observed properly and maintained at all levels and Post Exposure Prophylaxis (PEP) for all staff, if followed as per norms, will create a safe environment for health care providers to manage PLHA appropriately.

In order to ensure good adherence and for tracking the patients lost to follow up , it is desirable that patient is enrolled at ART center nearest to his current place of stay. He should be asked to furnish the documentary evidence of address proof in form of voter card/ ration card/ electricity or telephone bill etc. For patients from rural areas, a letter from the Panchayat chief will suffice as address proof. The ART Medical officer should get full contact details of patient including phone numbers before starting ART.

3.3 Supports from NGOs and Positive Network Groups

In order to improve the quality of care provided to HIV/AIDS patients, the hospital should have effective linkages with Community Based Organisations (CBO), Faith Based Organisations (FBO) and with Positive Network Groups in the region. Rapport building and development of positive relationships with these organisations will also help reduce the burden on the hospital. Such NGOs may provide vocational (or occupational) rehabilitation to deserving PLHA and family members, support children affected with AIDS (CAA) and children infected with AIDS (CIA) by providing educational support and/or care homes. They could also provide legal support when PLHA or their family members are deprived of their rights. In addition, they are often well equipped to provide psychosocial support and even nutritional support to the patients and, if necessary, their families.

SECTION

4 Standard Operating Procedures (SOP)

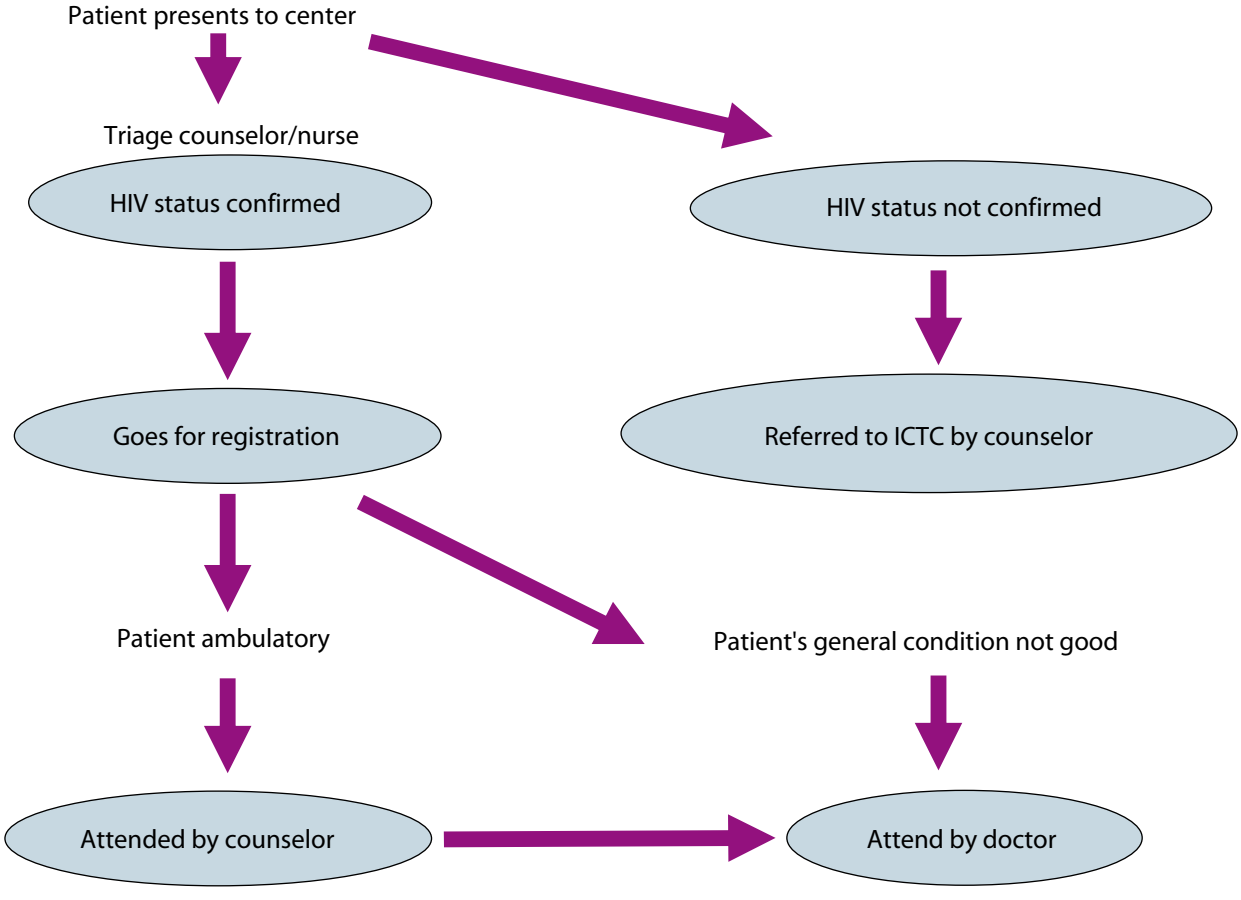
The SOP address the detailed process of patient flow as well as serve as a source of instructions to the staff of ART center that will optimally lead to good quality service delivery of ART, following the national guidelines. SOP are required for each of the following:

- Entry of patient into the care
- Flow of patient in the center
- Referral system for the patients

4.1 Entry into HIV Care

The ART center should enroll the person once he has a confirmed HIV test result. If a person has suggestions of the HIV disease but is not serologically confirmed, the person should be referred for HIV testing at ICTC. The common referral form should be used for all referrals in the program.

4.2 Flow of Patient at the ART center



4.2.1 The initial visit

In order to ensure good adherence and for tracking the patients lost to follow up , it is desirable that patient is enrolled at ART center nearest to his current place of stay. He should be asked to furnish the documentary evidence of address proof in form of voter card, ration card, electricity or telephone bill etc. For patients from rural areas, a letter from the Panchayat chief will suffice as address proof. The ART Medical officer should get full contact details of patient including phone numbers before starting ART

Having confirmed the HIV status, the patient is registered in the Pre-ART care by the counselor. The counselor also makes patient ID card and refers to the doctor. The principles of 5 A's in any chronic illness should be followed (Assess, Advise, Agree, Assist and Arrange). Doctor carries out a detailed medical examination during which he should

- Looks for OIs
- Classify the patient according to the WHO clinical staging
- Advise laboratory work-up - baseline test, OI investigation, CD4 count as indicated in technical guidelines
- Discuss briefly with patient and attendant (who knows the HIV status) about management of HIV with ART
- Give interim treatment, as required
- Call the patient for review after he gets the results of investigations
- Complete the information in the Pre-ART register

4.2.2 The Second Visit

- Patient returns with result of investigations
- Meets the counselor who re-emphasises about ART adherence; builds rapport.
- Refers to Doctor, who reviews all the investigations and takes decision about eligibility for starting ART as per guidelines
- If the patient is not eligible, gives pre-RT care and advises for follows up visits.
- If eligible for ART, doctor treats active OI and prescribes prophylaxis; sends for pre ART counseling or treatment readiness exercises;
- Pre-ART counseling may take 2-4 sessions on an average. Counselor should make sure that the patient understands the life long treatment, has gained knowledge about the treatment, is willing to take ART and follows the adherence guidelines. Counselor encourages family involvement/ guardianship
- Doctor gives follow up date after treatment readiness exercise after discussing with counselor.
- Once ART is initiated, the pre ART register is completed and the ART enrollment register and ART treatment record is filled by counselor and the MO (as per the guidelines).
- Doctor prescribes ARV and other necessary drugs
- Patient collects drugs from dispensing counter

4.2.3 Visit after ART is started (After 2 weeks of NVP initiation)

Patient goes to counselor. Counselor assesses

- Adherence to treatment
- Barriers in adherence, if any
- Any side effects, mentioned by patients
- Consider taking written consent for home visits
- Sends to MO

The Medical Officer

- Examines the patient
- Establish the status of previous OIs and symptoms
- Looks for side effects of ART
- Explains the possibility of IRS
- Makes any referral for patient, if needed
- Mentions the alarming signs and symptoms of side effects of the drug regime used
- Calls for follow-up after 1 month

During the visit, respective columns in the ART treatment record are filled by the counselor and the Medical Officer

4.2.4 Subsequent Follow-ups Visits (Once a month)

Responsibilities of various personnel during monthly follow-up visits are as under:

Counselor:

- Monitor adherence and ask for any potential or identified barriers
- Notes if any referral is required and informs the person in-charge for referral (SMO/MO or nurse)
- Links the patient to community based organization and rehabilitation centers, if available and desired. Should at least inform the patient about the existence of various support groups.
- Counseling of guardian
- Completes the columns in the ART record (White card)
- Sends to the nurse, if available or to the MO, if nurse is not available

Staff Nurse:

- Assess adherence
- See for side effects
- Look for IRS
- Stress the importance for adherence
- Make any required referrals
- Explain to patient that it may not be necessary to see MO every time. However, he should do so when asked by the ART center staff
- Gives follow up date after a month.

Doctor (SMO/MO)

- Take vital parameters
- Take weight
- See for oral thrush
- Ask for symptoms
- Make the entries in the relevant columns in the ART record
- Sends the patient to MO

4.2.5 Further follow up visits

- The patient is asymptomatic
- There is no weight loss or loss of appetite
- The oral cavity is normal (no ulcers, or oral thrush)

If the person is already on ART for 3 months, and does not wish to visit the doctor (has come to collect medicines), the same may be done after the nurse has looked for that:

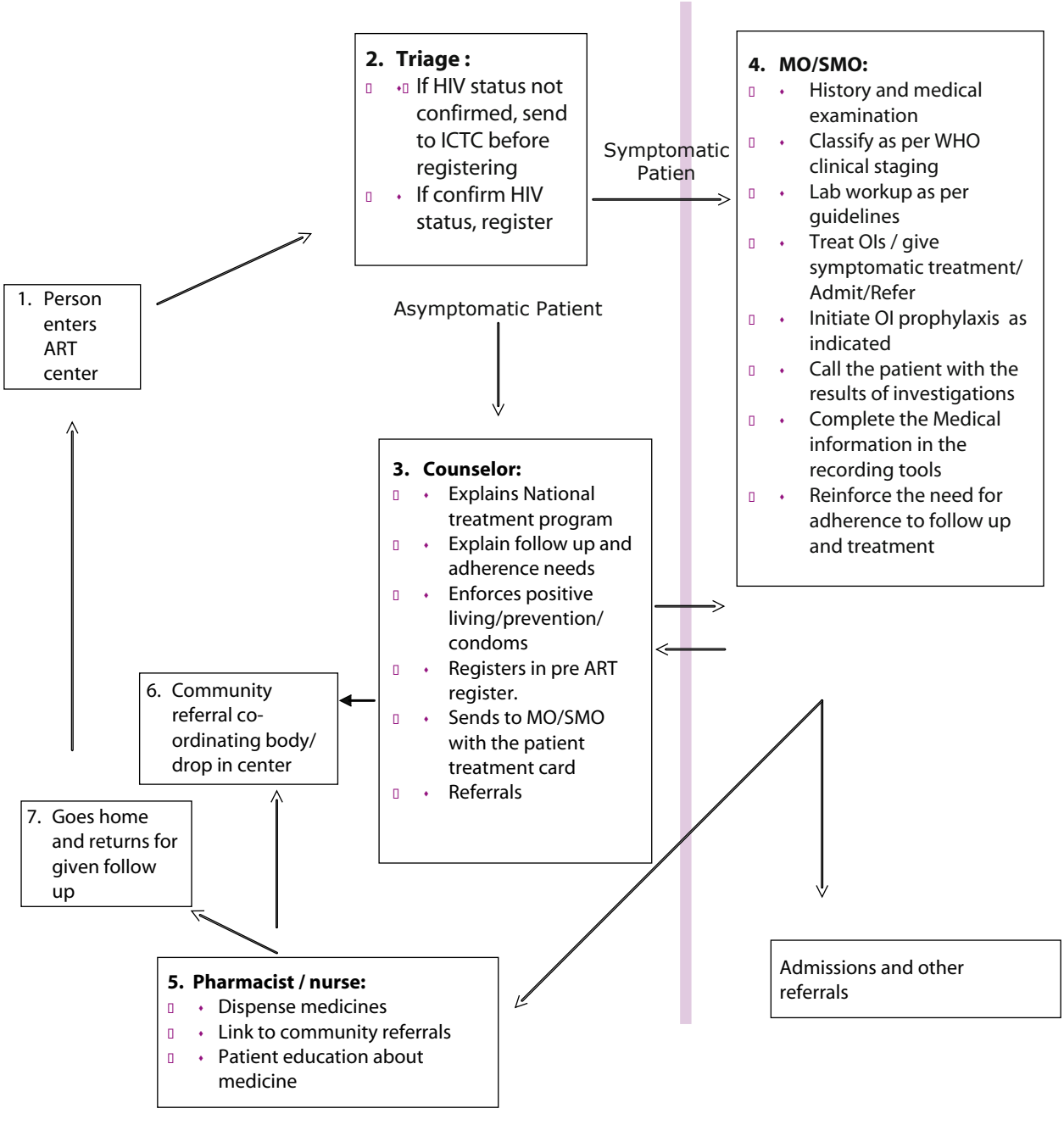
In such cases, the patient may meet the counselor and nurse, take the required medicines and leave after the follow up date is given.

CD4 counts and other laboratory investigations should be done as per guidelines or as required.

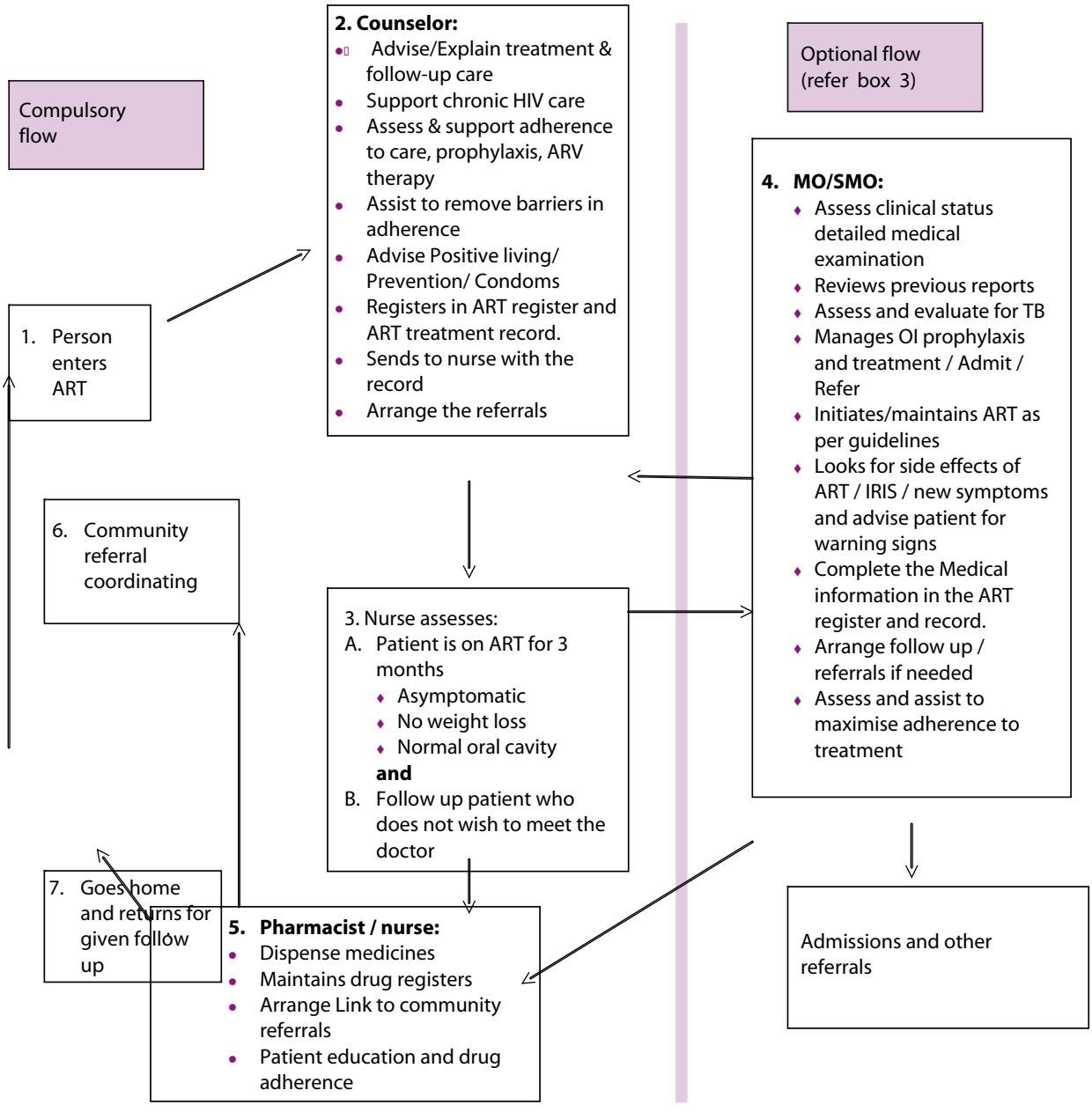
It is important to realise that HIV infection often affects the family rather than only an individual. Hence, the ART team should try and determine the status of those not on care and treatment (like parents of a child under treatment, spouse of HIV infected etc). The counselor, nurse and doctor should try and identify the family members with the HIV status and get them into care.

In order to ensure good adherence and for tracking the patients lost to follow up , it is desirable that patient is enrolled at ART center nearest to his current place of stay. He should be asked to furnish the documentary evidence of address proof in form of voter card/ ration card/ electricity or telephone bill etc. For patients from rural areas, a letter from the Panchayat chief will suffice as address proof. The ART Medical officer should get full contact details of patient including phone numbers before starting ART.

Patient Flow in the ART center (Pre ART)



Patient Flow at ART center (ART Care)



These SOP should address the detailed process of patient flow as well as serve as a source of instructions to the staff of ART center that will optimally.

SECTION 5

Public Private Partnership on ART

5.1 Expansion of ART programme to NGO/ PSUs/Corporate Sector/Trust/ Charitable Hospitals

It has been seen that many patients approach various NGO/Trust/Charitable Hospitals for HIV care including ART e.g. YRG Care, Chennai; CMC, Vellore; KLES Hospital, Belgaum; KMC Hospital, Manipur and AIDS Health Care Foundation, New Delhi. In addition, there are a number of hospitals under organisations like Railways, ESIC, Armed Forces Medical Services as well as PSUs like SAIL, Coal India Ltd., BHEL, NFL etc. which are already providing some services to HIV infected persons including ART in some of their hospitals. These services need to be streamlined as per National ART Guidelines and operational protocols.

In this regard a **Memorandum of Understanding (MOU)** for starting ART in NGOs/Corporate Sector/ PSUs has been developed at NACO and approved by the Department of Legal Affairs, Ministry of Law and Justice and National AIDS Control Board. The salient features of MOU are

I. Responsibilities of NACO

1) To provide support for one time training of personnel of these organisations.

2) To provide regular updates on National ART guidelines from time to time.

3) **For NGO collaborators**, NACO shall provide diagnostic kits, ART and OI drugs for a specified number of patients for a period of three years. For **PSUs/Corporate ART centers**, the organisation shall bear the entire cost of drugs, tests etc. for the treatment of its employees & their families. However for treatment being provided to the community at these centers, NACO/ will provide kits for diagnosis and drugs for ART/OIs.

II. Responsibilities Of NGO/Corporate/PSUs

1) To provide all health services related to provision of ART and treatment of opportunistic infections, free of cost to patients who require treatment and shall not deny services to any person living with HIV on any ground.

2) To comply with all the laws for the time being in force in India in the running of the ART center.

3) To follow the National ART guidelines (drug regimen as well as physical standards) issued by NACO from time to time.

4) To bear the costs related to the staff's salary (doctors, counselors, nutritionist, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure.

5) It shall conform to any guidelines issued by NACO from time to time.

The pattern of assistance to various sectors by NACO is as below

A copy of the MOUs approved for NGO and PSU/ Corporate centers is placed at Annexure VI.

5.2 Selection of NGO/Trust/ Charitable organisation for PPP

The selection criteria for NGO are

i) It should be run by a registered Society/Trust in India;

Assistance to ART centers in various sectors under NACP						
Component	**Public Health Sector**	**Other Govt. Sector**	**PSUs**	**Corporate Sector**	**NGOs**	**Remarks**
	Medical Colleges, Distt. Hosp.	**Rly, Defence, ESI, Paramilitary etc.**	**GOI undertakings**	**Criteria as per scheme**	**Criteria as per scheme**	
Land	X	X	X	X	X	Only for new constructions
Infrastructure Development	❒	X	X	X	X	Under NACP-III
Equipment (CD4 machine)	❒	X	X	X	X	
Additional Human Resources	❒	❒	X	X	X	* Only counselor if patients>1000
Diagnostic Kits (HIV/CD4)	❒	❒❒❒	❒❒❒	❒❒❒	❒	** For eligible patients from community
ARV Drugs (First Line)	❒	❒❒❒	❒❒❒	❒❒❒	❒	
Drugs for Opportunistic Infections	❒	❒❒❒	❒❒❒	❒❒❒	❒	
Training of key personnel	❒	❒	❒	❒	❒	TA/DA by sponsoring agency
IEC material	❒	❒	❒	❒	❒	
Operational Costs	❒	❒	❒	❒	❒	

ii) It should have sound financial position and should give commitment to support services for 3-5 years;

iii) It should have at least 2 years experience in ART provisioning;

iv) They should have facilities for CD4 and other lab tests needed at center or should have clear workable linkages for the same;

v) They should follow the same man-power for ART centers as is done at government run centers;

vi) They should follow NACO guidelines and report to NACO using M&E tools. They should not use the data collected without NACO's consent;

NACO shall give an advertisement in national newspaper about the PPP and invite applications. However to start with, this shall be implemented with the organisations which have already applied to NACO for the same. Before start/signing of MOU, the center shall be visited by an expert team of 3-5 persons including Programme officer at NACO, National /State ART Consultant, one national HIV expert and one person from Administration/finance section. The team shall use the standard ART site visit format (AnnexureVII). After satisfactory appraisal, the center shall sign an MOU with NACO as per annexure.

Annexure I

Name of officer	Tel number	email
Ms. Sujatha Rao. IAS Additional Secretary & Director General, National AIDS Control Organization	23325331; 23351700(fax)	**asdg@nacoindia.org**
Dr. Jotna Sokhey Addl. Project Director (Technical) National AIDS Control Organization	23325337, 23351714(fax)	**apd@nacoindia.org**
Dr.Damodar Bachani Joint Director (ART), National AIDS Control Organization	23731956	**dr.bachani@gmail.com**
Dr. B.B. Rewari National Program Officer (ART), National AIDS Control Organization	23351719	**drbbrewari@yahoo.com**
Dr. Sunil S. Raj Program Officer (Paed ART) National AIDS Control Organization	9810083644	**sunil.sraj@gmail.com**
Dr. Girish Makhija Program Officer (HRD-T) National AIDS Control Organization	9312223866	**hrdnaco@gmail.com**
Dr. Amit Chatterjee Program Officer (CCC) National AIDS Control Organization	9810303899	**dramitnaco@gmail.com**

Annexure II

Transfer out form (Form For transfer to Other ART center)

Name and address of the transferring ART center _____

Name and address of ART center where patient is transferred _____

Name of Patient :

Address:

Reason for transfer Date of transfer:

Date of starting ART: _____/____/_____ (Date/Month/Year); Cohort _____

Next date for dispensing drug is _____/_____/_____

Please find the following documents handed to the patient:

1. ART Treatment Card (Xerox)
2. Patient I D card/OPD card
3. Others, if any (mention)

Name and Signature of SMO/MO *Phone no and E mail of SMO/MO:*

_____

_____

To be filled by the receiving ART center and sent to the transferring ART center by post / email

……..(Name of Patient), referred by you on date…/…/… has reported and been registered with us on…./…../…….. The documents sent by you have been received.

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

_____

_____

(Back of this page has address of the ART center, transferring out the patient

Referral form

Date of referral: day / month / year _____ /_____ /_____

Referring Unit (please tick)

– ART center
– ICTC
– PPTCT
– Referral coordinating Body
– DOTs center
– STD clinics

Name of contact at referring body

Name of Patient

Age and sex

Referred to

– ART center
– ICTC
– PPTCT
– Other departments (please mention)
– RNTCP
– Community care center
– Referral coordinating body (for referrals outside institute, in community)

Purpose of referral

– Opinion
– Enrollment in care
– Social support
– Psychological support
– Nutritional support
– Peer group formation/registration
– other (please specify)

Back ground information about the patient

Feedback on The referral

Medical referrals.

Presumptive diagnosis

Suggested intervention or intervention done

Community based referrals(the referral coordinating body like drop in center should send the documented proof of the result of the referral)

– Referral completed
– Problems identified in referrals

Annexure III

WHO case definitions for AIDS surveillance in adults and adolescent where HIV testing facilities are not available.

The case definition for AIDS is fulfilled if at least 2 major signs and at least I minor sign are present.

Major signs

- Weight loss>10% of body weight
- Chronic diarrhea for more than 1 month.
- Prolonged fever for more than 1 month.

Minor signs

- Persistent cough for more than 1 month
- Generalised pruritic dermatitis
- History of herpes zoster
- Oropharyngeal candidiasis
- Chronic progressive or disseminated herpes simples infection
- Generalised lymphadenopathy

The presence of either generalised Kaposi sarcoma or cryptococcal meningitis is sufficient for the case definition of AIDS.

Annexure IV

Clinical stage 1

Asymptomatic
Persistent generalised lymphadenopathy

Clinical stage 2

Unexplained moderate weight loss (<10% of presumed or measured body weight)[1]
Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis)
Herpes zoster
Angular cheilitis
Recurrent oral ulceration
Papular pruritic eruptions
Seborrhoeic dermatitis
Fungal nail infections

Clinical stage 3

Unexplained[2] severe weight loss (>10% of presumed or measured body weight)[8]
Unexplained chronic diarrhoea for longer than one month
Unexplained persistent fever (above 37.5°C intermittent or constant for longer than one month)
Persistent oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis
Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia,)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Unexplained anaemia (<8 g/dl), neutropenia (<0.5 x 10^9 /L) and or chronic thrombocytopenia (<50 X 10^9 /L[3])

Clinical stage 4[3]

HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Extrapulmonary tuberculosis
Kaposi's sarcoma
Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacteria infection
Progressive multifocal leukoencephalopathy
Chronic cryptosporidiosis
Chronic isosporiasis
Disseminated mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
Recurrent septicaemia (including non-typhoidal salmonella)
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV associated nephropathy or Symptomatic HIV associated cardiomyopathy

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[1] Assessment of body weight in pregnant woman needs to consider expected weight gain of pregnancy.
[2] Unexplained refers to where the condition is not explained by other conditions.
[3] Some additional specific conditions can also be included in regional classifications (e.g. reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in Americas region, Penicilliosis in Asia).

Annexure V

Training schedule for ART Medical Officers		
Day 1- Monday:		
8- 9.30 am	:	Welcome, registration, orientation
9.30- 10.30 am	:	Pre test, ice breaking
10.45- 12 noon	:	Universal precautions and waste disposal
12- 1 pm	:	My hospital, my work
2- 3 pm	:	Epidemiology of HIV infection-Overview of NACP
3- 4.30 pm	:	Psychosocial aspects, including counseling
Day 2- Tuesday:		
8 am- 12.30 pm	:	Ward visit- review of universal precautions and waste disposal in the ward; interaction with positive people on issues of stigma and discrimination;
1.30- 2.15 pm	:	Principles of HIV prevention and care
2.15- 3.15 pm	:	Natural history of HIV infection
3.30- 4.15 pm	:	Testing related to HIV
4.15- 5 pm	:	My hospital, my work
Day 3- Wednesday:		
8 am- 12.30 pm	:	Ward visit- visit to laboratory; visit to VCCTC and review of use of NACO approves kits for testing
1.30- 2 pm	:	Clinical pharmacology of ARV drugs
2- 3.45 pm	:	Anti retroviral therapy
4- 4.30 pm	:	Adherence issues
4.30- 5 pm	:	Post exposure prophylaxis
Day 4- Thursday:		
8 am- 12.30 pm	:	Ward visit- visit to ART clinic; spending time on pre ARV counseling, counseling for ART, for counseling and adherence estimation. Discussion on ART initiation in some patients; follow up of patients on HAART
1.30- 2.15 pm	:	ART team
2.15- 3.45 pm	:	Monitoring and Evaluation
4- 5 pm	:	My hospital, my work
Day 5- Friday:		
8 am- 12.30 pm	:	Ward visit- visit to ART clinic- working of record keeper/ data entry operator, maintenance of records/ registers; writing some actual prescriptions
1.30- 1.45 pm	:	Approach to opportunistic infections
1.45- 2.45 pm	:	Fever and lung manifestations in HIV
2.45- 3.30 pm	:	Gastro intestinal manifestations in HIV
3.45- 4.45 pm	:	Neurological manifestations in HIV

Day 6- Saturday:		
8 am- 12.30 pm	:	Ward visit- bed side discussions on PLHA admitted with opportunistic infections
Day 7- Sunday	:	No sessions
Day 8- Monday:		
8 am- 12.30 pm	:	Ward visit- bed side discussions on PLHA admitted with opportunistic infections
1.30- 2.30 pm	:	HIV and tuberculosis
2.30- 3.30 pm	:	STI and HIV
3.45- 4.30 pm	:	Dermatological issues in HIV
4.30- 5.00 pm	:	Therapy in Special situations
Day 9- Tuesday:		
8 am- 12.30 pm	:	Ward visit- bed side discussions on PLHA admitted with opportunistic infections. Visit to DOTS clinic
1.30- 2.30 pm	:	Women and HIV, including PPTCT
2.30- 5 pm	:	Paediatric aspects of HIV
Day 10- Wednesday:		
8 am- 12.30 pm	:	Ward visit- visit to PPTCT program, labour room, paediatric wards
1.30- 5 pm	:	Paediatric aspects of HIV
Day 11- Thursday:		
8 am- 12.30 pm	:	Ward visit- visit to paediatric wards
1.30- 2.15 pm	:	Nutritional aspects
2.15- 3 pm	:	Palliative care
3- 3.30 pm	:	Impact of HIV and HAART
3.45- 4.15 pm	:	Socio economic correlates of HIV
4.15 - 5 pm	:	Stigma and discrimination, including Jyoti's hope (a video produced by ITech/GHTM, Tambaram)
Day 12- Friday:		
8 am- 12.30 pm	:	Ward visit- bedside discussions on patients on ART presenting with problems- IRIS, side effects, failure of therapy.
1.30- 2.00 pm	:	Blood banking
2.00- 3.30 pm	:	Problem solving and Prescription writing
3.45- 5 pm	:	Clinical exercises
Day 13- Saturday:		
8- 9 am	:	Post test
9-11a.m	:	Ward visit- Case discussions of admitted PLHA
11- 12.30 noon	:	Post test score distribution, and post test answers discussion
12.30 p.m	:	WRAP UP

Annexure VI

Agreement between
National AIDS Control Organisation (NACO)
Government of India
&
XXYYZZ (Name of NGO and Place)

This Agreement is made on _____ day of _____ 2006 by and between the President of India acting through [name of Additional Secretary and Director General], Additional Secretary and Director General, National AIDS Control Organisation, Department of Health, Ministry of Health and Family Welfare, Government of India, 9th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (hereinafter referred to as "NACO")

AND

XXYYZZ, a society / trust registered under the Societies Registration Act or [State] Public Trusts Act and bearing registration number _____ and having its registered office at _____ acting through _____, the authorised signatory, hereinafter referred to as "XXYYZZ", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

WHEREAS NACO is providing first line antiretroviral treatment (hereinafter referred to as ART) to persons living With HIV/AIDS (hereinafter referred to as PLHAs) in India through designated public hospitals as per the guidelines issued by the National AIDS Control Organisation (hereinafter referred to as NACO) from time to time;

AND WHEREAS NACO coordinates the aforementioned provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART;

AND WHEREAS NACO is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations;

AND WHEREAS XXYYZZ is a not-for-profit organisation registered under the Societies Registration Act or [State] Public Trusts Act with the object interalia of extending AIDS related treatment , care and other services to PLHAs regardless of ability to pay;

AND WHEREAS XXYYZZ has been running an HIV clinical programme at ___, which was initiated in……. and is presently providing ART to __ number of persons.

AND WHEREAS XXYYZZ has approached NACO and expressed its interest to assist NACO in addressing the above need at its sites in India;

AND WHEREAS the parties hereto have agreed to set up a collaborative ART project and hereby reduce the terms of the agreement to writing;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART PROJECT

The purpose of the present Agreement is to set up collaborative ART project between NACO and XXYYZZ that would seek to be a model for high quality provision of ART and associated healthcare and medical management of PLHAs in its sites in India.

II. RESPONSIBILITIES OF NACO

4) NACO shall provide and ensure an uninterrupted supply of antiretroviral medications and medications for the treatment of common bacterial, parasitic and fungal opportunistic infections to XXYYZZ for the number of patients as set out in Schedule II for a period of [three / five years] from the date of execution of this Agreement.

5) NACO shall organise training or provide support for training of personnel of XXYYZZ involved in the collaborative ART project.

6) NACO shall provide to XXYYZZ regular updates on National ART guidelines from time to time.

7) NACO and XXYYZZ shall form a committee comprising of representative from NACO, Director of XXYYZZ, which shall supervise and monitor the collaborative ART project to ensure provision of quality services.

8) On an application by XXYYZZ for certification of a site as a "designated ART center" NACO team shall inspect the site to ascertain facilities for providing treatment and counselling and financial status subject to its satisfaction as to clause 3 of part III, certify the site as a "designated ART center".

9) NACO will provide drugs on a [three] monthly basis on receipt of a requisition/s from XXYYZZ and certificate of utilisation of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES OF XXYYZZ

6) XXYYZZ has set up a center / plans to set up a center (s) at _____ and has appointed Dr._____, as the official contact for the proposed collaborative ART Project.

7) XXYYZZ represents that it provides / proposes to provide various health services to PLHAs, a description of which is set out at Schedule III to the present Agreement.

8) XXYYZZ undertakes that it will comply with all the laws for the time being in force in India in the running of the ART center. Further, as a condition precedent to the certification of the site as a "designated ART center, XXYYZZ shall have obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.

9) XXYYZZ shall strictly follow the National ART guidelines (drug regimen 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 will ensure that mechanisms needed for good treatment adherence are in place.

10) XXYYZZ shall respect the autonomy and privacy of the patients, and to this end provide pre- and post-test counselling, obtain written informed consent from the patient prior to a test or treatment, and maintain confidentiality of the patients on the principle of shared confidentiality.

11) XXYYZZ shall provide for data protection systems to ensure that the confidential records of the patients are computerised and are protected so that they are not accessible to any unauthorised person.

12) XXYYZZ shall provide a copy of all medical records to the patients on their request.

13) XXYYZZ shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Schedule III, free of cost to patients who require treatment. XXYYZZ shall not deny services to any person living with HIV on any ground.

14) XXYYZZ shall maintain all the registers and reporting formats as per NACO ART guidelines. They will send report of all adverse drug reactions to NACO.

15) XXYYZZ shall use standard NACO Monitoring and Evaluation tools.

16) XXYYZZ shall provide standard, anonymous monthly reports of patient numbers and relevant details for the previous month to NACO by the 7th of each month in prescribed formats in accordance with the guidelines laid down by NACO from time to time. NACO will be free to use the data so sent to them in an anonymous manner.

17) XXYYZZ shall provide details of the ART team at their center to NACO along with the names and technical qualifications of the staff and keep this updated from time to time.

18) XXYYZZ shall entirely bear the costs related to the staff's salary (doctors, counselors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. XXYYZZ represents that it has enough funds to run the programme for the next three / five years. XXYYZZ will permit NACO to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that NACO can verify the representation of sustainability of the collaborative ART project.

19) XXYYZZ shall establish a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living With HIV/AIDS or PLHA groups in the area for increasing access to treatment and for follow-up support.

20) The designated representatives of XXYYZZ shall attend the coordination meeting with NACO at their own costs.

21) XXYYZZ 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 center, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.

22) Use of any data obtained by XXYYZZ during the course of its collaborative ART project shall be done in an anonymised manner such that the identity of the patients enrolled at the collaborative ART project is not revealed in any manner.

23) XXYYZZ shall maintain the records for a period of five years from the time that this Agreement is terminated or lapses by efflux of time.

24) XXYYZZ shall constitute a grievance redressal mechanism. ***[A model grievance redressal mechanism is annexed hereto.]*** Further, XXYYZZ shall forward to NACO in an anonymised manner the nature of complaints received and action taken thereon on a monthly basis.

IV. COMMENCEMENT

1) This Agreement shall become effective upon signature by both the Parties and certification of the site of the collaborative ART project as "designated ART center" by NACO as per clause 5 of part II of this Agreement. It shall remain in full force and effect for a period of three / five years thereafter.

V. RENEWAL OF AGREEMENT

1) This Agreement is renewable at the option of NACO.

2) Six months prior to the expiry of the Agreement due to efflux of time NACO shall intimate XXYYZZ if it intends to renew or not to renew the Agreement.

3) In the event that NACO decides not to renew the Agreement, XXYYZZ shall intimate NACO about its ability to continue to provide treatment free of charge to the patients enrolled. If XXYYZZ fails to

continue to provide treatment free of charge or expresses its inability to do so, they shall give notice to the patients and NACO about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO. Further, upon such referral, XXYYZZ shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO or a person designated by NACO to receive such medical records. Thereupon, NACO will be responsible for ensuring that the patients continue to receive the drugs.

4) In the event that 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, XXYYZZ will have to re-apply for and re-obtain certification.

5) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

1) Any party may terminate this Agreement 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.

2) On such notice of termination being received by any party, XXYYZZ shall intimate NACO about its ability to continue to provide treatment free of charge to the patients enrolled. If XXYYZZ cannot continue to provide treatment free of charge, they shall give notice to the patients and NACO about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO. Further, upon such referral, XXYYZZ shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO or a person designated by NACO to receive such medical records. Thereupon, NACO will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY XXYYZZ

1) In case XXYYZZ is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART 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 NACO, MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.

2) If XXYYZZ 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 XXYYZZ, then without prejudice to any other right or consequence or mode of recovery, NACO may recover the amount thereof from XXYYZZ 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 Delhi. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.

3. The place of arbitration shall be either New Delhi or the site of the collaborative ART project, 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.

[In case the contract is entered into by the President through the DG, NACO, this needs to comply with the Rules of Business laid down in this behalf.]

SCHEDULE I

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO TO XXYYZZ

Signed For and on behalf of XXYYZZ AABBCC Director XXYYZZ Signature ..... Date ..... In the presence of Name and Signature .... Date	Signed For and on behalf of President of India Director General NACO Signature ..... Date ..... In the presence of Name and Signature .... Date .....

1. Treatment for Opportunistic Infections

   TMP SMX, Acyclovir, Fluconazole, Ciprofloxacin

   Amphotericin B

2. First line ART (in fixed dose combinations)
   (a) Stavudine
   (b) Lamivudine
   (c) Nevirapine
   (d) Zidovudine
   (e) Efavirenz

SCHEDULE II

MODEL FOR A FIVE YEAR AGREEMENT		
Year	**Centre**	**Number of PLHAs for whose treatment stock is to be provided**
2006–07		
2007–08		
2008–09		
2009–10		
2010–11		

Year	**Centre**	**Number of PLHAs for whose treatment for OIs is to be provided**
2006–07		
2007–08		
2008–09		
2009–10		
2010–11		

MODEL FOR A THREE YEAR AGREEMENT		
Year	**Centre**	**Number of PLHAs for whose treatment stock is to be provided**
2006–07		
2007–08		
2008–09		

Year	**Centre**	**Number of PLHAs for whose treatment OIs for is to be provided**
2006–07		
2007–08		
2008–09		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPSOED TO BE PROVIDED	
Address of site	
Outpatient	
Days	Monday to Saturday
Timings	0830 am to 330 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	WHO criteria. Attach any other criteria being followed
Treatment for OIs	
First line regimen	AZT/d4T+ 3TC+ NVP/EFV
Description of follow-up of patients	
Facilities available	❒
Personnel and their qualifications	

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for XXYYZZ to constitute a grievance redressal mechanism at the outset.]

(a) XXYYZZ 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 person.

(b) Every aggrieved person or an authorised representative of such person, who has a grievance against the XXYYZZ about the services provided or refused, has the right to approach the Complaints Officer to attend to such complaint and shall be informed of such rights by XXYYZZ.

(c) The Complaints Officer may inquire suo motu, and shall inquire, 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 complaints made.

(e) The Complaints Officer shall inquire into and decide a complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall decide the complaint 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 XXYYZZ to rectify the cause of the grievance, (ii) then counsel the person alleged to have committed the act and require such person to undergo training and social service. Upon subsequent violations by the same person, the Complaints Officer shall recommend to XXYYZZ to, and the institution shall, initiate disciplinary action against such person.

(g) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.

Agreement
between
National AIDS Control Organisation (NACO)
Government of India
&
XXYYZZ (Name of corporate Organisation)

This Agreement is made on _____ day of _____ 2006 by and between the President of India acting through [name of Additional Secretary and Director General], Additional Secretary and Director General, National AIDS Control Organisation, Department of Health, Ministry of Health and Family Welfare, Government of India, 9th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (hereinafter referred to as "NACO")

AND

XXYYZZ, a Corporate Organisation bearing registration number _____ and having its registered office at _____ acting through _____, the authorised signatory, hereinafter referred to as "XXYYZZ", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

WHEREAS NACO is providing first line antiretroviral treatment (hereinafter referred to as ART) to persons living With HIV/AIDS (hereinafter referred to as PLHAs) in India through designated public hospitals as per the guidelines issued by the National AIDS Control Organisation (hereinafter referred to as NACO) from time to time;

AND WHEREAS NACO coordinates the aforementioned provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART;

AND WHEREAS NACO is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations;

AND WHEREAS XXYYZZ is a Corporate Organisation registered under the Companies Registration Act. It has established/wants to establish a center to extend AIDS related treatment , care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHA's in the nearby areas as a part of their corporate social responsibility;

AND WHEREAS the parties hereto have agreed to set up a collaborative ART project and hereby reduce the terms of the agreement to writing;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART PROJECT

The purpose of the present Agreement is to set up collaborative ART project between NACO and XXYYZZ that would seek to be a model for high quality provision of ART and associated healthcare and medical management of PLHAs in its sites in India.

II. RESPONSIBILITIES OF NACO

10) NACO shall organise training or provide support for training of personnel of XXYYZZ involved in the collaborative ART project.

11) NACO shall provide to XXYYZZ regular updates on National ART guidelines from time to time.

12) NACO and XXYYZZ shall form a committee comprising of representative from NACO, Director of XXYYZZ, which shall supervise and monitor the collaborative ART project to ensure provision of quality services.

13) On an application by XXYYZZ for certification of a site as a "designated ART center" NACO team shall inspect the site to ascertain facilities for providing treatment and counselling and financial status subject to its satisfaction as to clause 3 of part III, certify the site as a "designated ART center".

14) NACO will provide drugs on a [three] monthly basis on receipt of a requisition/s from XXYYZZ and certificate of utilisation of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES OF XXYYZZ

25) XXYYZZ has set up a center / plans to set up a center (s) at _____ and has appointed Dr._____, as the official contact for the proposed collaborative ART Project.

26) XXYYZZ represents that it provides / proposes to provide various health services to PLHAs, a description of which is set out at Schedule III to the present Agreement.

27) XXYYZZ undertakes that it will comply with all the laws for the time being in force in India in the running of the ART center. Further, as a condition precedent to the certification of the site as a "designated ART center, XXYYZZ shall have obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.

28) XXYYZZ shall strictly follow the National ART guidelines (drug regimen 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 will ensure that mechanisms needed for good treatment adherence are in place.

29) XXYYZZ shall respect the autonomy and privacy of the patients, and to this end provide pre- and post-test counselling, obtain written informed consent from the patient prior to a test or treatment, and maintain confidentiality of the patients on the principle of shared confidentiality.

30) XXYYZZ shall provide for data protection systems to ensure that the confidential records of the patients are computerised and are protected so that they are not accessible to any unauthorised person.

31) XXYYZZ shall provide a copy of all medical records to the patients on their request.

32) XXYYZZ shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Schedule III, free of cost to patients who require treatment. XXYYZZ shall not deny services to any person living with HIV on any ground. The ARV drugs used for community will be supplied by NACO

33) XXYYZZ shall maintain all the registers and reporting formats as per NACO ART guidelines. They will send report of all adverse drug reactions to NACO

34) XXYYZZ shall use standard NACO Monitoring and Evaluation tools.

35) XXYYZZ shall provide standard, anonymous monthly reports of patient numbers and relevant details for the previous month to NACO by the 7th of each month in prescribed formats in accordance with the guidelines laid down by NACO from time to time. NACO will be free to use the data so sent to them in an anonymous manner.

36) XXYYZZ shall provide details of the ART team at their center to NACO along with the names and technical qualifications of the staff and keep this updated from time to time.

37) XXYYZZ shall entirely bear the costs related to the staff's salary (doctors, counselors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. XXYYZZ represents that it has enough funds to run the programme for the next three / five years. XXYYZZ will permit NACO to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that NACO can verify the representation of sustainability of the collaborative ART project.

38) **XXYYZZ shall bear the entire cost of drugs, diagnostic reagents & kits required for the treatment of its employees & their families**. For treatment being provided to the community, NACO/ XXXSACS

will provide drugs for ART on receipt of a requisition/s from XXYYZZ and certificate of utilisation of drugs in a prescribed format supplied earlier

39) XXYYZZ shall establish a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living With HIV/AIDS or PLHA groups in the area for increasing access to treatment and for follow-up support.

40) The designated representatives of XXYYZZ shall attend the coordination meeting with NACO at their own costs.

41) XXYYZZ 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 center, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.

42) Use of any data obtained by XXYYZZ during the course of its collaborative ART project shall be done in an anonymised manner such that the identity of the patients enrolled at the collaborative ART project is not revealed in any manner.

43) XXYYZZ shall maintain the records for a period of five years from the time that this Agreement is terminated or lapses by efflux of time.

44) XXYYZZ shall constitute a grievance redressal mechanism. ***[A model grievance redressal mechanism is annexed hereto.]*** Further, XXYYZZ shall forward to NACO in an anonymised manner the nature of complaints received and action taken thereon on a monthly basis.

IV. COMMENCEMENT

2) This Agreement shall become effective upon signature by both the Parties and certification of the site of the collaborative ART project as "designated ART center" by NACO as per clause 5 of part II of this Agreement. It shall remain in full force and effect for a period of three / five years thereafter.

V. RENEWAL OF AGREEMENT

6) This Agreement is renewable at the option of NACO.

7) Six months prior to the expiry of the Agreement due to efflux of time NACO shall intimate XXYYZZ if it intends to renew or not to renew the Agreement.

8) In the event that NACO decides not to renew the Agreement, XXYYZZ shall intimate NACO about its ability to continue to provide treatment free of charge to the patients enrolled. If XXYYZZ fails to continue to provide treatment free of charge or expresses its inability to do so, they shall give notice to the patients and NACO about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO. Further, upon such referral, XXYYZZ shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO or a person designated by NACO to receive such medical records. Thereupon, NACO will be responsible for ensuring that the patients continue to receive the drugs.

9) In the event that 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, XXYYZZ will have to re-apply for and re-obtain certification.

10) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

3) Any party may terminate this Agreement 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.

4) On such notice of termination being received by any party, XXYYZZ shall intimate NACO about its ability to continue to provide treatment free of charge to the patients enrolled. If XXYYZZ cannot continue to provide treatment free of charge, they shall give notice to the patients and NACO about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO. Further, upon such referral, XXYYZZ shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO or a person designated by NACO to receive such medical records. Thereupon, NACO will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY XXYYZZ

3) In case XXYYZZ is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART 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 NACO, MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.

4) If XXYYZZ 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 XXYYZZ, then without prejudice to any other right or consequence or mode of recovery, NACO may recover the amount thereof from XXYYZZ and/or its office bearers as arrears of land revenue.

VIII. SETTLEMENT OF DISPUTES

5. 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.

6. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India Delhi. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.

7. The place of arbitration shall be either New Delhi or the site of the collaborative ART project, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.

8. 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 AABBCC Director XXYYZZ Signature ..... Date ..... In the presence of Name and Signature .... Date	Signed For and on behalf of President of India Director General NACO Signature ..... Date ..... In the presence of Name and Signature .... Date .....

[In case the contract is entered into by the President through the DG, NACO, this needs to comply with the Rules of Business laid down in this behalf.]

SCHEDULE I

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO TO XXYYZZ

1. Treatment for Opportunistic Infections

TMP SMX, Acyclovir, Fluconazole, Ciprofloxacin

Amphotericin B

2. First line ART (in fixed dose combinations)

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(d) Zidovudine

(e) Efavirenz

SCHEDULE II

MODEL FOR A FIVE YEAR AGREEMENT		
Year	**Centre**	**Number of PLHAs for whose treatment stock is to be provided**
2006–07		
2007–08		
2008–09		
2009–10		
2010–11		

Year	**Centre**	**Number of PLHAs for whose treatment for OIs is to be provided**
2006–07		
2007–08		
2008–09		
2009–10		
2010–11		

MODEL FOR A THREE YEAR AGREEMENT		
Year	**Centre**	**Number of PLHAs for whose treatment stock is to be provided**
2006–07		
2007–08		
2008–09		

Year	**Centre**	**Number of PLHAs for whose treatment OIs for is to be provided**
2006–07		
2007–08		
2008–09		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPSOED TO BE PROVIDED	
Address of site	
Outpatient	
Days	Monday to Saturday
Timings	0830 am to 330 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	WHO criteria. Attach any other criteria being followed
Treatment for OIs	
First line regimen	AZT/d4T+ 3TC+ NVP/EFV
Description of follow-up of patients	
Facilities available	❒
Personnel and their qualifications	

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for XXYYZZ to constitute a grievance redressal mechanism at the outset.]

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(g) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.

Annexure VII

Format to assess the preparedness of an ART center

(This is one time assessment conducted prior to starting ART center in order to evaluate wheather the treatement unit is ready for delivery of ART services)

Name of ARV Rx Unit: _____ Date of visit_____

Name of Supervisor: _____

Name of ARV Rx Unit In charge: _____

Indicator	Readiness status	Problem identified
Organisation & Infrastructure		
1) Head of the health care facility (M.S) committed to provide ART care and support	❒ Yes ❒ No	
2) Ten member ART team identified for referrals	❒ Yes ❒ No	
3) ART unit strategically located in medical OPD	❒ Yes ❒ No	
Space Requirement		
4) Medical Examination Rooms – 2 Nos.	❒ Yes ❒ No	
5) Counseling cabins – 2 Nos.	❒ Yes ❒ No	
6) Patient waiting area	❒ Yes ❒ No	
7) Medical records, drug & supplies room	❒ Yes ❒ No	
8) Blood and specimen collection room	❒ Yes ❒ No	
Human Resources		
9) Medical Officer in-charge ART center in place	❒ Yes ❒ No	
10) Ten member ART team for referrals trained	❒ Yes ❒ No	
11) Trained lab. personnel (microbiologists & bio-chemists) available in the health care facility	❒ Yes ❒ No	
12) ART counselor recruited	❒ Yes ❒ No	
13) ART counselor trained	❒ Yes ❒ No	
14) ART record keeper recruited	❒ Yes ❒ No	
15) ART record keeper trained	❒ Yes ❒ No	
16) ART Pharmacist available	❒ Yes ❒ No	

Indicator	Readiness status	Problem identified
Availability of Drugs		
17) Adequate stock of first line drugs available	❒ Yes ❒ No	
18) Adequate drugs for opportunistic infections available	❒ Yes ❒ No	
Partnerships		
19) PLHA networks contacted and involved	❒ Yes ❒ No	
20) NGOs contacted and involved	❒ Yes ❒ No	
21) Private providers contacted and involved	❒ Yes ❒ No	
22) Other support groups contacted and involved	❒ Yes ❒ No	
Documents Available		
23) NACO registers, monthly report and cohort report format available	❒ Yes ❒ No	
24) Adequate recording / reporting forms available	❒ Yes ❒ No	
25) National ART guidelines	❒ Yes ❒ No	
26) National guidelines on OIs, CD4 testing, and HIV testing	❒ Yes ❒ No	
27) National guidelines on counseling (adherence)	❒ Yes ❒ No	
Laboratory Services Available		
28) Microbiology Lab with adequate space and technical expertise to perform following tests	❒ Yes ❒ No	
29) HIV testing	❒ Yes ❒ No	
30) Laboratory diagnosis of OIs, STIs	❒ Yes ❒ No	
31) Enumeration of CD4 cells	❒ Yes ❒ No	
32) Monitoring of patient on ART (viral load)?	❒ Yes ❒ No	
33) Biochemistry and haematology labs with adequate space and technical expertise to perform the following tests	❒ Yes ❒ No	
34) CBC and other routines biochemistry investigations	❒ Yes ❒ No	
35) LFT	❒ Yes ❒ No	
36) Blood sugar	❒ Yes ❒ No	
37) Lipid profile	❒ Yes ❒ No	
38) S. Creatinine	❒ Yes ❒ No	
39) S. Lactate	❒ Yes ❒ No	
40) S. Lipase	❒ Yes ❒ No	
41) Pregnancy test	❒ Yes ❒ No	

Overall Preparedness ❒ Recommended for starting service delivery ❒ Not recommended

Problems	**Suggested follow-up actions**
1.	
2.	

Signature of the appraisal team leaderOther Comments _____

Format for subsequent supervisory visits to ART center

(This checklist is to be used by the designated supervisory team in conjunction with the ARV treatment unit staff during their visit to an ART center. The aim is to see the quality of services offered, their conformity to national guidelines, to identify problems and take corrective actions. Each ART center in the State should be visited at least once a year by identified team from other state)

Name of ARV Rx Unit: _____ Date of visit_____

Name of Supervisor: _____

Name of ARV Rx Unit In charge: _____

I	**Discuss with key leadership and staff**		
1)	Is there high commitment to the national ART programme: this will be indicated by no of individuals accessing ART?	❒ Yes	❒ No
2)	Are the ART services well organised: will be indicated by the channel of movement of the patient to access services as required (clinical, lab, drugs, counseling).	❒ Yes	❒ No
3)	Is the ARV unit staffed as per the NACO guidelines?	❒ Yes	❒ No
4)	Is there adequate co-ordination of the ART unit with other intake departments of the hospital to maximise uptake of patients?	❒ Yes	❒ No
5)	Has the institution made adequate efforts to build partnerships with NGOs, PLWHAs, community based organisations & other support groups?	❒ Yes	❒ No
6)	Has sensitisation of all the hospital staff been carried out?	❒ Yes	❒ No
7)	Has the sensitisation of private doctors been carried out?	❒ Yes	❒ No
II	**Review records**		
8)	Are the NACO specified patient and programme monitoring records being maintained (Pre ART, ART Enrollment, Drug Stock, Drug Dispensing, Patient Treatment record)?	❒ Yes	❒ No
9)	Is confidentiality of records maintained?	❒ Yes	❒ No
10)	Are the eligibility criteria for initiating ARVs being followed?	❒ Yes	❒ No
11)	Are the patient treatment records up to date??	❒ Yes	❒ No
12)	Are the entries on patient treatment card correct and legible?	❒ Yes	❒ No
13)	Are the national guidelines for ART being followed?	❒ Yes	❒ No
14)	Is adherence issue being given due importance (adherence counseling)?	❒ Yes	❒ No
15)	Has an internal SOP for the functioning of the ART center been developed?(specifies roles and responsibilities, patient flow, etc)	❒ Yes	❒ No
III	**Observe drug stocks**		
16)	Is the drug stock register up to date?	❒ Yes	❒ No
17)	Are there adequate drugs for the next 3 months(stock position)?	❒ Yes	❒ No
18)	Are the drugs stored as per the specifications?	❒ Yes	❒ No
19)	Is the "First In First Out" principle followed?	❒ Yes	❒ No
20)	Were there any drug stock-out situations in the past year?	❒ Yes	❒ No
21)	Are there adequate measures in place to prevent pilferage?	❒ Yes	❒ No
IV	**Laboratory Services Availability**		
22)	Microbiology Lab with adequate space and technical expertise to perform the following tests	❒ Yes	❒ No
23)	HIV testing	❒ Yes	❒ No
24)	Laboratory diagnosis of OIs, STIs	❒ Yes	❒ No

25) Enumeration of CD4 cells	❒ Yes ❒ No
26) Monitoring of patient on ART (viral load)?	❒ Yes ❒ No
27) Biochemistry and hematology labs with adequate space and technical expertise to perform the following tests	❒ Yes ❒ No
28) CBC and other routines biochemistry investigations	❒ Yes ❒ No
29) LFT	❒ Yes ❒ No
30) Blood sugar	❒ Yes ❒ No
31) Lipid profile	❒ Yes ❒ No
32) S. Creatinine	❒ Yes ❒ No
33) S. Lactate	❒ Yes ❒ No
34) S. Lipase	❒ Yes ❒ No
35) Pregnancy test	❒ Yes ❒ No
IV Carry out exit interview (circle appropriate response)	
36) How many patients are satisfied with staff's attitude towards them?	0 1 2 3 4 5
37) How many know that ARV treatment is life-long?	0 1 2 3 4 5
38) How many know the importance of taking medicines regularly and on time?	0 1 2 3 4 5
39) How many brought the empty blister packet back from the previous month?	0 1 2 3 4 5
40) How many know the importance of practicing safe sex even while on ART?	0 1 2 3 4 5

Other Comments_____

_____

_____

_____

_____

II Review records at the center

Step by Step Instructions for Supervisory Visits

This section will help supervisors assess the functioning of the recording and reporting system

1) Ask the ART center in charge to show you the 4 NACO ART Registers
2) Check that the all 4 registers are completed and up to date (see date of last entry)
3) Check where the Patient Treatment Record (white 3 page fold out) is stored
4) Take a random patient treatment record and check for last entry of patient follow-up visit (section 11)
5) Ask the ART in charge to show you where this patient's information is recorded in the ART Enrollment register
6) Compare the patient information (CD4 count, Clinical stage, weight, functional status) in the patient treatment record (section 11: 3, 4 & section 12) with the ART enrollment register column 10, 11, 12) for 6, 12, 24 month visits if applicable
7) Compare other variables such as adherence, etc
8) Repeat this exercise for a second or third patient
9) Ask the ART In charge to show you the last monthly ART center report
10) Make sure that all sections in the monthly report format have been completed.
11) Compare the total number of patients ever started on ART (8.4 in the monthly report) with the number in the enrollment register
12) Compare the cumulative number of deaths in the monthly report (9.1) and count the number of deaths recorded in the ART enrollment register (section 18) (this may not be possible for ART centers with more than 500 patients)
13) Compare the cumulative number of patients Lost to Follow-up (LFU) in the monthly report (9.4) and count the number of LFU in the ART enrollment register (section 18)
14) Take a look at the DOTS and ART treatment rate in the monthly report (section 9.7). Discuss treatment issues with the ART center in charge
15) Take a look at the treatment adherence rate in the monthly report (section 10). Discuss issues of adherence with the ART center in charge and the counselors.
16) Take a look at the number of patients on other regimens (or second line) in the monthly report (Section 11) Discuss with the ART center in charge.
17) Check for Drug stock outs reported in the monthly report and the action taken (Section 12)
18) Check the involvement of NGOs. Discuss issues with the ART center in charge.

IV Patient Interview at the center

ART Patient Satisfaction Form (new patients)

This question form is undertaken to evaluate the quality of services provided of the ART Center. Your honest comments would help us to improve the quality of care and support we provide. Kindly read each statement carefully and be frank about your opinion. The information provided by you will be kept confidential. Do not mention your name on this form and fill it up in private.

Name of the ART Center:

1) I had no problem locating the ART center in the hospital/institution. Y / N
2) There was place for me to sit while I was waiting Y / N

3)	I felt comfortable while talking to the staff.	Y / N
4)	ART Counselor was attentive and listened to my problem	Y / N
5)	ART center staff explained to me about AIDS treatment	Y / N
a.	AIDS has no cure	Y / N
b.	Treatment is life long	Y / N
c.	Treatment has side effects	Y / N
d.	Adherence to treatment is crucial	Y / N
e.	Practicing safe sex while on treatment is important	Y / N
6)	I felt that other health concerns were taken care off.	Y / N
7)	I felt comfortable asking questions to the ART center staff.	Y / N
8)	I feel ART center staff treated me with respect was supportive and helpful.	Y / N
9)	I felt that my personal information was kept confidential.	Y / N
10)	I understood everything that I was told.	Y / N
11)	I plan to visit the ART Center again.	Y / N
12)	I intend to tell others about the ART Center.	Y / N
13)	My overall experience in the ART Center was	good / ok / bad

Old patients:

14)	I have missed	10% - 20% - 30% of my appointments
15)	I have problems with side effects	Y / N
16)	I brought my empty blister package in this visit	Y / N

Any other comments.

_____

_____

_____

_____

_____

Summary Recommendations of Supervisory Visit

(This report should be prepared in consultation with the ARV Rx unit in charge)

Name of ARV Rx Unit: _____ Date of Visit _____

Name of Supervisor: _____

Name of ARV Rx Unit In charge: _____

Problem Identified	Recommendations	Responsible Person
A. Commitment		
B. Organisation of services		
C. Uptake		
D. Treatment and Follow-up including adherence issues		
E. Drugs and Logistics		
F. Record Maintenance		
G. Others		

Signatures of the team members along with the ART center in charge _____